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# Shared Decision-Making for Lung Cancer Screening: A Systematic Review

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October 2024

**VA**



**U.S. Department of Veterans Affairs**

Veterans Health Administration  
*Health Systems Research*

**Recommended citation:** Landsteiner A, Zerzan N, Ullman KE, et al. Shared Decision-Making for Lung Cancer Screening: A Systematic Review. Washington, DC: Evidence Synthesis Program, Health Systems Research, Office of Research and Development, Department of Veterans Affairs. VA ESP Project #09-009; 2024.

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## PREFACE

The VA Evidence Synthesis Program (ESP) was established in 2007 to conduct timely, rigorous, and independent systematic reviews to support VA clinicians, program leadership, and policymakers improve the health of Veterans. ESP reviews have been used to develop evidence-informed clinical policies, practice guidelines, and performance measures; to guide implementation of programs and services that improve Veterans' health and wellbeing; and to set the direction of research to close important evidence gaps. Four ESP Centers are located across the US. Centers are led by recognized experts in evidence synthesis, often with roles as practicing VA clinicians. The Coordinating Center, located in Portland, Oregon, manages program operations, ensures methodological consistency and quality of products, engages with stakeholders, and addresses urgent evidence synthesis needs.

Nominations of review topics are solicited several times each year and submitted via the [ESP website](#). Topics are selected based on the availability of relevant evidence and the likelihood that a review on the topic would be feasible and have broad utility across the VA system. If selected, topics are refined with input from Operational Partners (below), ESP staff, and additional subject matter experts. Draft ESP reviews undergo external peer review to ensure they are methodologically sound, unbiased, and include all important evidence on the topic. Peer reviewers must disclose any relevant financial or non-financial conflicts of interest. In seeking broad expertise and perspectives during review development, conflicting viewpoints are common and often result in productive scientific discourse that improves the relevance and rigor of the review. The ESP works to balance divergent views and to manage or mitigate potential conflicts of interest.

## ACKNOWLEDGMENTS

The authors are grateful to the external peer reviewers for their review and careful critique of this project.

### ***Operational Partners***

Operational partners are system-level stakeholders who help ensure relevance of the review topic to the VA, contribute to the development of and approve final project scope and timeframe for completion, provide feedback on the draft report, and provide consultation on strategies for dissemination of the report to the field and relevant groups.

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### ***Technical Expert Panel***

To ensure robust, scientifically relevant work, the technical expert panel (TEP) guides topic refinement; provides input on key questions and eligibility criteria, advising on substantive issues or possibly overlooked areas of research; assures VA relevance; and provides feedback on work in progress. TEP members included:



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**Disclosures**

This report was prepared by the Evidence Synthesis Program Center located at **Minneapolis VA Health Care System**, directed by Timothy J. Wilt, MD, MPH and Wei Duan-Porter, MD, PhD and funded by the Department of Veterans Affairs, Veterans Health Administration, Health Systems Research.

The findings and conclusions in this document are those of the author(s) who are responsible for its contents and do not necessarily represent the views of the Department of Veterans Affairs or the United States government. Therefore, no statement in this article should be construed as an official position of the Department of Veterans Affairs. The final research questions, methodology, and/or conclusions may not necessarily represent the views of contributing operational and content experts. No investigators have affiliations or financial involvement (eg, employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties) that conflict with material presented in the report.



# *Executive Summary*

## KEY FINDINGS

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- ▶ A wide range of lung cancer screening (LCS) communication strategies and tools were studied across settings/encounters, approaches, and targeted individuals.
  - Authors often did not provide adequate information to determine if studied tools met criteria for a patient decision aid (DA).
  - Shared decision making (SDM) strategies were characterized as health care professional-facing (in-clinic to guide discussion) or patient-facing (inform patient prior to or during visit but not guide discussion).
    - Within health care professional-facing strategies: tools were meant to be used by a clinician or LCS navigator.
    - Within patient-facing strategies: tools were used prior to, or during, a SDM visit or if meant to generate a SDM visit.
  - Some strategies combined SDM tools with care coordinators or navigators.
  - The most commonly studied tool ( $k = 7$ ) was a 5–15 minute web or print-based DA available in English, Spanish, and Chinese ([www.shouldiscreen.com](http://www.shouldiscreen.com)). The tool was updated to include 2021 USPSTF recommendations and content.
- ▶ While most studies reported on knowledge, few addressed receipt of initial, or adherence to follow-up LCS, concordance of screening decision with values, decisional conflict/regret, distress/anxiety, or information quality.
  - Studies did not report on many other outcomes of interest including smoking behaviors; resource allocations/usage (eg, clinician time, clinical staff/patient time, medical media support, IT support); or cost or cost effectiveness.
- ▶ SDM strategies and tools may increase LCS participation, have acceptable information quality, and do not increase decisional conflict/regret. A decision aid may be superior to an educational tool, and the choice of decision aid may not impact uptake.
  - DA selection should be guided by feasibility and population/setting.
- ▶ Limitations in, and heterogeneity of, study design, interventions, comparators, outcome measures, and study risk of bias precluded synthesizing evidence or deriving conclusive statements on most interventions/outcomes, resulting in low to very low certainty of evidence.
  - There was little to no evidence on whether effects varied by patient (age, sex, race/ethnicity, smoking status, comorbidities, education) or clinic characteristics (primary care, prevention, smoking cessation clinics or public forums).
- ▶ Broad barriers to LCS SDM implementation included resource availability, particularly clinician time constraints; patients' reticence and lack of engagement with SDM; and patients' negative response to SDM. Facilitators included use of a DA during the SDM encounter.

- ▶ Among implementation studies conducted in VHA, facilitators included a culture receptive to SDM; available resources including time and tools; prioritization among other clinic demands and expectations; and innovation among deliverers and recipients.
  - ▶ Research is needed to enhance SDM and appropriate LCS implementation including identifying accurate, efficient, and effective SDM tools adaptable to settings and patients; reducing barriers to appropriate LCS and follow-up; promoting tobacco abstinence; and more accurately assessing willingness to adhere and competing mortality risk in individuals otherwise considered LCS eligible.
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## BACKGROUND

Despite declines in smoking rates in recent decades, over 230,000 new cases of lung and bronchus cancer will be diagnosed in the US in 2024, and 125,070 deaths attributable to lung cancer will occur in the same period. Both incidence and mortality have declined but lung cancer remains the leading cause of cancer deaths in the US. The 5-year survival rate for lung cancer remains low at 25% with a median age at death of 73 years. Lung cancer rates and mortality in the US are highest in non-Hispanic Black men, but markedly lower in Hispanic and non-Hispanic Asian/Pacific Islanders.

Lung cancer screening (LCS) is meant to reduce lung cancer mortality through early identification and treatment of lung cancer. LCS net benefit depends upon an individual's lung cancer risk (largely based on age and smoking history), adherence to initial and subsequent screening as well as evaluation and treatment of abnormal findings on LCS, competing risk due to comorbidities, and LCS harms such as false-positive results and incidental findings that lead to subsequent testing and treatment, overdiagnosis and radiation exposure. LCS trials using low dose CT (LDCT) scans have shown a reduction in lung cancer mortality. However, they have generally enrolled healthy persons, so those findings may not accurately reflect benefits and harms in persons with comorbidities. Therefore, shared decision making (SDM), a process that involves both the patient and the clinician in the decision-making process, is encouraged for potentially eligible individuals prior to undergoing LCS. SDM includes providing patients with information on treatment/test options, probabilities of beneficial and harmful outcomes, and methods to clarify, elicit, support, and incorporate patient preferences and values. SDM is particularly important when the decision to undergo a test/treatment may reasonably vary for many individuals based on their individual weighting of benefits/harms and values (*ie*, preference-sensitive decisions).

In 2015, the Centers for Medicare and Medicaid Services (CMS) enacted a stipulation that counseling and SDM were a prerequisite for LCS reimbursement. CMS stated that “before a Medicare beneficiary’s first lung cancer LDCT screening, the beneficiary must receive a counseling and shared decision-making visit that meets all of the following criteria, and is appropriately documented in the beneficiary’s medical records: 1) Determination of beneficiary eligibility; 2) Shared decision-making, including the use of one or more decision aids; 3) Counseling on the importance of adherence to annual lung cancer LDCT screening, and impact of comorbidities and ability or willingness to undergo diagnosis and treatment; and 4) Counseling on the importance of maintaining cigarette smoking abstinence if they formerly used cigarettes; or the importance of smoking cessation if they currently smoke and, if appropriate, furnishing of information about tobacco cessation interventions.” SDM has been defined as “an approach where clinicians and patients share the best available evidence when faced with the task of making decisions, and where patients are supported to consider options, to achieve informed preferences.” Decision aids and educational tools have been developed to facilitate

SDM processes, improve patient LCS knowledge about LCS, and reduce decisional conflict and regret. A distinction between a decision aid and educational tool is that a decision aid is not meant to advise people to choose one option over another, instead it is meant to provide people with information needed to make an informed and values-based decision with their clinician.

The Veterans Health Administration (VHA) serves approximately 9 million Veterans, many of whom are racial or ethnic minorities or members of other historically underserved populations. A large portion of these individuals are older male US Veterans with multiple comorbid conditions and are people who currently or formerly smoked. A higher proportion of Veterans are of Black race than the general US population. A study by Kinsinger et al in 2016 estimated that nearly 900,000 VHA patients would meet earlier 2013 USPSTF LCS eligibility criteria. The same analysis estimated that nearly half of eligible patients would agree to initial screening, and of these patients, more than half would require additional tracking. LCS requires an annual commitment from the patient to schedule and complete LDCT scans. Resources are required to identify, counsel, track, and ensure adherence. LCS harms include false positive results and subsequent testing, identification of incidental findings, overdiagnosis, and radiation exposure. Therefore, harms may offset benefits in many and result in high resource use. SDM for potentially eligible individuals is meant to ensure patients referred for LCS have accurate information to make decisions concordant with benefits and harms and individual preferences and values and to enhance long-term LCS adherence and follow-up among screenees.

## CURRENT REVIEW

The VA's National Center for Lung Cancer Screening (NCLCS) is tasked with expanding equitable access to LCS for the estimated 1-1.5 million Veterans eligible under the 2021 USPSTF expanded recommendations. NCLCS requested a review of the evidence on benefits and harms of SDM practices and strategies to inform policies on the use of formal decision aids.

### Key Questions

<b>Key Question 1</b>	What communication strategies, tools, and/or approaches used for shared decision-making (SDM) in lung cancer screening are reported in the literature?
<b>Key Question 2a</b>	What is the effectiveness and comparative effectiveness of communication strategies, tools, and/or approaches used to enhance SDM for lung cancer screening?
<b>Key Question 2b</b>	Does effectiveness vary by patient (i) or clinical setting (ii) characteristics: i. age, race/ethnicity, comorbidities, current smoking status, socioeconomic status/education, residency, geographic region, rural/urban ii. primary care, smoking cessation, prevention clinics, public forums
<b>Key Question 3</b>	What are the harms of the communication strategies, tools, and/or approaches used to enhance SDM for lung cancer screening?
<b>Key Question 4</b>	What are the barriers and facilitators of implementing different communication strategies, tools, and/or approaches for lung cancer screening SDM?



## METHODS

We searched Embase and Medline via Ovid and CINAHL via EbscoHost with a starting publication date of January 2010 through December 6, 2023, using terms for lung cancer and decision-making. English-language titles, abstracts, and full-text articles were independently reviewed by 2 reviewers. Effect information and population, intervention, comparator characteristics and outcomes were abstracted from included studies. We assessed risk of bias (ROB) using 1 of the following tools dependent upon study design: ROB 2.0, JBI Cohort ROB tool, JBI Quasi-Experimental ROB tool, or the CASP Qualitative Checklist.

To synthesize the qualitative studies, 2 reviewers independently coded each study by extracting relevant text and assigning that text to the respective Consolidated Framework for Implementation Research (CFIR) domain. Reviewers then met and finalized code assignment by consensus.

As study design, methods, assessment tools, and outcome definitions varied widely across studies, we were unable to provide a pooled estimate for the included outcomes. We narratively synthesize, organize and present evidence by whether the tool was a health care provider-facing tool (*eg*, used in clinic and meant to guide the discussion) or a patient-facing tool or material (*eg*, meant to inform the patient either prior to or during the visit but not guide discussion). We also conducted stratified or sensitivity analyses and reported results separately for RCTs and those of any SDM tool/strategy versus usual care. Qualitative studies are summarized separately.

We rated the certainty of evidence (CoE) for each outcome using standard GRADE methodology. Among all the included outcomes we solicited outcome prioritization from partners and TEP members. The following were ranked the top 6 of clinical importance and CoE ascertained: receipt of lung cancer screening, distress/anxiety, adherence to subsequent screening, concordance of decision with patient's values and preferences, decisional conflict/regret, and quality of communication.

## RESULTS

We identified 129 potentially relevant articles after deduplication and title and abstract screening. Of those, 39 studies met eligibility criteria (31 for KQ1-3 and 9 for KQ4); 30 provided quantitative outcomes, 8 qualitative outcomes, and 1 study provided both quantitative and qualitative outcomes. Two quantitative and 4 qualitative studies were in Veterans.

A pre-post design was most commonly used (15/39), though 12 studies (31%) were RCTs. Two-thirds (26/39) used patient-facing tools, typically web- or print-based, and 9 were health care provider facing. Only 4 studies evaluated SDM tools/strategies versus usual care (3 RCTs, 1 cohort) and 2 included care coordinators or patient navigators as a main component to enhance LCS. Studies ranged in follow-up duration from 1 day to 14 months and included population sizes from 15 to over 19,000.

The quantitative studies varied in design, intervention of interest, comparator, and analytic methodology. Study purpose varied, with investigative intention including comparison of intervention delivery mode, comparison of decision aids, comparison of decision aid to educational tool, and comparison of decision aid or educational tool to usual care. This heterogeneity across many domains provided a challenge in grouping of studies.

Assignment of the intervention to the decision aid or educational tool category was not always feasible, as not all authors provided a copy or access to the intervention. We relied on author report of the tool

as a decision aid or educational tool; we refer throughout the text to both of these items as SDM tools. The most commonly studied tool ( $k = 7$ ) was a 5–15-minute web or print-based decision aid available in English, Spanish, and Chinese ([www.shouldiscreen.com](http://www.shouldiscreen.com)). The current version of the tool includes the 2021 USPSTF recommendations and content. A summary of our certainty of evidence ratings for prioritized outcomes according to whether interventions were patient or provider facing is provided below. While most studies reported on knowledge, few addressed measures of effectiveness and harms including receipt of initial, or adherence to subsequent, LCS; adherence to diagnostic evaluations or treatment of findings on LCS, concordance of screening decision with values; decisional conflict/regret; distress/anxiety; or information quality. There was little to no information on the effects of SDM strategies according to patient or clinic characteristics (ES Table).

Nine studies captured barriers and facilitators related to LCS SDM. All but 1 study interviewed health care providers, and 4 studies interviewed patients. While all 9 studies assessed health care professionals or patients' perceptions of SDM, 5 studies identified a specific tool and the remaining 4 assessed SDM as a concept. Studies varied in their analytic approach to summarize themes identified from the interviews. We extracted themes grouped by CFIR domains and constructs. Two domains appeared repeatedly across the studies. The first was resource availability. Health care professionals' (eg, clinicians, nurses, and LCS coordinators) time constraints were frequently mentioned as a barrier to implementing SDM. The second repeatedly used CFIR domain was innovation recipients (who receives or delivers the innovation). Several studies reported a theme around patients' reticence and lack of engagement with SDM and patients' negative response to SDM. Themes regarding facilitators focused on enthusiasm for a decision aid use during the SDM encounter. Among implementation studies conducted in VHA, facilitators included available resources including expertise and tools; prioritization among other clinic demands and expectations; and innovation among deliverers and recipients.

## CONCLUSIONS

SDM tools and strategies (that may include care coordinators or patient navigators) may increase LCS participation, have acceptable information quality, and do not increase decisional conflict/regret. A decision aid may be superior to an educational tool, and the choice of decision aid may not impact LCS screening. Variation in study design, SDM tools and communication strategies, comparator, delivery mode and timing, and outcomes presents challenges in evaluation and implementation. While most studies reported on knowledge, few addressed important clinical and patient-centered outcomes including receipt of initial, or subsequent LCS, adherence with diagnostic evaluations or treatments for findings on LCS, concordance of screening decision with values, decisional conflict/regret, distress/anxiety, or information quality. There was little evidence on whether effects varied by patient or clinic characteristics.

Implementation barriers and facilitators were present at the patient, clinician, and health system level. Studies conducted in VHA provide specific suggestions for facilitating LCS-SDM.

Research is needed to determine accurate, effective, feasible, and low-burden SDM tools/strategies that are adaptable to different settings and patients; reduce barriers to identify and refer individuals eligible for LCS; enhance LCS adherence and follow-up; promote tobacco abstinence; and decrease referral of ineligible individuals, those unlikely to benefit due to comorbidities, or those unlikely to adhere.

**ES Table. Certainty of Evidence Ratings**

Outcome	Study Design	Follow-Up	Total N	Certainty	Summary Statement
<i>Health Care Professional-Facing Tools or Materials: Tools for Clinician (eg, Physician or Nurse Practitioner) Use During SDM Clinic Visit to Guide Discussion With Patient</i>					
<b>Receipt of Lung Cancer Screening</b>	1 CCT	9-12 months	2,116	⊕⊕⊕○ Moderate <sup>a,b</sup>	An EMR-integrated SDM tool probably results in a greater % receiving lung cancer screening, compared with no EMR integrated tool.
	2 Observational (pre-post and cohort)	1-3 months	197	⊕○○○ Very low <sup>a,c</sup>	The evidence is very uncertain on the effect of SDM on receipt of LCS.
<b>Decisional Conflict or Regret</b>	1 RCT	6 months	237	⊕⊕○○ Low <sup>a,c</sup>	Option Grids may result in less decisional conflict or regret when compared with shouldscreen.com.
<b>Quality of Communication</b>	1 RCT	6 months	237	⊕⊕○○ Low <sup>a,c</sup>	There may be little to no difference in quality of communication in SDM using Option Grids compared with shouldscreen.com.
<i>Health Care Professional-Facing Tools or Materials: Tools for LCS navigator (eg, LCS coordinator) Use During SDM Clinic Visit to Guide Discussion With Patient</i>					
<b>Receipt of Lung Cancer Screening</b>	2 RCTs	280 days – 1 year	3,547	⊕⊕○○ Low <sup>a,d</sup>	SDM tools plus care coordinators or patient navigators may result in increased receipt of LCS compared with usual care (UC).
<b>Decisional Conflict or Regret</b>	1 Pre-post	30 days	28	⊕○○○ Very low <sup>a,e</sup>	The evidence is very uncertain on the effect of SDM tools on decisional conflict/regret.
<i>Patient-Facing Tools or Materials: Tools for Patient Use During or Prior to SDM Clinic Visit</i>					
<b>Receipt of Lung Cancer Screening</b>	1 RCT	2 months	66	⊕○○○ Very low <sup>a,e</sup>	The evidence is very uncertain on the effect of LungCare on receipt of LCS compared with UC.
	1 RCT	6 months	140	⊕⊕○○ Low <sup>a</sup>	LCSDecTool may result in increased LCS compared with UC (attention control) (AC).
<b>Quality of Communication</b>	2 Pre-post	Same day – 1 month	438	⊕○○○ Very low <sup>a,e,f</sup>	The evidence is very uncertain on the effect of SDM tools on quality of communication.
<b>Decisional Conflict or Regret</b>	1 RCT	3 months	140	⊕⊕○○ Low <sup>a</sup>	LCSDecTool may result in little to no difference in distress/anxiety compared with AC.
<b>Distress/Anxiety</b>	1 RCT	3 months	140	⊕⊕○○ Low <sup>a</sup>	LCSDecTool may result in little to no difference in distress/anxiety compared with AC.
<i>Patient-Facing Tools or Materials: Tools or Materials for Patient Education About Screening and to Potentially Generate SDM Visits</i>					
<b>Receipt of Lung Cancer Screening</b>	1 RCT	6 months	516	⊕⊕⊕⊕ High	“Lung Cancer Screening: Is It Right for Me?” video results in no difference in receipt of lung cancer screening compared with a 2-page brochure from a lung cancer advocacy group.
	1 RCT	6 months	298	⊕○○○ Very low <sup>d,g</sup>	The evidence is very uncertain on the effect of web-based SDM compared with print-based SDM on receipt of LCS.
	2 RCTs	4-6 months	1469	⊕○○○ Very low <sup>d,g</sup>	The evidence is very uncertain on the effect of a LCS brochure + additional materials compared with LCS brochure alone on receipt of LCS.

Outcome	Study Design	Follow-Up	Total N	Certainty	Summary Statement
<b>Concordance of Decision</b>	1 Pre-post	Same day	60	⊕○○○ Very low <sup>h</sup>	The evidence is very uncertain on the effect of SDM tools on concordance of decision.
	1 Pre-post	6 months	74	⊕○○○ Very low <sup>e,i</sup>	The evidence is very uncertain on the effect of SDM tools on concordance of decision.
<b>Quality of Communication</b>	1 RCT	1 week	60	⊕⊕○○ Low <sup>a,i</sup>	LungTalk may result in little to no difference in quality of communication compared to a non-tailored LCS information sheet.
	1 RCT	4 months	298	⊕○○○ Very low <sup>g,i</sup>	The evidence is very uncertain on the effect of SDM web compared with SDM print on quality of communication.
<b>Decisional Conflict or Regret</b>	1 RCT	4 months	298	⊕○○○ Very low <sup>g</sup>	The evidence is very uncertain on the effect of SDM web compared with SDM print on decisional conflict and regret.
	1 RCT	1 week	516	⊕⊕⊕⊕ High	“Lung Cancer Screening: Is It Right for Me?” video results in less decisional conflict/regret compared with a two-page brochure from a lung cancer advocacy group.
<b>Distress or Anxiety</b>	1 RCT	4 months	298	⊕○○○ Very low <sup>c,g</sup>	The evidence is very uncertain on the effect of shouldiscreen.com web compared with shouldiscreen.com print on distress/anxiety.
<i>Other: SDM Tools Not Specified</i>					
<b>Adherence</b>	1 Observational	15 months	7,193	⊕○○○ Very low <sup>a</sup>	The evidence is very uncertain on the effect of SDM on LCS adherence.
<b>Receipt of Lung Cancer Screening</b>	1 Observational	3 months	19,221	⊕○○○ Very low <sup>a</sup>	The evidence is very uncertain on the effect of SDM on receipt of LCS.

GRADE Working Group grades of evidence:

High certainty: We are very confident that the true effect lies close to that of the estimate of the effect.

Moderate certainty: We are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low certainty: Our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.

Very low certainty: We have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations:

- a. Rated down 1 level for study limitations (rated some concerns or moderate risk of bias).
- b. Rated down 1 level for imprecision (optimal information size not met, sample size <400).
- c. Rated up 1 level for magnitude of effect.
- d. Rated down 1 level for imprecision (event rate too low).
- e. Rated down 2 levels for imprecision (OIS not met, sample size <150).
- f. Rated down 1 level for indirectness (study used unvalidated measurement tool).
- g. Rated down 2 levels for study limitations (study rated high risk of bias).
- h. Rated down 2 level for indirectness (study population included participants not eligible for LCS).
- i. Rated down 1 level for indirectness (questions were not comprehensive of quality).

**Abbreviations.** CCT=controlled clinical trial; EMR=electronic medical record; LCS=lung cancer screening; LCSDecTool=lung cancer screening decision tool; OR=odds ratio; RCT=randomized controlled trial; SDM=shared decision making.

# *Main Report*

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## ABBREVIATIONS TABLE

Abbreviation	Definition
ACS	American Cancer Society
CASP	Critical Appraisal Skills Programme
CCT	Controlled clinical trial
CFIR	Consolidated Framework for Implementation Research
CINAHL	Cumulative Index to Nursing and Allied Health Literature
CMS	Centers for Medicare and Medicaid Services
CoE	Certainty of evidence
CT	Computed tomography
DCP	Decision Counseling Program
DCS	Decisional Conflict Scale
DCS-LL	Decisional Conflict Scale – Low Literacy
HER	Electronic health record
EMR	Electronic medical record
ESP	Evidence Synthesis Program
FAQ	Frequently asked questions
GRADE	Grading and Recommendations, Assessment, Development, and Evaluations
ICD	International Classification of Diseases
IPDAS	International Patient Decision Aid Standards
IQR	Interquartile range
IT	Information technology
JBI	Joanna Briggs Institute
KQ	Key question
LCS	Lung cancer screening
LCSDecTool	Lung Cancer Screening Decision Tool
LDCT	Low-dose computed tomography
LungRADS	Lung CT Screening Reporting & Data System
Mo	Month
MRI	Magnetic resonance imaging
NA	Not applicable
NCI	National Cancer Institute
NCLCS	National Center for Lung Cancer Screening
NELSON	Nederlands–Leuvens Longkanker Screenings Onderzoek (Dutch-Belgian lung cancer screening trial)
NIH	National Institute of Health
NLST	National Lung Screening Trial
No	Number
NR	Not reported
OR	Odds ratio



Abbreviation	Definition
PCP	Primary care provider
PDA	Patient decision aid
PET	Positron emission tomography
PLCO	Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial
PROSPERO	International Prospective Register of Systematic Reviews
RCT	Randomized controlled trial
RoB	Risk of bias
SAILS	Supporting Appropriate Implementation of Lung Cancer Screening
SCT	Social Cognitive Theory
SD	Standard deviation
SDM	Shared decision-making
SE	Standard error
SES	Socioeconomic status
TEP	Technical Expert Panel
UNC	University of North Carolina
USPSTF	United States Preventative Services Task Force
UTAUT	Unified Theory of Acceptance and Use of Technology
VA	Veterans Affairs
VAS	Visual analog scale
VHA	Veterans Health Administration
Wk	Week
Yr	Year

## BACKGROUND

Despite declines in smoking rates in recent decades, over 230,000 new cases of lung and bronchus cancer will be diagnosed in the US in 2024, and 125,070 deaths attributable to lung cancer will occur in the same period.<sup>1</sup> Both incidence and mortality have declined but lung cancer remains the leading cause of cancer deaths in the US. The 5-year survival rate for lung cancer remains low at 25% with a median age at death of 73 years.<sup>1</sup> Lung cancer rates and mortality in the US are highest in non-Hispanic Black men, but markedly lower in Hispanic and non-Hispanic Asian/Pacific Islanders.<sup>2</sup>

The US National Lung Screening Trial (NLST) enrolled primarily men of White race, aged 55-74, who currently or formerly smoked heavily. Results of NLST found that 3 rounds of annual lung cancer screening (LCS) with low-dose CT scanning (LDCT) reduced lung cancer mortality during 7 years of follow-up. Absolute reductions persisted at 3.3 lung cancer deaths per 1,000 through 12 years of follow-up but were no longer statistically significant (95% CI [-0.2 to 6.8]). Harms identified during the trial included LDCT radiation-induced cancers, false positive results, incidental findings, short-term anxiety and distress, and possible overdiagnosis. Although randomized LDCT screening trials have consistently reported benefits, participants in these trials were generally younger, more highly educated, had less racial and ethnic diversity, and were less likely to be people currently smoking than the US screening-eligible population.<sup>3</sup> Older adults in the US (including Veterans) also face higher risk of death from competing causes compared with trial participants.<sup>3</sup>

Despite concerns about unrepresentativeness, the above findings along with results from incidence and modeling studies led the US Preventive Services Task Force (USPSTF) to issue a 2021 update to its lung cancer screening recommendation with expanded indications for eligible populations: annual LCS screening with LDCT in adults aged 50–80 who have a 20 pack-year smoking history and currently smoke or have quit within the past 15 years. Discontinuation of screening is recommended once a person has not smoked for 15 years or develops a health problem that substantially limits life expectancy or the ability or willingness to have curative lung surgery.<sup>4</sup> The new recommendations are also intended to reduce racial/ethnic disparities in LCS mortality and access to screening.

As noted by others,<sup>3</sup> the US population eligible for lung cancer screening (including Veterans) may be less likely to benefit from early detection compared with participants in NLST and other key trials, given that they face a high risk of death from competing causes, such as heart disease and stroke.<sup>5</sup> Additionally, data from the 2012 Health and Retirement Study showed a lower 5-year survival rate and life expectancy in screening-eligible persons compared with NLST participants. Because the likelihood of a net benefit of LCS is largely dependent upon an individual's lung cancer risk and comorbidities, the requirement to ensure that patients are aware of both the benefits and harms prior to undergoing LCS was enacted. Shared decision-making (SDM), a process that involves both patients and clinicians in the decision-making process, is encouraged for potentially eligible individuals prior to LCS.<sup>5</sup>

SDM involves providing patients with information on treatment/testing options as well as chances of beneficial and harmful outcomes. SDM is also intended to give clinicians methods, and encourage them, to clarify and support patient preferences and values. SDM is considered particularly important in preference-sensitive decisions (when the decision to undergo a test/treatment may reasonably vary from patient to patient based on their individual weighting of benefits, harms, and values). In 2015 (updated in 2022), the Centers for Medicare and Medicaid Services (CMS) enacted a stipulation that counseling and SDM were a prerequisite for LCS to be reimbursable.<sup>6,7</sup> Specifically CMS stated that “before the Medicare beneficiary's first lung cancer LDCT screening, the beneficiary must receive a

counseling and shared decision-making visit that meets all of the following criteria, and is appropriately documented in the beneficiary's medical records: 1) Determination of beneficiary eligibility; 2) Shared decision-making, including the use of one or more decision aids; 3) Counseling on the importance of adherence to annual lung cancer LDCT screening, and impact of comorbidities and ability or willingness to undergo diagnosis and treatment; and 4) Counseling on the importance of maintaining cigarette smoking abstinence if former smoker; or the importance of smoking cessation if current smokers and if appropriate, furnishing of information about tobacco cessation interventions." SDM has been defined as "an approach where clinicians and patients share the best available evidence when faced with the task of making decisions, and where patients are supported to consider options, to achieve informed preferences."<sup>8</sup> Several decision aids and educational tools have been developed for SDM in LCS and are designed to improve patient knowledge about lung cancer screening, reduce decisional conflict and regret, and enhance LCS uptake and long-term compliance among individuals most likely to have a benefit that exceeds harms. A key distinction between a decision aid and educational tool is that a patient decision aid is not meant to advise people to choose one option over another; instead, it is meant to provide people with information needed to make an informed and values-based decision.<sup>9</sup>

The Veterans Health Administration (VHA) serves approximately 9 million Veterans,<sup>10</sup> many of whom are racial or ethnic minorities or members of other historically underserved populations. A large portion of these individuals are older male US Veterans with multiple comorbid conditions and are people who currently or formerly smoked. A higher proportion of Veterans are of Black race than the general US population. A study by Kinsinger et al in 2016 estimated that nearly 900,000 VHA patients would meet earlier 2013 USPSTF LCS eligibility criteria.<sup>11</sup> The same analysis estimated that nearly half of eligible patients would likely agree to initial screening, and of these patients, more than half would require additional tracking. LCS requires an annual commitment from the patient to schedule and complete annual low dose CT scans. Additionally, resources are required to identify, counsel, track, and ensure adherence. LCS harms include false positive results and subsequent testing, identification of incidental findings, overdiagnosis, and radiation exposure. Therefore, harms may offset benefits in many and result in high resource use. Thus, SDM for potentially eligible individuals is meant to ensure patients referred for LCS have accurate information to make decisions concordant with clinical benefits and harms and individual preferences and values and to enhance long-term LCS adherence and follow-up among individuals undergoing LCS.

The VA's National Center for Lung Cancer Screening (NCLCS) is tasked with equitably expanding LCS access to the estimated 1-1.5 million Veterans eligible under the updated USPSTF recommendations.<sup>11</sup> Considerations for VA (and non-VA health care systems) include the resources necessary to identify and counsel eligible patients, track patients including evaluation of abnormal LDCT scans, and ensure adherence to annual screenings. NCLCS requested the present review of evidence on benefits and harms of SDM practices and strategies to inform policies on the use of formal decision aids.

## METHODS

### REGISTRATION AND REVIEW

A preregistered protocol for this review can be found on the PROSPERO international prospective register of systematic reviews ([CRD42024511257](https://doi.org/10.1111/CRD4.2024511257)). A draft version of this report was reviewed by external peer reviewers; their comments and author responses are located in the [Appendix](#).

### KEY QUESTIONS AND ELIGIBILITY CRITERIA

The following key questions were the focus of this review:

<b>Key Question 1</b>	What communication strategies, tools, and/or approaches used for shared decision making (SDM) in lung cancer screening are reported in the literature?
<b>Key Question 2a</b>	What is the effectiveness and comparative effectiveness of communication strategies, tools, and/or approaches used to enhance SDM for lung cancer screening?
<b>Key Question 2b</b>	Does effectiveness vary by patient (i) or clinical setting (ii) characteristics: i. age, race/ethnicity, comorbidities, current smoking status, socioeconomic status/education, residency, geographic region, rural/urban ii. primary care, smoking cessation, prevention clinics, public forums
<b>Key Question 3</b>	What are the harms of the communication strategies, tools, and/or approaches used to enhance SDM for lung cancer screening?
<b>Key Question 4</b>	What are the barriers and facilitators of implementing different communication strategies, tools, and/or approaches for lung cancer screening SDM?

Study eligibility criteria are shown in the table below.

Eligibility Criteria		
	Inclusion Criteria	Exclusion Criteria
<b>Population</b>	Adults ( $\geq 18$ years of age) in the US	Individuals considering lung cancer screening modalities other than LDCT (such as chest radiography) Populations at increased risk for lung cancer unrelated to smoking exposure/history (eg, non-Hodgkin's lymphoma)
<b>Intervention</b>	Shared decision-making tools/aids	Non-lung cancer screening decision making tools/communication strategies/approaches
<b>Comparator</b>	Any	
<b>Outcomes</b>	KQ1: Types of SDM stratified by patient decision aid or educational tool, tool format, and tool environment  KQ2: <ul style="list-style-type: none"> <li>Patient experience (eg, quality of communication, satisfaction with decision, decisional conflict/regret, concordance of decision with patient's values and preferences, distress/anxiety)</li> </ul>	

Eligibility Criteria		
	Inclusion Criteria	Exclusion Criteria
	<ul style="list-style-type: none"> <li>• Participation in the screening program</li> <li>• Receipt of lung cancer screening</li> <li>• Receipt of additional tests/procedures for identified findings</li> <li>• Adherence to subsequent screening</li> <li>• Knowledge of screening benefit and harms</li> <li>• Participant need for additional information</li> <li>• Smoking behaviors</li> <li>• Resource allocations/usage (eg, primary clinician time, additional clinical staff time, staff, patient time, medical media support, IT support)</li> <li>• Cost (eg, cost or cost effectiveness)</li> </ul> <p>KQ2b: (KQ2 outcomes stratified by the following effect modifiers)</p> <ul style="list-style-type: none"> <li>• Rural/urban</li> <li>• Regional</li> <li>• Ethnicity</li> <li>• Health literacy</li> <li>• Lung cancer risk</li> <li>• Competing comorbidities</li> <li>• Serious mental illness</li> </ul> <p>KQ3: Any harm reported by study authors</p> <p>KQ4:</p> <ul style="list-style-type: none"> <li>• Barriers (staff time, patient time, cost, method of delivery, counseling required, care visits (eg, consult of visit to SDM appointment), language, readability/communication, access to care)</li> <li>• Facilitators (staff education, support from leadership, allocated time, ease of delivery, etc)</li> </ul>	
<b>Timing</b>	2010 (post guidance for use of shared decision making for lung cancer screening)	< 2010
<b>Setting</b>	US Clinics, including community outreach	Hospice
<b>Study Design</b>	KQs 1–3: RCT, observational with comparator or quasi-experimental KQ4: Observational	Systematic reviews, abstracts, conference proceedings, case studies, editorials

## SEARCHING AND SCREENING

To identify articles relevant to the key questions, a research librarian searched Embase, Medline, and CINAHL from January 2010 through December 6, 2023, using controlled vocabulary (MeSH, Emtree) and key words for lung cancer and decision making (see [Appendix](#) for complete search strategies). Additional citations were identified from hand-searching reference lists and consultation with content

experts. English-language titles, abstracts, and full-text articles were independently reviewed by 2 reviewers, and a single yes response moved a citation forward to full text review. Full text review was completed independently by 2 reviewers and disagreements were resolved by consensus. If consensus could not be reached, a third member of the review team was consulted to mediate and make final determination.

## DATA ABSTRACTION AND RISK OF BIAS ASSESSMENT

Effect information and population, intervention, and comparator characteristics were abstracted from all included studies. As both RCTs and studies employing an observational design were eligible for inclusion, the internal validity (risk of bias [RoB]) of each included study was rated using one of the following tools according to its design: RoB 2.0,<sup>12</sup> JBI Cohort RoB tool,<sup>13</sup> JBI Quasi-Experimental RoB tool,<sup>14</sup> or the CASP Qualitative Checklist.<sup>15</sup> RoB was completed independently by 2 reviewers and a third reviewer was included if consensus could not be reached. All data abstraction was first completed by 1 reviewer and then checked; disagreements were resolved by consensus or discussion with a third reviewer (see [Appendix](#) for risk of bias ratings).

To synthesize the qualitative studies, we used the Consolidated Framework for Implementation Research framework (CFIR).<sup>16</sup> Two reviewers independently coded each study by extracting relevant text and assigning to the respective CFIR domain (see [Appendix](#) for CFIR domains). Each of these codes and associated text were captured in Distiller. The 2 reviewers and other team members then met to review the extracted text and assign the final code by consensus. A priori codes were generated from CFIR. A best-fit framework synthesis was applied to adapt the frameworks and generate overarching themes reported in the evidence.<sup>16</sup>

## SYNTHESIS

As study design, methods, assessment tools, and outcome definitions varied widely across studies, we were unable to pool study results for the included outcomes. We provide a high-level summary of all the included studies. We then present evidence by whether the tool was a health care provider-facing tool (*eg*, used in clinic and meant to guide the discussion) or a patient-facing tool or material (*eg*, meant to inform the patient either prior to or during the visit but not guide discussion). Within the health care provider-facing tools, we stratified by whether the tool was meant to be used by a clinician or LCS navigator and patient. Within the patient-facing tools, we stratified by whether the tool was meant to be used prior to, or during, a scheduled SDM visit or if the tool was meant to generate a SDM visit. Studies that investigated tools or settings that did not fit into the previously mentioned category were summarized as “other” category. We separately reported results from RCTs and studies versus with usual care to gauge the sensitivity of findings to the study design and comparator employed.

Included qualitative studies are summarized separately in the results section, using tables to provide study characteristics and brief synopses of the study text supporting the identified theme.

### **Strength of Evidence**

After synthesizing available evidence, we rated the certainty of evidence (CoE) for each outcome based on the methodology and RoB of available studies, the consistency and certainty of findings, and the directness of outcomes (whether reported outcomes are relevant to patients and providers) using standard GRADE methodology.<sup>17</sup> Of note, the CoE assessment starts at high for RCTs and begins at low for observational studies. Prior to results analyses, we conducted a ranking exercise among our

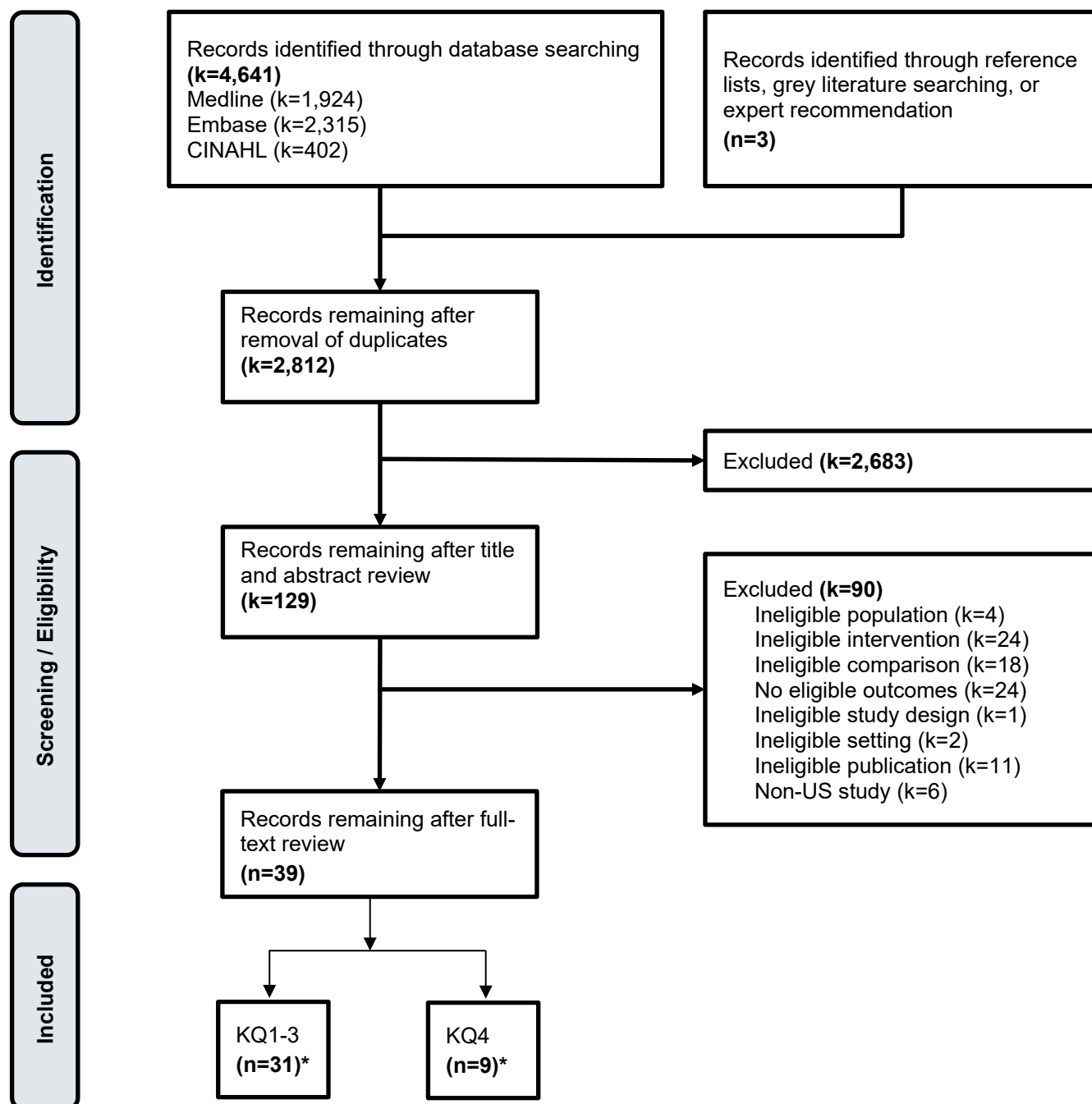
content experts, operational partners, and TEP to determine which of the included outcomes were most important. Among the included outcomes, the following were ranked the top 6 and CoE ascertained: receipt of LCS, distress/anxiety, adherence to subsequent screening, concordance of decision with patient's values and preferences, decisional conflict/regret, and quality of communication.

As noted above, studies varied in interventions, delivery modes, clinic settings, and whether interventions were patient- or health care professional-facing. We primarily assessed CoE for each outcome separately by these factors. To assess "effectiveness" of SDM overall, we also assessed CoE for studies of any SDM versus usual care (concurrent or pre-post comparisons) regardless of intervention, delivery mode, clinical setting, or targeted individual. Due to limited reporting on the outcomes of adherence to subsequent LCS, concordance of decision with patient's values and preferences, and distress/anxiety, we focused this assessment on receipt of LCS, decisional conflict/regret, and quality of communication. We also separately reported results from RCTs.

# RESULTS

## LITERATURE FLOW DIAGRAM

The literature flow diagram summarizes the results of the study selection process. A full list of excluded studies is provided in the [Appendix](#).



Notes. \*One study reported both qualitative and quantitative data.

Abbreviations. KQ=key question.



## OVERVIEW OF INCLUDED STUDIES

Our search identified 129 potentially relevant articles after deduplication and title and abstract screening. Of these, 39 primary studies met eligibility criteria. Of the included studies, 30 provided only quantitative outcomes, 8 provided only qualitative outcomes, and 1 study provided quantitative and qualitative outcomes.<sup>18</sup>

Characteristics of included quantitative studies are shown in Table 1. A pre-post design was most used (15/39), though 12 studies (31%) were RCTs. Two-thirds (26/39) used patient-facing tools, typically web or print based. Studies ranged in follow-up duration from 1 day to 14 months and included population sizes from 15 to over 19,000. Most studies had a follow-up of  $\leq 6$  months and used a variety of delivery methods. In addition to differences in design, intervention of interest, and follow-up period, studies also varied in analytic methodology and comparison condition. Comparators differed based on whether the study aim was to identify the optimal intervention delivery mode or to examine whether a decision aid was superior to another decision aid, to an educational tool, or to usual care. Additionally, we conducted a narrative synthesis of just the RCTs which follows the summarization of all included studies. We identified 22 ongoing or recently funded studies (see [Appendix](#)).

Two quantitative studies evaluating effectiveness<sup>19,20</sup> and 2 qualitative studies assessing barriers and facilitators were in Veteran populations.<sup>21,22</sup> Of the quantitative studies, 1 was an RCT that compared the LCSDec tool to an attention control intervention.<sup>19</sup> The second quantitative study used a cohort design and followed a group of individuals who received an LCS brochure in conjunction with an in-person or telephone visit with a health care provider.<sup>20</sup> Neither study evaluated the tool currently available from the VA Lung Cancer Program Office and mentioned in a [VA guidance statement](#). One additional study evaluated the tool developed for the VA LCS demonstration project and compared it to shouldiscreen.com, the most commonly referenced SDM tool among the included studies.<sup>23</sup>

The quantitative studies varied in design, intervention of interest, comparator, and analytic methodology. Thus, we provide a narrative synthesis rather than quantitative analysis. Study purpose also varied, with investigative intention including comparison of intervention delivery mode; different decision aids; decision aid to educational tool; and decision aid or educational tool to usual care. This heterogeneity across so many domains made study grouping challenging. To facilitate narrative synthesis, we grouped available studies by whether they examined a health care professional-facing tool ( $k = 9$ ) or patient-facing tool ( $k = 26$ ). Within the studies assessing health care-professional facing SDM tools, we further subdivided these into studies evaluating a tool for clinician (*eg*, physician or nurse practitioner) use or studies evaluating tools for LCS navigator use (*eg*, study coordinator or SDM program navigator). Two studies did not fit into either large category; these are discussed in an “other” group. Studies with a patient-facing tool were subdivided into those used during or prior to a SDM clinic visit or those meant to generate a SDM visit.

Assignment of the intervention to either the decision aid or educational tool category (or whether they met criteria for shared/informed medical decision-making or would meet CMS criteria) was not always feasible, as not all authors provided a copy or access to the tested intervention. As such, we relied on author report of the tool as a decision aid or educational tool; we refer throughout the text to both as SDM tools. Similarly, we did not assess the accuracy of information provided in any of the SDM tools or concordance with current US-based national LCS recommendations.

We first describe the SDM tools or communication approaches compared with usual care, to assess SDM overall. Next, we describe results for effectiveness and comparative effectiveness RCTs. In the subsequent sections, we describe results grouped by type of intervention, as described above.

**Table 1. Characteristics of Included Quantitative Studies**

	Risk of Bias			Total
	Low	Moderate/Some Concerns	High	
Study Design				
Cohort	0	3	1	4
Pre/Post	5	9	0	14
RCT	3	6	3	12
CCT	0	1	0	1
Health Care Professional- or Patient-Facing				
Health care professional-facing	1	8	0	9
Patient-facing	7	10	3	20
Other	0	1	1	2
Follow-Up				
Same day (0)	2	7	1	10
1 – 6 months	2	6	3	11
≥ 6 months	4	6	0	10
Intervention Delivery Method*				
Web (static)	3	7	1	11
Web (video)	3	6	0	9
Person	1	8	2	11
Print	3	8	3	14
SDM not specified	0	2	1	3
Decision Aid				
Author described as decision aid	6	14	1	21
Not described as decision aid	2	5	3	10
International Patient Decision Aid Standards (Among Studies Described as a Decision Aid)				
Author described decision aid as meeting IPDAS standards	5	7	1	13
Not described as meeting IPDAS standards	1	7		8
Trial Population (N)				
10-100	5	9	0	14
101-500	2	5	2	9
501-2,500	1	4	1	6
≥ 2,500	0	1	1	2

Notes. \*Groups are not mutually exclusive.

Abbreviations. CCT=controlled clinical trial; IPDAS=International Patient Decision Aids Standards; RCT=randomized controlled trial; SDM=shared decision-making.

## KEY QUESTION 1: TOOLS AND STRATEGIES REPORTED

Table 2 provides a list and brief description with author name and citation of reported tools and strategies characterized by whether they were print/brochure, video, or website/electronic viewing. As noted earlier, authors frequently did not provide sufficient information to determine if the studied tools met Medicare requirements of using an evidence-based patient decision aid or whether the tools met or were developed in accordance with International Patient Decision Aid Standards (IPDAS) criteria for a decision aid.<sup>6,24</sup> Among the 21 tools, 13 (62%) were described by authors as decision aids. The most studied tool was a decision aid available in English, Spanish, and Chinese at ([www.shouldiscreen.com](http://www.shouldiscreen.com)) first deployed in 2015 after feedback from potential users and health risk communication experts. The tool was updated to include 2021 USPSTF recommendations and content.

**Table 2. Tools or Approaches Identified for Use in Shared Decision-Making**

Tool or Approach Identified	Publications
<i>Brochures and Printed Materials</i>	
2-page brochure from a lung cancer advocacy group	Volk, 2020*
Brochure about LCS with a tear-off feature to promote contact with their health care provider; coupled with in-depth messaging from quit line staff via telephone	Sharma, 2018
Mailed letter, facemask, LCS brochure; second mailing including Native American traditional medicine and story book about traditional tobacco	Robichaux, 2023
Option Grid 1-page printed document in FAQ format	Ito Fukunaga, 2022* Han, 2019*
<i>Videos</i>	
"Lung Cancer Screening: Is It Right for Me?" (6- and 9.5-minute versions)	Volk, 2014* Volk, 2020* Hoffman, 2018*
A YouTube educational video on lung cancer screening (runtime not reported)	Strong, 2020
6-minute Supporting Appropriate Implementation of Lung Cancer Screening (SAILS) decision aid video	Reuland, 2018*
A 4.5-minute video decision aid including incidental findings	Clark, 2022*
6-minute video slideshow	Mazzone, 2017*
<i>Websites or Electronic Viewing/Interaction</i>	
<a href="http://www.shouldiscreen.com">www.shouldiscreen.com</a>	Webster, 2023*
5-15 minutes as electronic or print versions; available in English, Spanish, Chinese	Lau, 2015* Lau, 2021* Crothers, 2016* Mazzone, 2017* Tanner, 2019* Sferra, 2021*
Decision Counselling Program (online software application)	Bittner Fagan, 2023* Bittner Fagan, 2020* DiCarlo, 2022*
Option Grids	DiCarlo, 2022* Sferra, 2021*

Tool or Approach Identified	Publications
Brief educational narrative coupled with an exercise on decisional regret administered through a website	Studts, 2020
LungTalk (computer-tailored decision support tool, with messages tailored by smoking status)	Carter-Harris, 2020*
Generic information sheet online about lung cancer screening developed by the American Cancer Society	Carter-Harris, 2020*
LungCare (administered on a touch tablet in waiting room prior to primary care appointment)	Walsh, 2023*
LCSDecTool is an online tool intended to be used independently before a clinic visit	Schapira, 2023*
Web-based 10-page guide that provided general information on cancer prevention and screening guidelines	Schapira, 2023*
<b>Other Miscellaneous</b>	
Education on screening via 1 of 3 formats: numbers, numbers plus icons, or numbers plus slides	Fraenkel, 2016
Patients attend a group education class led by specialists before a personal shared decision-making visit is scheduled	Sakoda, 2020
Two educational sessions, one led by a radiologist focused on LCS process, and a second led by mental health clinician focused on smoking cessation	Flores, 2021
Patient navigation program: navigators discussed screening and helped patients through the health care system	Percac-Lima, 2018
PLCOm2012 risk calculator	Han, 2019* Tanner, 2019*
Clinician-facing EHR prompts and an EHR-integrated SDM tool	Kukhareva, 2023*

Notes. \*Author referred to tool as “decision aid.”

Abbreviations. EHR=electronic health record; FAQ=frequently asked questions; LCS=lung cancer screening; LCSDecTool=lung cancer screening decision tool; SDM=shared decision-making.

## KEY QUESTION 2: EVIDENCE STRATIFIED BY TYPE OF INTERVENTION

We organized and present evidence by whether the tool was a health care provider-facing tool (*eg*, used in clinic and meant to guide the discussion) or a patient-facing tool or material (*eg*, meant to inform the patient either prior to or during the visit but not guide discussion). Within the health care provider-facing tools, we stratified by whether the tool was meant to be used by a clinician or LCS navigator. Within the patient-facing tools, we stratified by whether the tool was meant to be used prior to, or during, a scheduled SDM visit or if the tool was meant to generate a SDM visit. Studies that investigated tools or settings that did not fit into the previously mentioned categories were summarized separately. Of note, no studies reported on the following outcomes: receipt of additional tests/procedures for identified findings; participant need for additional information; smoking behaviors; and resource allocations/usage (*eg*, primary clinician time, additional clinical staff time, patient time, medical media support, IT support, cost, or cost effectiveness).

### Health Care Professional-Facing Tools or Materials

We identified 9 studies that evaluated tools or materials that were used in conjunction with a conversation with a health care professional and categorized as “health care professional-facing tools or materials.”<sup>18,20,25-31</sup> We further categorized these studies into 2 groups: tools used by a clinician (*eg*, physician or nurse practitioner) and tools used by lung cancer screening coordinators or patient

navigators. Tools described below were used during an in-person or phone encounter with a health care professional. These tools are all described as “health care professional-facing,” though it is possible that the patients were also viewing the tools during in-person visits. This was not clearly reported in most studies. Therefore, we referred to these as “health care professional-facing” tools throughout for consistency.

### *Tools for Clinician Use During SDM Clinic Visit to Help Guide Discussion With The Patient*

Five studies used an intervention that involved a conversation with a clinician (eg, physician or nurse practitioner) and the utilization of a decision aid. Two pre-post studies used the same single-page paper-based decision aid designed to guide the conversation.<sup>18,28</sup> One RCT and 1 cohort study utilized shouldiscreen.com in various ways. The RCT compared shouldiscreen.com to Option Grids,<sup>31</sup> and the cohort study evaluated an in-person versus a phone SDM visit, using a paper decision aid (not provided), a risk assessment with the Prostate, Lung, Colorectal and Ovarian (PLCO) calculator, and shouldiscreen.com.<sup>20</sup> One controlled clinical trial evaluated an integrated clinician-facing electronic medical record (EMR) template, comparing data before and after implementation.<sup>29</sup>

Most studies were rated moderate/some concerns RoB,<sup>20,28,29,31</sup> and only 1 was rated as low RoB.<sup>18</sup> Three studies reported on receipt of LCS,<sup>17,19,26</sup> 3 reported on decisional conflict/regret,<sup>19,25,28</sup> 2 reported on patient knowledge,<sup>25,28</sup> 1 reported on quality of communication,<sup>28</sup> and 1 reported on satisfaction with decision.<sup>19</sup> No studies reported on concordance of decision, receipt of additional tests or procedures, patient need for additional information, smoking behaviors, resource allocation/usage, cost, or adherence to the screening program. Outcomes reported and the direction of effect are provided in Table 3. Certainty of evidence ratings for selected outcomes are reported in Table 4. Detailed study characteristics and results can be found in the [Appendix](#).

### *Receipt of Lung Cancer Screening*

Three studies evaluated the effect of SDM on receipt of LCS. One pragmatic clinical trial ( $N = 2,116$ ) investigated a SDM tool integrated into the electronic medical record (EMR). This study compared a 12-month pre-implementation period to a 9-month post-implementation period and concluded that the integrated EMR tool significantly increased the proportion of eligible patients that received LCS (OR = 4.7, 95% CI [3.1, 7.1]) (moderate CoE, Table 4). This trial noted similar effects regardless of patient sex (female: OR = 4.8, 95% CI [2.4, 9.5]; male: OR = 4.6; 95% CI [2.7, 7.8]). Authors planned to investigate the effect in different race/ethnicity groups but did not provide information.<sup>29</sup>

One cohort study compared an in-person SDM visit to a telephone SDM visit, finding little to no difference between the modes of SDM delivery in regards to receipt of lung cancer screening at 1-month follow-up (very low CoE, Table 4).<sup>20</sup> The third study was a pre-post study that reported 100% of the participants received screening after engaging in SDM with a printed “FAQ” document.<sup>18</sup>

### *Decisional Conflict/Regret*

Three studies, all rated moderate or “some concerns” RoB, evaluated decisional conflict or regret. One RCT concluded that SDM using Option Grids led to significantly less decisional conflict/regret compared with SDM using shouldiscreen.com, as measured with the Ottawa Decision Regret scale (range 0-100 with higher scores indicating more regret) at 6 months (low CoE, Table 4).<sup>31</sup> One cohort study compared an in-person SDM visit to a telephone SDM visit, finding little to no difference between the modes of SDM delivery in decisional conflict or regret as measured by the Decisional

Conflict Scale at 1-month follow-up (range 0-20 with higher scores indicating greater conflict).<sup>20</sup> The third study was a pre-post study that concluded decisional conflict or regret was significantly reduced after viewing a 1-page printed FAQ document.<sup>28</sup>

### *Quality of Communication*

One RCT rated some concerns RoB concluded that there was no significant effect between Option Grids and shouldiscreen.com when measuring quality of communication with CollaboRATE at 6-month follow-up (mean scores of 97.4% vs 98.6%, respectively) (low CoE, Table 4).<sup>31</sup>

### *Satisfaction with Decision*

One cohort study rated moderate RoB reported that there was no significant difference in satisfaction with decision between in-person ( $26.7 \pm 2.8$ ) versus telephone ( $24.6 \pm 5.6$ ) SDM visits, as measured with the Satisfaction With Decisions scale (range 0-30 with higher scores indicating greater satisfaction) at 1-month follow-up.<sup>20</sup>

### *Knowledge*

Two studies evaluated knowledge of LCS benefits and harms. One RCT rated some concerns RoB concluded that there was no significant effect between Option Grids and shouldiscreen.com when measuring knowledge with an author-developed scale at 6-month follow-up (mean scores of 67.4% vs 62.4% correctly answered questions in each group, respectively).<sup>31</sup> The second pre-post study rated moderate RoB only provided knowledge scores collected immediately post intervention.<sup>28</sup>

**Table 3. Outcomes Reported and Direction of Effect for Tools for Clinician Use**

Author, Year Sample Size Intervention	Outcomes With Certainty of Evidence Assessments						Outcomes Without Certainty of Evidence Assessments			
	Adherence	Receipt of Lung Cancer Screening	Concordance of Decision	Decisional Conflict/ Regret	Distress/ Anxiety	Overall Quality of Communi- cation	Receipt of Additional Tests/ Procedures	Satisfaction with Decision	Participant Need for Additional Information	Knowledge
<i>RCT</i>										
<b>Sferra, 2021<sup>31</sup></b> N = 237 SDM discussion utilizing Option Grids vs shouldscreen.com	-	-	-	↓	-	↔	-	-	-	↔
<i>Controlled Clinical Trial</i>										
<b>Kukhareva, 2023<sup>29</sup></b> N = 2116 EHR prompts and integrated SDM tool (pre-post implementation of tool)	-	↑	-	-	-	-	-	-	-	-
<i>Cohort</i>										
<b>Tanner, 2019<sup>20</sup></b> N = 137 In-person vs telephone SDM visit with printed materials, PLCom2012 calculator, and shouldscreen.com	-	↔	-	↔	-	-	-	↔	-	-
<i>Pre-Post</i>										
<b>Han, 2019<sup>18</sup></b> N = 60 Option Grid 1-page FAQ and PLCom2012 calculator	-	↔	-	-	-	-	-	-	-	-
<b>Ito Fukunaga, 2022<sup>28</sup></b> N = 23 Option Grid 1-page FAQ	-	-	-	↓	-	-	-	-	-	NA*

Notes. \*Knowledge scores were only reported post-intervention.

↑ mean scores increased after receiving intervention, in favor of intervention

↓ mean scores decreased after receiving intervention, in favor of intervention

↔ no difference between arms after receiving intervention

Abbreviations. EHR=Electronic health record; FAQ=frequently asked questions; PLCO=Prostate, Lung, Colorectal and Ovarian; SDM=shared decision-making.



**Table 4. Certainty of Evidence for Clinician-Facing SDM Tools or Approaches**

Outcome	Measurement Tool Follow-up	Total № of Participants (Studies)	Findings	Certainty	Importance
<b>Receipt of Lung Cancer Screening</b>	% receiving screening in 12-mo pre-intervention phase vs 9-months post intervention phase	<i>N</i> = 2116 (1 CCT) <sup>29</sup>	OR = 4.7, 95% CI [3.1, 7.1], <i>p</i> < 0.001	⊕⊕⊕○ Moderate <sup>a,b</sup>	<b>An EMR-integrated SDM tool probably results in a greater % receiving lung cancer screening, compared with no EMR integrated tool.</b>
	% receiving screening at 1-3 months	<i>N</i> = 197 (1 cohort) <sup>20</sup>	One cohort study reported 88.4% and 88.2% in the in-person and telephone groups (respectively)	⊕○○○ Very low <sup>a,c</sup>	<b>The evidence is very uncertain on the effect of in-person compared with telephone SDM on receipt of lung cancer screening.</b>
<b>Decisional Conflict or Regret</b>	Ottawa Decision Regret Scale 6 months	<i>N</i> = 237 (1 RCT) <sup>31</sup>	Mean scores 6.0 (Option Grids) vs. 10.2 (shouldiscreen.com), <i>p</i> = 0.02	⊕⊕○○ Low <sup>a,c</sup>	<b>Option Grids may result in less decisional conflict or regret compared with shouldiscreen.com.</b>
<b>Quality of Communication</b>	CollaboRATE 6 months	<i>N</i> = 237 (1 RCT) <sup>31</sup>	Mean scores 97.4% (Option Grids) vs. 98.6% (shouldiscreen.com), <i>p</i> = 0.6	⊕⊕○○ Low <sup>a,c</sup>	<b>There may be little to no difference in quality of communication in SDM using Option Grids compared with shouldiscreen.com.</b>

Notes. GRADE Working Group grades of evidence:

High certainty: We are very confident that the true effect lies close to that of the estimate of the effect.

Moderate certainty: We are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low certainty: Our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.

Very low certainty: We have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations:

a. Rated down 1 level for study limitations (rated some concerns or moderate risk of bias).

b. Rated up 1 level for magnitude of effect.

c. Rated down 1 level for imprecision (optimal information size not met, sample size <400).

Abbreviations. RCT=randomized controlled trial; SDM=shared decision-making.



### *Tools for LCS navigator Use to Help Guide SDM Discussion*

Four included studies evaluated SDM tools intended for the use of LCS navigators: decision counselors,<sup>25,26</sup> care coordinators,<sup>27</sup> and patient navigators.<sup>30</sup> SDM tools varied across studies: 3 studies used the Decision Counseling Program in some capacity,<sup>25-27</sup> 1 used Option Grid,<sup>27</sup> and another used a patient navigation program to introduce SDM to participants.<sup>30</sup> Two studies were RCTs,<sup>27,30</sup> 1 was a cohort study,<sup>26</sup> and 1 was a pre-post design.<sup>25</sup>

All studies were rated moderate or some concerns RoB. All 4 studies reported receipt of LCS,<sup>25-27,30</sup> 1 study reported decisional conflict/regret,<sup>25</sup> and 1 study reported receipt of additional tests/procedures.<sup>30</sup> No studies reported the effect of tools for LCS navigator SDM on adherence, concordance of decision, distress/anxiety, overall quality of communication, satisfaction with decision, participant need for additional information, knowledge, smoking behaviors, resource allocation/usage, or costs. Outcomes reported and the direction of effect are provided in Table 5. Certainty of evidence ratings for selected outcomes are reported in Table 6. Detailed study characteristics and results can be found in the [Appendix](#).

### *Receipt of Lung Cancer Screening*

Two RCT studies,<sup>27,30</sup> 1 cohort study,<sup>26</sup> and 1 pre-post study assessed the number of individuals that completed at least 1 LCS appointment.<sup>25</sup> Both RCTs found a statistically significant difference for receipt of lung cancer screening favoring the intervention arms that included care coordinators and patient navigators (low CoE, Table 6). LCS rates were low in both studies. The trial that compared outreach with a mailed informational material, including a print decision aid (Option Grid), with a review guided by a care coordinator with (OC-DC) and without (OC) an online support application (Decision Counseling Program) versus usual care (UC) found that 5.5% of participants in the combined 2 SDM groups (OC + OC-DC) completed LCS, compared with 1.8% of those receiving usual care (UC) ( $p = 0.001$ ) at 280 days. Of note, LCS did not differ between those receiving online support (OC-DC) and those who did not (OC) (7.0% and 4.0% respectively,  $p = 0.12$ ).<sup>27</sup> Authors did not evaluate the statistical significance separately of either OC-DC or OC versus UC. The other trial evaluated a patient navigation program to promote LCS and provide SDM compared with usual care among low socioeconomic people who currently smoke. Authors found that 23.5% of the intervention arm completed LCS, compared with 8.6% of usual care ( $p < 0.001$ ).<sup>30</sup> Results did not differ by race, sex, or age category.

The cohort study started with a pool of 1,359 potentially eligible participants, of which 80 met eligibility criteria and agreed to be in the study. Of the included 80 participants, 64 used the Decision Counseling Program, while 16 were not reached and did not receive the intervention. The study found that 45.3% (29/64) of those that completed the counseling session also completed lung cancer screening, compared with 0% (0/16) in those that did not use the SDM tool ( $p = 0.0003$ ).<sup>26</sup>

Finally, the pre-post study enrolled 28 participants from a pool of 829 eligible participants, of which 20 received the intervention. This study found that 45% (9/20) of participants that completed the intervention received LCS.<sup>25</sup>

### *Decisional Conflict/Regret*

One pre-post study evaluated decisional conflict using a 16-item 5-point Likert decisional conflict scale to compare pre and post the intervention. Only 11 of the 20 participants who received the

intervention completed the follow-up assessment. Among those that completed the follow-up assessment, there was no statistically significant difference in decisional conflict compared with their pre-intervention assessment (very low CoE, Table 6). The study also analyzed people who currently and formerly smoked separately. While there was still not statistically significant difference in decisional conflict, sample sizes were small.<sup>25</sup>

#### *Receipt of Additional Tests/Procedures*

One RCT reported that following LCS additional tests and procedures (including additional imaging, biopsies, surgery, and chemotherapy) were “similar in both” the navigated and usual care groups.<sup>30</sup>

**Table 5. Outcomes Reported and Direction of Effect for Tools for LCS Navigator Use**

Author, Year Sample Size Intervention	Outcomes With Certainty of Evidence Assessments						Outcomes Without Certainty of Evidence Assessments			
	Adherence	Receipt of Lung Cancer Screening	Concordance of Decision	Decisional Conflict/ Regret	Distress/ Anxiety	Overall Quality of Communi- cation	Receipt of Additional Tests/ Procedures	Satisfaction With Decision	Participant Need for Additional Information	Knowledge
<i>RCT</i>										
<b>DiCarlo, 2022<sup>27</sup></b> N = 2376 Reviewed mailed material including printed Option Grid decision aid with care coordinator, with or without additional review of Decision Counseling Program vs usual care	-	↑	-	-	-	-	-	-	-	-
<b>DiCarlo, 2022<sup>27</sup></b> N = 628 Reviewed mailed material including printed Option Grid decision aid with care coordinator, with vs without additional review of Decision Counseling Program	-	↔	-	-	-	-	-	-	-	-
<b>Percac-Lima, 2018<sup>30</sup></b> N = 1200 Patient navigator program plus SDM vs usual care	-	↑	-	-	-	-	↔	-	-	-
<i>Cohort</i>										
<b>Bittner Fagan, 2023<sup>26</sup></b> N = 80 Phone call guiding patient through Decision Counseling Program, followed by visit with PCP or LCS program	-	↑	-	-	-	-	-	-	-	-
<i>Pre-Post</i>										
<b>Bittner Fagan, 2020<sup>25</sup></b> N = 28 Phone call with decision counselor who guided patient using Decision Counseling Program	-	45%	-	↔	-	-	-	-	-	-



mean scores increased after receiving intervention, in favor of intervention



no difference between arms after receiving intervention



mean scores decreased after receiving intervention, in favor of intervention

Abbreviations. LCS=lung cancer screening; PCP=primary care provider; SDM=shared decision-making.

**Table 6. Certainty of Evidence for LCS Navigator-Facing SDM Tools or Approaches**

Outcome	Measurement Tool Follow-Up	Total No of Participants (Studies)	Findings	Certainty	Importance
<b>Receipt of Lung Cancer Screening</b>	% receiving screening 280 days – 1 year	<i>N</i> = 3,547 (2 RCTs) <sup>27,30</sup>	127/999 (12.7%) SDM tools plus care coordination vs 100/2548 (3.9%) usual care	⊕⊕○○ Low <sup>a,b</sup>	<b>SDM tools combined with care coordination may result in increased receipt of lung cancer screening compared with usual care.</b>
<b>Decisional Conflict or Regret</b>	Decisional Conflict Scale 30 days	<i>N</i> = 28 (1 pre-post) <sup>25</sup>	Mean difference = -0.57	⊕○○○ Very low <sup>a,c</sup>	<b>The evidence is very uncertain on the effect of SDM tools on decisional conflict/regret.</b>

Notes. GRADE Working Group grades of evidence:

High certainty: We are very confident that the true effect lies close to that of the estimate of the effect.

Moderate certainty: We are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low certainty: Our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.

Very low certainty: We have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations:

a. Rated down 1 level for study limitations (studies rated some concerns RoB).

b. Rated down 1 level for imprecision (event rate too low).

c. Rated down 2 levels for imprecision (OIS not met, sample size <150).

Abbreviations. RCT=randomized controlled trial; SDM=shared decision-making.

## ***Patient-Facing Tools or Materials***

We identified 20 studies that evaluated tools or materials that were developed with the intention that the patient or participant would view the item either prior to or during the SDM clinic visit. We categorized these studies into 2 groups: 1 consisting of tools used prior to or during the visit, and 1 consisting of tools that were meant to inform the patient or participant and potentially generate an SDM visit but no requirement to interact with a health care professional.

### ***Tools for Patients' Use During or Prior to SDM Clinic Visit***

Five studies incorporated materials provided to patients to review during or before a scheduled visit with a clinician to help guide the discussion or inform the patients about LCS prior to discussing options with their clinician.<sup>19,32-35</sup>

Tools varied across the studies, with 3 making use of web or video content and the remaining 2 studies using counseling by specialists associated with lung cancer screening (Table 7). Two studies were RCTs<sup>19,35</sup> and the remaining 3 were a pre-post design.<sup>32-34</sup>

The following outcomes were not reported in any of the included studies that included an intervention aimed at patients to use before or during a SDM visit: adherence, satisfaction with decision, concordance of decision, receipt of additional tests/procedures, participant need for additional information, smoking behaviors, resource allocations/usage, or costs. Outcomes reported and the direction of effect are provided in Table 7. Certainty of evidence ratings for selected outcomes are reported in Table 8. Detailed study characteristics and results can be found in the [Appendix](#).

### ***Receipt of Lung Cancer Screening***

Two RCTs<sup>19,35</sup> and 1 pre-post study<sup>33</sup> captured the number of individuals that completed a first LCS appointment, with all 3 finding that exposure to SDM increased uptake of LCS. The 2 RCTs found a difference in uptake between the intervention and control arms, with those in the intervention arm having greater lung cancer screening. One cluster-randomized trial compared those randomized to SDM using the tablet-based LungCare tool with those receiving usual care.<sup>35</sup> Among the subset of patients randomized to LungCare who completed baseline and follow-up surveys (32/41), 32% completed a LCS visit versus 13% ( $p = 0.01$ ) in the usual care control arm (very low CoE, Table 8). The second trial compared a web-based LCSDecTool with a web-based attention control guide that included general information on cancer prevention and the USPSTF LCS screening guidelines. Authors reported an 18.8 percentage point difference (95% CI [4.4, 33.2];  $p = 0.02$ ) between the intervention (31 of 69, 44.9%) and control (18 of 71, 25.4%) arm at 9 months (low CoE, Table 8).<sup>19</sup> The 1 pre-post study used EHR records to assess uptake of LCS after an in-person SDM visit that included a review of patient eligibility criteria, presentation of a 6-min narrated video slide show describing the benefits and harms of LCS, the use of a decision aid (shouldiscreen.com), and an opportunity for patients to ask questions throughout the visit. Authors reported 94.6% of individuals attending and completing the SDM visit completed an LCS visit.<sup>33</sup>

### ***Decisional Regret***

The RCT by Schapira, 2023 reported decisional regret as an outcome, finding no difference between the intervention and control groups over time (low CoE, Table 8).<sup>19</sup> Study authors used the Decisional Conflict Scale (DCS; a 16-item scale with 5 subscales, with scores ranging from 0 to 100; a score lower than 25 is associated with implementing decisions and greater than 37.5 with decision delay or

feeling unsure about implementation) to measure decisional conflict immediately and 1 and 3 months post intervention. Immediately after the intervention, those in the intervention arm had a lower DCS mean score 22.2 (95% CI [18.3, 26.0]) score than those in the control arm 31.1 (26.1, 36.0;  $p = 0.004$ ). However, by the first and third month, between-group differences were no longer statistically significant ( $p = 0.18$  and  $0.33$ , respectively). Decisional regret was also measured using a scale developed by Brehaut et al immediately after intervention, 1-month, and 3-months follow up.<sup>36</sup> There was no between-group difference at any of the 3 time points. Authors analyzed decisional conflict and regret separately for those identifying as African American or Black. They compared those that identified as African American or Black in the intervention arm to those identifying as African American or Black in the control arm and at 3 months found no between-group difference in decisional conflict.

### *Distress/Anxiety*

One RCT<sup>19</sup> and 1 pre-post study<sup>32</sup> reported distress and anxiety after completion of the SDM visit. Schapira, 2023 used the State Trait Anxiety Inventory (range 20-80 with higher scores indicating greater distress) to measure anxiety among those exposed to the LCSDecTool compared with controls, immediately after the SDM visit, 1 month, and 3 months. At all 3 time points the level of anxiety did not differ between the LCSDecTool and control groups ( $p = 0.86, 0.30, 0.74$ , respectively) (Low CoE, Table 8). The pre-post study by Flores, 2021 found a reduction ( $p = 0.03$ ) in distress/anxiety, measured with an author-developed question, after the study population had participated in an educational session on LCS.<sup>32</sup>

### *Quality of Communication*

Two pre-post studies<sup>32,33</sup> measured various aspects of what we categorized as “quality of communication” among a subset of participants. Among those responding to the post survey, the majority (93% and 86.4%) described the SDM tool positively, with those in the Flores, 2021 study<sup>32</sup> strongly agreeing or agreeing with: “Overall, I was satisfied with the educational sessions” and 57 of the 66 respondents in the Mazzone et al study<sup>33</sup> providing positive feedback such as: “good presentation helped me to make an informed choice,” “Excellent!,” or “No unnecessary pressure-honest, highly intelligent, and sensitive to needs of my whole life” (Low CoE, Table 8).

### *Knowledge*

Four of the 5 studies reported a measure of knowledge, with all 4 reporting an increase in knowledge after viewing of the SDM tool.<sup>19,33-35</sup> Each study created its own tool to assess knowledge and assessed knowledge at varying time points, from immediately<sup>34</sup> to 3 months<sup>19</sup> after use of the SDM tool. In the RCT by Schapira, 2023, improvement in LCS knowledge score (range 0-12 with higher scores indicating greater knowledge) was higher immediately after intervention (7.0 vs 4.9, mean difference = 2.0; 95% CI [1.2, 2.8];  $p < 0.001$ ) and remained higher at 1- and 3-months follow-up. In the RCT by Walsh, 2023,<sup>35</sup> knowledge scores based on the mean total number of correct answers out of 10 were greater in the intervention group (6.5 [range 3-9] vs 5.5 [range 3-8],  $p < 0.01$ ).

**Table 7. Outcomes Reported and Direction of Effect for Patient-Facing Tools for Patient Use During or Prior to SDM Clinic Visit Results**

Author, Year Sample Size Intervention	Outcomes With Certainty of Evidence Assessments						Outcomes Without Certainty of Evidence Assessments			
	Adherence	Receipt of Lung Cancer Screening	Concordance of Decision	Decisional Conflict/ Regret	Distress/ Anxiety	Overall Quality of Communi- cation	Receipt of Additional Tests/ Procedures	Satisfaction With Decision	Participant Need for Additional Information	Knowledge
<i>RCT</i>										
<b>Walsh, 2023</b> <sup>35</sup> N = 66 LungCare delivered on tablet in waiting room prior to visit	-	↑	-	-	-	-	-	-	-	↑
<b>Schapira, 2023</b> <sup>19</sup> N = 140 Web-based Lung Cancer Screening Decision Tool (LCSDecTool) used independently before clinic visit versus attention control	-	↑	-	↔	↔	-	-	-	-	↑
<i>Pre-Post</i>										
<b>Flores, 2021</b> <sup>32</sup> N = 15 Two 30-minute educational sessions led by a radiologist and mental health clinician	-	-	-	-	↓	93% (satisfied with tool)	-	-	-	-
<b>Sakoda, 2020</b> <sup>34</sup> N = 680 Group education class led by a specialist prior to a clinic visit	-	-	-	-	-	-	-	-	-	↑
<b>Mazzone, 2017</b> <sup>33</sup> N = 423 Counseling and a 6 min video (shouldiscreen.com)	-	94.6% screened	-	-	-	86.4% (positive comments)	-	-	-	↑*

Notes. \*Knowledge scores were reported for knowledge domains: age eligibility, smoking eligibility, benefits of LCS, and harms of LCS.

↑ mean scores increased after receiving intervention, in favor of intervention  
↓ mean scores decreased after receiving intervention, in favor of intervention

↔ no difference between arms after receiving intervention

**Table 8. Certainty of Evidence for Tools for Patient Use During or Prior to SDM Visit**

Outcome	Measurement Tool Follow-up	Total № of Participants (Studies)	Findings	Certainty	Importance
<b>Receipt of Lung Cancer Screening</b>	% receiving screening 2 months	<i>N</i> = 66 (1 RCT) <sup>35</sup>	32% LungCare vs 13% usual care	⊕○○○ Very low <sup>a,b</sup>	The evidence is very uncertain on the effect of LungCare on receipt of lung cancer screening compared with usual care.
<b>Receipt of Lung Cancer Screening</b>	% receiving screening 6 months	<i>N</i> = 140 (1 RCT) <sup>19</sup>	18 percentage point difference between LungCare and usual care	⊕⊕○○ Low <sup>b</sup>	LCSDecTool may result in increased lung cancer screening compared with usual care (attention control).
<b>Quality of Communication</b>	Author-developed Same day –1 month	<i>N</i> = 438 (2 pre-post) <sup>32,33</sup>	93% and 86.4% described SDM tool positively	⊕○○○ Very low <sup>a,c</sup>	The evidence is very uncertain on the effect of SDM tools on quality of communication.
<b>Decisional Conflict/Regret</b>	Decisional Conflict Scale 3 months	<i>N</i> = 140 (1 RCT) <sup>19</sup>	LungCare 24.2 (20.8, 27.6) vs usual care 27.5 (23.3, 31.7) with a between group difference of -2.9 (-8.9, 3.0), <i>p</i> = 0.33	⊕⊕○○ Low <sup>b</sup>	LCSDecTool may result in little to no difference in distress/anxiety compared with usual care (attention control).
<b>Distress/Anxiety</b>	State Trait Anxiety Index 3 months	<i>N</i> = 140 (1 RCT) <sup>19</sup>	No statistically significant difference between LungCare and usual care	⊕⊕○○ Low <sup>b</sup>	LCSDecTool may result in little to no difference in distress/anxiety compared with usual care (attention control).

Notes. GRADE Working Group grades of evidence:

High certainty: We are very confident that the true effect lies close to that of the estimate of the effect.

Moderate certainty: We are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low certainty: Our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.

Very low certainty: We have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations:

a. Rated down 1 level for study limitations (study rated some concerns/moderate RoB).

b. Rated down 2 levels for imprecision (OIS not met, sample size <150).

c. Rated down 1 level for indirectness (study used unvalidated measurement tool).

Abbreviations. LCSDecTool=lung cancer screening decision tool; RCT=randomized controlled trial.



### Tools or Materials for Patient Education and to Potentially Generate SDM Visits

Fifteen studies included materials or tools that were provided to patients at risk for lung cancer to inform them about lung cancer screening but without a conversation with a clinician or any type of scheduled clinic visit within a health care system.<sup>23,37-39,40-42,43-47,48-50</sup>

Authors utilized diverse tools. Four studies<sup>23,37-39</sup> utilized a version of shouldscreen.com, 3 studies<sup>40-42</sup> used a decision aid video called “Lung Cancer Screening: Is It Right For Me?”, 5 studies<sup>43-47</sup> used a variety of video and/or web based media, and the remaining 3 studies<sup>48-50</sup> used printed materials (Table 9). Seven studies were RCTs<sup>37,41,45,46,48-50</sup> and 9 were pre-post studies.<sup>23,38-40,42-44,47</sup> Of the 7 RCTs, 2 compared tools or materials with usual care and 5 compared 1 tool type or delivery mode with another.

The following outcomes were not reported in any of the included studies: adherence, smoking behaviors, resource allocation/usage, or costs. Outcomes reported and the direction of effect are provided in Table 10. Certainty of evidence ratings for selected outcomes are reported in Table 11. Detailed study characteristics and results can be found in the [Appendix](#).

**Table 9. Description of Interventions and Comparisons for Tools or Materials for Patient Education and to Potentially Generate SDM Visits**

Author, Year (Design)	Intervention	Comparison
<i>RCT</i>		
<b>Carter-Harris, 2020</b>	LungTalk; a computer-tailored decision support tool, with messages tailored by smoking status	Viewed generic information sheet online about lung cancer screening developed by the American Cancer Society
<b>Clark, 2022</b>	A 4.5-minute video decision aid including incidental findings information	Same video, without incidental findings information (4-min)
<b>Fraenkel, 2016</b>	Education on screening via 3 different formats: Numbers	Numbers plus icons; numbers plus slides
<b>Robichaux, 2023</b>	Mailed letter, facemask, LCS brochure; second mailing including Native American traditional medicine and story book about traditional tobacco	Mailed letter, facemask, LCS brochure
<b>Sharma, 2018</b>	Brochure about LCS with a tear-off feature to promote contact with their health care provider; coupled with in-depth messaging from quit line staff via telephone	Brochure about LCS with a tear-off feature to promote contact with their health care provider
<b>Volk, 2020</b>	9.5-minute narrated video “Lung Cancer Screening: Is It Right for Me?”	2-page brochure from a lung cancer advocacy group
<b>Webster 2023</b>	Provided with shouldscreen.com website when contacting Quitline	Provided with shouldscreen.com printed materials when contacting Quitline
<i>Pre-Post</i>		
<b>Crothers, 2016</b>	Review of shouldscreen.com and printed pamphlet during focus groups	NA
<b>Hoffman, 2018</b>	“Lung Cancer Screening: Is It Right for Me?” viewed online	NA
<b>Lau, 2015</b>	Initial development of shouldscreen.com	NA
<b>Lau, 2021</b>	Provided with shouldscreen.com website at community center	NA

Author, Year (Design)	Intervention	Comparison
Reuland, 2018	6-minute SAILS decision aid video	NA
Strong, 2020	An educational video about lung cancer screening hosted on YouTube	NA
Studts, 2020	Brief educational narrative coupled with an exercise on decisional regret administered through a website	NA
Volk, 2014	6-minute video "Lung Cancer Screening: Is It Right for Me?"	NA

### *Receipt of Lung Cancer Screening*

Four RCTs reported participants who completed a LCS appointment.<sup>37,41,48,49</sup> All reported no difference in receipt of LCS at 4-6 months between intervention and control arms. Volk, 2020 evaluated the video “Lung Cancer Screening: Is It Right for Me?” vs standard educational materials.<sup>41</sup> “Lung Cancer Screening: Is It Right for Me?” video results in no difference in receipt of lung cancer screening compared with 2-page brochure from a lung cancer advocacy group (high CoE, Table 11). The other 3 RCTs evaluated different tools/modes of SDM delivery (very low CoE, Table 11).<sup>37,48,49</sup> In their pre-post study, Reuland, 2018 reported that 10 out of 50 (20%) participants received LCS after viewing the SAILS Decision Aid.<sup>47</sup>

### *Concordance of Decision*

Two pre-post studies reported on concordance, participants’ LCS preference, and eligibility.<sup>38,39</sup> Lau, 2015 utilized the Ottawa Decision Support Framework and defined concordance as “participants who preferred to get screened and were also eligible for screening.” 14 participants (23.7%) were considered concordant pre-viewing of shouldiscreen.com and 35 participants (59.3%) were considered concordant post-viewing ( $p < 0.001$ ; very low CoE, Table 11).<sup>39</sup> Lau, 2021 determined concordance by the first question from the Decisional Conflict Scale: “Which option do you prefer? A) I prefer to screen; B) I prefer not to screen; C) Unsure.” There was a significant increase (+12 percentage points,  $p = 0.016$ ) in participants’ concordance from pre-viewing of shouldiscreen.com (21%) to post-viewing (33%) (very low CoE, Table 11).<sup>38</sup>

### *Decisional Conflict/Regret*

Two RCTs<sup>37,41</sup> and 4 pre-post studies<sup>38-40,44</sup> reported decisional conflict/regret. The 2 RCTs reported no difference in the measured decisional regret between the intervention and control arms, whereas the 4 pre-post studies reported an improvement after viewing of the intervention materials.<sup>37-41,44</sup> Lau, 2015 and Lau, 2021 reported significant ( $p < 0.001$ ) decreases in participants’ mean (SD) overall Decisional Conflict Scale score post-viewing of shouldiscreen.com (2015: 17.5 [11.4] vs 8.9 [9.7]; 2021: 46.3 [29.7] vs 15.1 [25.8], respectively).<sup>38,39</sup> Hoffman, 2018 and Volk, 2020 reported the Values Clarity subscale of the Decisional Conflict Scale (range 0-100 with higher scores indicating less clarity about personal values).<sup>40,41</sup> Hoffman, 2018 reported a mean score of 3.9 after watching the “Lung Cancer Screening: Is It Right for Me?” video. Volk, 2020 reported a significant ( $p < 0.001$ ) mean difference of -14.1 (95% CI [-19.5, -8.7]) between “Lung Cancer Screening: Is It Right for Me?” video and standard education groups at 1-week follow-up, with participants in the video group showing lower decisional conflict than those in the standard education group.<sup>41</sup> Additionally, Volk, 2020 reported a significant mean difference of -14.9 (95% CI [-20.1, -9.7];  $p < 0.001$ ) in the Decisional Conflict Scale-Informed subscale (range 0-100 with higher scores indicating feeling more uninformed) at 1 week between the video and standard education groups. “Lung Cancer Screening: Is It Right for Me?” video results in less decisional conflict/regret compared to a 2-page brochure from a lung cancer advocacy group at 1

week (high CoE, Table 11). A single pre-post study by Studts, 2020 utilized the modified low literacy DCS (DCS-LL) to help reduce the time burden for participants to complete the survey.<sup>44</sup> Participants showed significantly lower mean decisional conflict scores after viewing a web-based educational narrative and completing an exercise on decisional regret (47.6 vs 18.3,  $p < 0.0001$ ). Additionally, the authors found no significant differences in scores based on age, race/ethnicity, SES/education, or smoking status. Finally, a single RCT by Webster, 2023 used the Health Care Decisions scale to measure decisional conflict/regret.<sup>51</sup> The authors reported mean (SD) scores for the shouldiscreen.com (2.9 [1.1]) and delayed intervention (2.7 [1.1]) at baseline and found no significant differences within or between groups at either 1 or 4 months (very low CoE, Table 11).<sup>37</sup>

### *Distress/Anxiety*

A single RCT by Webster, 2023 asked participants if the materials made them feel “nervous or fearful about either LCS or about lung cancer.”<sup>37</sup> They found that 47 (52.2%) participants in the shouldiscreen.com arm and 62 (54.4%) participants in the delayed intervention arm responded that they were “only a little,” “somewhat,” or “very much” nervous/fearful about LCS or lung cancer. There were no significant differences between groups. Shouldiscreen.com web may cause little to no difference compared to shouldiscreen.com print on distress/anxiety at 4 months (low CoE, Table 11).

### *Quality of Communication*

Three RCTs<sup>37,41,46</sup> and 1 pre-post study<sup>42</sup> used author-developed questionnaires to measure participants’ perceived quality of communication. Webster, 2023 asked participants if “any parts of the materials were confusing or difficult to understand” and reported that 23 (25.6%) participants in the shouldiscreen.com group and 38 (33.3%) participants in the delayed intervention group answered “a little bit,” “moderately,” or “extremely.”<sup>37</sup> Authors also asked participants if the materials helped prepare them to talk with their doctor about what matters most to them. They reported that only 9 (10%) participants in the intervention group and 5 (4.4%) participants in the delayed intervention group answered “not at all” to this question, though there were no significant group differences (very low CoE, Table 11). Authors state that while feedback for amount of information provided and preparedness was generally positive, 53.4% of participants reported “feeling at least ‘a little’ nervous or fearful about LCS or lung cancer.” Carter-Harris, 2020<sup>46</sup> asked participants about their satisfaction with the LungTalk intervention or a non-tailored lung screening information sheet, as well their preparedness to talk to their clinician about LCS. They reported that satisfaction was significantly higher in the LungTalk group and that participants in both groups felt “prepared” or “very prepared” to discuss LCS with their clinician, though they did not report a p-value. However, there were no significant differences between groups on preparedness ( $p = 0.52$ ). LungTalk may result in little to no difference in quality of communication compared to a non-tailored lung cancer screening information sheet at 1 week (low CoE, Table 11). In their pre-post study, Volk, 2014 asked participants for feedback on the video “Lung Cancer Screening: Is It Right for Me?” and found that “more than 94% of patients viewed the entire video, would recommend it to others, felt it held their interest, and wanted to view similar videos about health care decisions.”<sup>42</sup> Volk, 2014 also reported 78.8% of participants stated that they would be more interested in screening after viewing.<sup>42</sup> Finally, Volk, 2020 asked participants in the video decision aid group only for feedback and found that 198 (87.2%) participants thought that the video contained sufficient information to help them decide about LCS.<sup>41</sup>

*Receipt of Additional Tests/Procedures*

A single pre-post study by Reuland, 2018 reported a count of participants that received any additional tests or procedures after LCS. One (2%) patient had a category 4a LungRADS nodule and the 3-month follow-up scan showed resolution.<sup>47</sup>

*Satisfaction with Decision*

A single RCT by Webster, 2023 asked participants about their degree of satisfaction with their screening decision on a 5-point Likert scale at 1 and 4 months.<sup>37</sup> Authors reported that in the web version of shouldscreen.com, 96 (85.7%) participants at 1 month and 93 (86.1 %) participants at 4 months “strongly agreed” or “agreed” with their screening decision. In the printed version of shouldscreen.com, 110 (93.2%) participants at 1 month and 99 (90.8%) participants at 4 months “strongly agreed” or “agreed” with their screening decision. Results were not statistically significant between groups.

*Participant Need for Additional Information*

One RCT<sup>37</sup> and 2 pre-post studies<sup>40,44</sup> reported participants’ need for additional information. In the RCT by Webster, 2023 comparing web and print versions of shouldscreen.com, only 5 (5.6%) participants in the print group and 6 (5.3%) participants in the web group requested additional information, and there were no significant differences between groups.<sup>37</sup> However, it was unclear exactly when participants requested additional information. Hoffman, 2018 asked how informed participants felt about lung cancer screening after watching the video “Lung Cancer Screening: Is It Right for Me?” and participants responded on a 10-point VAS scale (range 0-10 with higher scores indicating feeling more informed).<sup>40</sup> Participants reported a mean (SD) VAS score of 8.7 (1.6). Finally, Studts, 2020 utilized the Informed subscale of modified version of the DCS-LL before and after viewing a web-based educational narrative and completing on exercise on decisional regret. Participants reported a pre-intervention mean (SD) score of 52.2 (30.5) and a post-intervention score of 16.9 (24.5).<sup>44</sup> The difference of 35.3 between time points was significant ( $p < 0.0001$ ).

*Knowledge*

5 RCTs<sup>37,41,45,46,50</sup> and 7 pre-post studies<sup>23,38-40,42,43,47</sup> reported knowledge of screening benefits and harms as an outcome. Two studies utilized the 12-item LCS measure.<sup>40,43</sup> Hoffman, 2018 reported a statistically significant improvement ( $p < 0.001$ ) in the mean (SD) score of 3.9 (2.9) post-viewing of the video “Lung Cancer Screening: Is It Right for Me?”<sup>40</sup> Similarly, Strong, 2020 showed statistically significant improvement in participants’ knowledge after watching a video on lung cancer screening (95% CI of the difference [-3.9, -1.9];  $p = 0.00$ ).<sup>43</sup> Two studies utilized the Ottawa Decision Support Framework, or a measure derived from it, to measure change in knowledge after viewing shouldscreen.com.<sup>38,39</sup> Both studies found statistically significant ( $p < 0.001$ ) improvements in knowledge. While Lau, 2015<sup>39</sup> only reported the mean (SD) scores pre-intervention (7.5 [1.9]) and post-intervention (10.9 [2.2.]), Lau, 2021<sup>38</sup> reported a 1.4-point improvement after viewing the video compared with before viewing. Volk, 2020 utilized a questionnaire developed by Lowenstein et al<sup>52</sup> to measure the percentage of questions answered correctly at 6 months following use of a decision aid or standard education.<sup>41</sup> Patients in the decision aid group answered 49.9% (95% CI [47.5, 52.3]) of questions correctly and the standard education group answered 40% (95% CI [37.6, 42.4]) of the questions correctly ( $p < 0.001$ ). Carter-Harris, 2020 utilized the Knowledge of Lung and Lung Cancer Screening scale to measure change in knowledge after 1 week.<sup>46</sup> The LungTalk intervention group had

an improvement in mean scores of 2.3 points, while the general lung cancer information sheet group had an improvement of 1.1 points. Both changes were statistically significant ( $p < 0.01$ ).

Five studies utilized an author-developed knowledge questionnaire.<sup>23,42,45,47,50</sup> Clark, 2022 reported that changes in overall mean scores from pre- to post-intervention were similar in the group that watched a video that included information on incidental findings (2.8) versus the group that watched a video without incidental findings information (2.6 [SD NR];  $p = 0.2$ ).<sup>45</sup> However, the participants that watched the video with the segment on incidental findings answered more questions correctly than those that watched the video without the incidental findings segment (94.8% vs 73.7%,  $p = 0.02$ ). Reuland, 2018 found a significant increase ( $p < 0.001$ ) of 2.8 points (95% CI [2.1, 3.6]) in participants' mean knowledge scores before and after the viewing the SAILS decision aid video.<sup>47</sup> Fraenkel, 2015 compared the presentation of information on LCS in 3 different formats: numbers only, numbers + icon array, and numbers + slides on LCS scans.<sup>50</sup> Authors reported differences in knowledge (model-estimated mean [SE]) of 0.7 (0.01) in the numbers only arm, 1.2 (0.01) in the numbers + icon array arm, and 1.0 (0.01) in the numbers + slides arm. Only the comparison between the numbers only and the numbers + icon array were statistically different. Volk, 2014 stated that the mean (SD) percentage of correct answers on their knowledge questionnaire increased significantly ( $p < 0.01$  for each question) from 25.5% (20.7) to 74.8% (20.2) after participants viewed the video "Lung Cancer Screening: Is It Right for Me?"<sup>42</sup> Finally, Crothers, 2016 created a questionnaire with 20 true/false questions and reported the percentages of participants who answered each individual question correctly before and after a focus group and reading 2 decision aids.<sup>23</sup> There was statistically significant improvement ( $p < 0.05$ ) for 12 of the 20 questions. However, authors did not report any measure of mean overall knowledge.

**Table 10. Outcomes Reported and Direction of Effect for Tools or Materials for Patient Education to Potentially Generate SDM Visit**

Author, Year Sample Size Intervention	Outcomes With Certainty of Evidence Assessments						Outcomes Without Certainty of Evidence Assessments			
	Adherence	Receipt of Lung Cancer Screening	Concordance of Decision	Decisional Conflict/ Regret	Distress /Anxiety	Overall Quality of Communi- cation	Receipt of Additional Tests/ Procedures	Satisfaction With Decision	Participant Need for Additional Information	Knowledge
<i>RCT</i>										
<b>Carter-Harris, 2020<sup>46</sup></b> N = 60 LungTalk vs generic info sheet on lung cancer screening from the ACS	-	-	-	-	-	73% very satisfied (intervention), 28% very satisfied (comparator)	-	-	-	↑
<b>Clark, 2022<sup>45</sup></b> N = 348 Video decision aid with incidental findings segment vs video decision aid w/o incidental findings segment	-	-	-	-	-	-	-	-	-	↑
<b>Fraenkel, 2015<sup>50</sup></b> N = 253 Education interface on screening via numbers only vs numbers + icons, or numbers + slides	-	-	-	-	-	-	-	-	-	↑
<b>Robichaux, 2023<sup>48</sup></b> N = 469 Mailed letter, face mask, LCS brochure, & story about Native American traditional medicine vs LCS brochure alone	-	↔	-	-	-	-	-	-	-	-
<b>Sharma, 2018<sup>49</sup></b> N = 1000 LCS brochure with tear-off feature, in- depth messaging from quit line staff vs LCS brochure alone	-	↔	-	-	-	-	-	-	-	-
<b>Volk, 2020<sup>41</sup></b> N = 516 “Lung Cancer Screening: Is It Right for Me?” video vs standard educational material	-	↔	-	↔	-	87.2% (sufficient info)	-	-	-	↑

Author, Year Sample Size Intervention	Outcomes With Certainty of Evidence Assessments						Outcomes Without Certainty of Evidence Assessments			
	Adherence	Receipt of Lung Cancer Screening	Concordance of Decision	Decisional Conflict/ Regret	Distress /Anxiety	Overall Quality of Communica- tion	Receipt of Additional Tests/ Procedures	Satisfaction With Decision	Participant Need for Additional Information	Knowledge
<b>Webster, 2023</b> <sup>37</sup> N = 298 Shouldscreen.com print vs web	-	↔	-	↔	↔	No differences (preparedness or clarity)	-	↔	↔	↔
<i>Pre-Post</i>										
<b>Crothers, 2016</b> <sup>23</sup> N = 45 Shouldscreen.com, printed pamphlet	-	-	-	-	-	-	-	-	-	↑
<b>Hoffman, 2018</b> <sup>40</sup> N = 30 "Lung Cancer Screening: Is It Right for Me?" video	-	-	-	↓	-	-	-	-	↑	↑
<b>Lau, 2015</b> <sup>39</sup> N = 60 Initial development of shouldscreen.com	-	-	↑	↓	-	-	-	-	-	↑
<b>Lau, 2021</b> <sup>38</sup> N = 74 Shouldscreen.com	-	-	↑	↓	-	-	-	-	-	↑
<b>Reuland, 2018</b> <sup>47</sup> N = 50 6-min SAILS decision aid video	-	10 participants	-	-	-	-	1 participant	-	-	↑
<b>Strong, 2020</b> <sup>43</sup> Educational YouTube video on LCS	-	-	-	-	-	-	-	-	-	↑
<b>Studts, 2020</b> <sup>44</sup> Online educational narrative coupled with decisional regret exercise	-	-	-	↓	-	-	-	-	↓	-
<b>Volk, 2014</b> <sup>42</sup> "Lung Cancer Screening: Is It Right for Me?" video	-	-	-	-	-	94% would recommend to others	-	-	-	↑

↑ mean scores increased after receiving intervention, in favor of intervention  
 ↓ mean scores decreased after receiving intervention, in favor of intervention

↔ no difference between arms after receiving intervention

Abbreviations. ACS=American Cancer Society; LCS=lung cancer screening.



**Table 11. Certainty of Evidence for Patient Education to Potentially Generate SDM Visit**

Outcome	Measurement Tool Follow-up	No of Participants (Studies)	Findings	Certainty	Importance
<b>Receipt of Lung Cancer Screening</b>	% receiving screening 6 months	516 (1 RCT) <sup>41</sup>	57/259 (22%) SDM vs 68/257 (26.5%) LCS brochure	⊕⊕⊕⊕ High	“Lung Cancer Screening: Is It Right for Me?” video results in no difference in receipt of lung cancer screening compared with a 2-page brochure from a lung cancer advocacy group.
	% receiving screening 6 months	N = 298 (1 RCT) <sup>37</sup>	11.0% shouldiscreen.com web vs 11.2% shouldiscreen.com print	⊕○○○ Very low <sup>a,b</sup>	The evidence is very uncertain on the effect of shouldiscreen.com web compared to shouldiscreen.com print on receipt of lung cancer screening.
	% receiving screening 4-6 months	1469 (2 RCTs) <sup>48,49</sup>	41/734 (5.6%) LCS brochure + additional materials vs 40/735 (10.9%) LCS brochure alone	⊕○○○ Very low <sup>c,d</sup>	The evidence is very uncertain on the effect of a LCS brochure + additional materials compared to a LCS brochure alone on receipt of lung cancer screening.
<b>Concordance of Decision</b>	Ottawa Decision Support Framework 0 days	N = 60 (1 pre-post) <sup>39</sup>	23.7% concordant pre-intervention vs 59.3% concordant post-intervention	⊕○○○ Very low <sup>e</sup>	The evidence is very uncertain on the effect of SDM tools on concordance of decision.
	Question from Decisional Conflict Scale 6 months	N = 74 (1 pre-post) <sup>38</sup>	21% concordant pre-intervention vs 33% concordant post-intervention	⊕○○○ Very low <sup>f,g</sup>	The evidence is very uncertain on the effect of SDM tools on concordance of decision.
<b>Decisional Conflict/Regret</b>	Decisional Conflict Scale (Informed and Values Clarity subscales) 1 week	N = 516 (1 RCT) <sup>41</sup>	Mean difference -14.1	⊕⊕⊕⊕ High	“Lung Cancer Screening: Is It Right for Me?” video results in less decisional conflict/regret compared with 2-page brochure from lung cancer advocacy group.
	Health Care Decisions Scale 4 months	N = 298 (1 RCT) <sup>37</sup>	2.9 shouldiscreen.com web vs 2.7 shouldiscreen.com print	⊕○○○ Very low <sup>a,h</sup>	The evidence is very uncertain on the effect of shouldiscreen.com web compared with shouldiscreen.com print on decisional conflict and regret.
<b>Distress/Anxiety</b>	Author-developed 4 months	N = 298 (1 RCT) <sup>37</sup>	52.2% shouldiscreen.com web vs 54.4% shouldiscreen.com print were distressed/anxious	⊕⊕○○ Low <sup>a</sup>	Shouldiscreen.com web may cause little to no difference compared with shouldiscreen.com print on distress/anxiety.



Outcome	Measurement Tool Follow-up	No of Participants (Studies)	Findings	Certainty	Importance
Quality of Communication	Author-developed 1 week	N = 60 (1 RCT) <sup>46</sup>	73% SDM tool very satisfied vs 28% usual care, no difference in preparedness	⊕⊕○○ Low <sup>f,i</sup>	<b>LungTalk may result in little to no difference in quality of communication compared with non-tailored LCS information sheet.</b>
	Author-developed 4 months	N = 298 (1 RCT) <sup>37</sup>	25.6% shouldiscreen.com web vs 33.3% shouldiscreen.com print were confused by the material	⊕○○○ Very low <sup>a,j</sup>	<b>The evidence is very uncertain on the effect of SDM web compared with SDM print on quality of communication.</b>

Notes. GRADE Working Group grades of evidence:

High certainty: We are very confident that the true effect lies close to that of the estimate of the effect.

Moderate certainty: We are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low certainty: Our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.

Very low certainty: We have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations:

a. Rated down 2 levels for study limitations (study rated high risk of bias).

b. Rated down 1 level for imprecision (low event rate [around 10%]).

c. Rated down 2 levels for study limitations (study rated high risk of bias).

d. Rated down 1 level for imprecision (low event rate [around 5%]).

e. Rated down 1 level for indirectness (study population included participants not eligible for LCS).

f. Rated down 1 level for indirectness (not comprehensive scale).

g. Rated down 2 levels for imprecision (study did not meet OIS, sample size >150).

h. Rated down 1 level for imprecision (OIS not met, sample size <400).

i. Rated down 1 level for study limitations (study rated some concerns risk of bias).

j. Rated down 1 level for indirectness (questions were not comprehensive of quality).

Abbreviations. RCT=randomized controlled trial; SDM=shared decision-making.

## SDM Tools Non-Specified

Two cohort studies used EMR data and ICD codes to investigate the effect of SDM in general (no specific tool or approach was reported) on receipt of or adherence to screening.<sup>53,54</sup>

One moderate RoB cohort study ( $N = 7,193$ ) concluded that individuals with a documented SDM visit had “25% higher odds of adherence to annual lung cancer screening than those without SDM documentation (OR = 1.25, 95% CI [1.01, 1.54])” at 15-months follow-up (very low CoE, Table 12).<sup>53</sup>

One high RoB cohort study ( $N = 19,221$ ) analyzed retrospective data to determine if there was an association between the SDM clinician specialty and the receipt of lung cancer screening. Compared with family physicians, the adjusted odds ratio of undergoing screening after an SDM visit was significantly higher with a radiologist (OR = 9.09, 95%CI [4.2, 19.9]) or a nurse practitioner (OR = 1.70, 95% CI [1.4, 2.1]). However, there was little to no difference with a pulmonary specialist (OR = 0.84, 95% CI [0.7, 1.0]) (very low CoE, Table 12). This study also reported adjusted odds ratios of undergoing screening by race, finding little to no difference in receipt of lung cancer screening in Black (OR = 0.87, 95% CI [0.7, 1.1]) or Hispanic (OR = 0.86, 95% CI [0.6, 1.2]) individuals, when compared with non-Hispanic White individuals.<sup>54</sup>

**Table 12. Certainty of Evidence for SDM Tools Non-Specified**

Outcome	Measurement Tool Follow-up	Total № of Participants (Studies)	Findings	Certainty	Importance
<b>Adherence</b>	Participants with complete lung cancer screening claim within 15 months of SDM claim	$N = 7193$ (1 observational) <sup>53</sup>	OR = 1.25, 95% CI [1.01, 1.54]	⊕○○○ Very low <sup>a</sup>	The evidence is very uncertain on the effect of radiologists, nurse practitioners, or pulmonary specialists providing SDM compared with family physicians on adherence to lung cancer screening.
<b>Receipt of Lung Cancer Screening</b>	Participants with complete lung cancer screening claim within 3 months of SDM claim	$N = 19,221$ (1 observational) <sup>54</sup>	Radiologist: OR = 9.09, 95% CI [4.16, 19.85] Nurse practitioner: OR = 1.70, 95% CI [1.42, 2.05] Pulmonary specialist: OR = 0.84, 95% CI [0.70, 1.01]	⊕○○○ Very low <sup>a</sup>	The evidence is very uncertain on the effect of clinician providing SDM visit on receipt of lung cancer screening.

Notes. GRADE Working Group grades of evidence:

High certainty: We are very confident that the true effect lies close to that of the estimate of the effect.

Moderate certainty: We are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low certainty: Our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.

Very low certainty: We have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations:

a. Downgraded 1 level for study limitations (rated some concerns or moderate risk of bias).

Abbreviations. CI=confidence interval; OR=odds ratio; SDM=shared decision-making.

## KEY QUESTION 2: ANY SDM TOOL OR DECISION AID COMPARED WITH USUAL CARE

Four studies (3 RCTs<sup>27,30,35</sup> and 1 cohort study<sup>26</sup>) evaluated SDM compared with usual care. All found higher LCS with SDM. Walsh evaluated a tablet-based tool provided to patients in clinic prior to their primary care appointment. Authors randomized 78 individuals but evaluated 66 participants who completed baseline and follow-up surveys (1.5% of those initially contacted and meeting preliminary eligibility criteria). They reported that 4/32 (13%) completed LCS among controls versus 11/34 (32%) in the intervention group ( $p = 0.01$ ) (4/41; 9.8% vs 11/37; 39.7% among those initially randomized) (very low CoE, Table 13).<sup>35</sup>

The other 2 RCTs included (or primarily evaluated) care coordinators or patient navigators in addition to SDM. DiCarlo evaluated outreach contact (OC) with mailed LCS information, a print decision aid, and contact with care coordinator to review material, assess LCS interest, and offer to schedule an LCS appointment alone or with additional interactive Decision Counseling (OC-DC) with a 10-minute interactive decision support software application versus usual care (UC).<sup>27</sup> The third RCT by Percac-Lima evaluated a patient LCS navigation program among people who currently smoke. Navigators trained in motivational interviewing contacted patients to determine LCS eligibility, introduce LCS-SDM, provide brief smoking cessation counseling, schedule appointments with primary care clinicians, and help overcome barriers obtaining LCS (including translation, insurance, and transportation), communicating findings, and ensuring follow-up. Primary care clinicians received education about LCS guidelines, SDM, and LCS ordering but did not receive patient navigator support.<sup>30</sup> Across both of these studies, 127/999 (12.7%) of those who received SDM tools received screening versus 100/2548 (3.9%) of those in usual care (low CoE, Table 13).

The cohort study by Bittner Fagan evaluated the online decision-aid program Decision Counseling Program (DCP) delivered by telephone via a trained decision counselor plus mailed follow-up educational material and additional SDM discussion with either PCP or LCS program staff to age-eligible people who currently smoke. Out of 1,359 potentially eligible patients, 336 could be contacted and 80 agreed to participate. LCS at 1 year was conducted in 29/64 (45.3%) of those who completed counseling versus 0/16 who did not (very low CoE, Table 13).<sup>26</sup> Overall, evidence is sparse on the independent effects of SDM on LCS or other outcomes.

**Table 13. Certainty of Evidence for Any SDM Tool Compared With Usual Care**

Outcome	Measurement Tool Follow-up	Total No of Participants (Studies)	Findings	Certainty	Importance
Receipt of Lung Cancer Screening	% receiving screening 280 days – 1 year	N = 3,547 (2 RCTs) <sup>27,30</sup>	127/999 (12.7%) SDM tools vs 100/2548 (3.9%) usual care	⊕⊕○○ Low <sup>a,b</sup>	SDM tools may result in increased receipt of lung cancer screening compared with usual care.
	% receiving screening 2 months	N = 66 (1 RCT) <sup>35</sup>	32% LungCare vs 13% control	⊕○○○ Very low <sup>a,c</sup>	The evidence is very uncertain on the effect of LungCare on receipt of lung cancer screening compared with usual care.
	# completed LDCT within 1 year of SDM appointment	N = 80 (1 cohort) <sup>26</sup>	45.3% telephone DCP with counselor plus mailed educational material plus SDM discussion with PCP or LCS program vs 0% usual care	⊕○○○ Very low <sup>a,d</sup>	The evidence is very uncertain on the effect of combined telephone DCP with counselor plus mailed educational material plus SDM discussion with PCP or LCS program on receipt of LCS compared with usual care.

Notes. GRADE Working Group grades of evidence:

High certainty: We are very confident that the true effect lies close to that of the estimate of the effect.

Moderate certainty: We are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low certainty: Our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.

Very low certainty: We have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations:

a. Rated down 1 level for study limitations (study rated some concerns RoB).

b. Rated down 1 level for imprecision (event rate too low).

c. Rated down 2 levels for imprecision (OIS not met, study had sample size <100).

d. Rated down 1 level for study limitation (study rated moderate RoB).

Abbreviations. DCP=decision counseling program; LCS=lung cancer screening; PCP=primary care physician; RCT=randomized controlled trial; SDM=shared decision-making.

## KEY QUESTION 2: EVIDENCE FROM RCTS

Here, we summarize the evidence identified from eligible RCTs ( $k = 12$ ) for efficacy/effectiveness and comparative effectiveness. Two RCTs assessed efficacy,<sup>30,35</sup> 1 trial assessed both efficacy and comparative effectiveness,<sup>27</sup> and 9 trials assessed comparative effectiveness (Table 14).<sup>19,31,37,41,45,46,48-50</sup> One RCT included an intervention that involved a conversation with a physician and the utilization of a decision aid.<sup>31</sup> Two RCTs included interventions that non-physician health care workers used to help guide SDM discussions.<sup>27,30</sup> Two RCTs included patient-facing tools or materials that were used prior to or during an SDM visit.<sup>19,35</sup> The remaining 7 RCTs included interventions that were patient-facing tools or materials that were meant to generate an SDM visit.<sup>37,41,45,46,48-50</sup> Receipt of LCS was the most commonly reported outcome where CoE was assessed (9 trials). Decisional regret/conflict ( $k = 4$ ), communication quality ( $k = 3$ ) and distress/anxiety ( $k = 2$ ) were less frequently reported. Knowledge was reported in 8 RCTs.

**Table 14. Outcomes Reported and Direction of Effect for RCTs**

Author, Year Sample Size Intervention	Outcomes With Certainty of Evidence Assessments**						Outcomes Without Certainty of Evidence			
	Adherence	Receipt of Lung Cancer Screening	Concordance of Decision	Decisional Conflict/ Regret	Distress/ Anxiety	Overall Quality of Communi- cation	Receipt of Additional Tests/ Procedures	Satisfaction With Decision	Participant Need for Additional Information	Knowledge
<b>Effectiveness</b>										
<b>DiCarlo, 2022<sup>27</sup></b> N = 2376 Reviewed mailed material including printed Option Grid™ decision aid with care coordinator, with or without additional review of Decision Counseling Program vs usual care	-	↑*	-	-	-	-	-	-	-	-
<b>Walsh, 2023<sup>35</sup></b> N = 66 LungCare delivered on tablet in waiting room prior to visit vs usual care	-	↑	-	-	-	-	-	-	-	↑
<b>Percac-Lima, 2018<sup>30</sup></b> N = 1200 Navigators contacted patients about SDM vs usual care	-	↑	-	-	-	-	↔	-	-	-
<b>Comparative Effectiveness – Mode of Delivery</b>										
<b>Robichaux, 2023<sup>48</sup></b> N = 469 Mailed letter, face mask, LCS brochure, & story about Native American traditional medicine vs LCS brochure alone	-	↔	-	-	-	-	-	-	-	-
<b>Webster, 2023<sup>37</sup></b> N = 298 Shouldscreen.com print vs web	-	↔	-	↔	↔	No differences (prepared- ness or clarity)	-	↔	↔	↔
<b>Sharma, 2018<sup>49</sup></b> N = 1000 LCS brochure with tear-off feature, in- depth messaging from quit line staff vs LCS brochure alone	-	↔	-	-	-	-	-	-	-	-

Author, Year Sample Size Intervention	Outcomes With Certainty of Evidence Assessments**						Outcomes Without Certainty of Evidence			
	Adherence	Receipt of Lung Cancer Screening	Concordance of Decision	Decisional Conflict/ Regret	Distress/ Anxiety	Overall Quality of Communi- cation	Receipt of Additional Tests/ Procedures	Satisfaction With Decision	Participant Need for Additional Information	Knowledge
<i>Comparative Effectiveness – Decision aid vs. educational tool</i>										
Schapira, 2023 <sup>19</sup> N = 140 Lung Cancer Screening Decision Tool (LCSDecTool) used independently before clinic visit vs general information on cancer screening + USPSTF lung and other cancer guideline	-	↑	-	↔	↔	-	-	-	-	↑
Carter-Harris, 2020 <sup>46</sup> N = 60 LungTalk vs generic information sheet without LCS developed by ACS	-	-	-	-	-	73% very satisfied (intervention), 28% very satisfied (comparator)	-	-	-	↑
Clark, 2022 <sup>45</sup> N = 348 Video decision aid about incidental findings vs video aid w/o incidental findings	-	-	-	-	-	-	-	-	-	↑
Fraenkel, 2015 <sup>50</sup> N = 253 Education on screening via numbers vs. numbers + icons vs numbers + slides	-	-	-	-	-	-	-	-	-	↑
Volk, 2020 <sup>41</sup> N = 516 “Lung Cancer Screening: Is It Right for Me?” video vs standard educational material	-	↔	-	↔	-	87.2% (sufficient info)	-	-	-	↑
DiCarlo, 2022 <sup>27</sup> N = 628 Reviewed mailed material including printed Option Grid decision aid with care coordinator, with versus without	-	↔*	-	-	-	-	-	-	-	-

Author, Year Sample Size Intervention	Outcomes With Certainty of Evidence Assessments**						Outcomes Without Certainty of Evidence			
	Adherence	Receipt of Lung Cancer Screening	Concordance of Decision	Decisional Conflict/ Regret	Distress/ Anxiety	Overall Quality of Communica- tion	Receipt of Additional Tests/ Procedures	Satisfaction With Decision	Participant Need for Additional Information	Knowledge
additional review of Decision Counseling Program										
<i>Comparative Effectiveness – Decision aid vs Decision Aid</i>										
<b>Sferra, 2021</b> <sup>31</sup> N = 237 Option Grid vs Shouldiscreen.com	-	-	-	↔	-	↔	-	-	-	↔

**Notes.** \*Study compared 2 groups of SDM against usual care and found a statistically significant difference. However, there no statistically significant difference between the 2 SDM groups.

\*\*These outcomes were priority ranked to identify the top 6 outcomes using a forced choice ranking including at least 1 "harm" to have certainty of evidence performed.

↑	mean scores increased after receiving intervention, in favor of intervention
↓	mean scores decreased after receiving intervention, in favor of intervention

↔ no difference between arms after receiving intervention

**Abbreviations.** LCS=lung cancer screening; SDM=shared decision-making.



### Efficacy/Effectiveness Trials

The 3 trials compared different decision aids, processes, mode of delivery, and targeted individuals (patient and/or provider) (Table 15).<sup>27,30,35</sup> Interventions included a video administered on a touch tablet titled LungCare plus care coordination,<sup>35</sup> outreach with mailed educational information with or without a telephone administered tool called Decision Counseling,<sup>27</sup> and a patient navigation program with education materials.<sup>30</sup> All had a usual care control. The studies reported few outcomes in common, however all reported LCS uptake (Table 16). One trial reported receipt of additional tests or procedures<sup>30</sup> and another trial reported LCS knowledge.<sup>35</sup> All 3 RCTs reported that those in the intervention arm had a significantly higher uptake of LCS than those in the control arm.<sup>27,30,35</sup> The single trial that measured knowledge found that those in the intervention arm had significantly higher knowledge scores than the usual care arm.<sup>35</sup>

One trial<sup>30</sup> which reported the number of individuals that required additional testing or procedures found, "In the intervention group, 12 (12.8%) patients had Lung-RADS 3 findings and required a six-month follow up compared to 6 (8.7%) in the control group. Seven (7.4%) in the intervention group and 6 (9.6%) in control patients had Lung-RADS 4 finding and required immediate follow-up. The number of additional diagnostic tests post-screening was similar in both groups..."

**Table 15. Efficacy RCT Study Characteristics**

Author, Year Risk of Bias Follow-Up	Intervention	Comparator	Mode of Delivery; Patient or Provider Facing	Tool Domains
<b>Walsh, 2023<sup>35</sup></b> Some concerns 2 months	LungCare Video provided to patient on tablet in waiting room	Usual care	Web-video; Patient-facing	Eligibility for lung cancer screening; what screening is; individual risk for lung cancer screening; where to get screening; time commitment; harms
<b>DiCarlo, 2022<sup>27</sup></b> Some concerns 280 days	Outreach with mailed educational information plus telephone Decision Counseling Program	Usual care	Person and print; Patient and Provider facing	Eligibility for lung cancer screening; what screening is; harms
<b>Percac-Lima, 2018<sup>30</sup></b> Some concerns 1 year	A patient navigation program that included SDM	Usual care	Person and print; Provider facing	Eligibility for lung cancer screening; what screening is; harms

**Table 16. Certainty of Evidence for SDM Tools versus Usual Care (Effectiveness RCTs)**

Outcome	Measurement Tool Follow-up	Total № of Participants (Studies)	Findings	Certainty	Importance
<i>LCS Navigator Facing</i>					
<b>Receipt of Lung Cancer Screening</b>	% receiving screening 280 days – 1 year	N = 3,547 (2 RCTs) <sup>27,30</sup>	127/999 (12.7%) SDM tools plus care coordination vs 100/2548 (3.9%) usual care	⊕⊕○○ Low <sup>a,b</sup>	<b>SDM tools combined with care coordination may result in increased receipt of LCS compared with usual care.</b>
<i>Patient Facing During or Prior To Visit</i>					
<b>Receipt of Lung Cancer Screening</b>	% receiving screening 2 months	N = 66 (1 RCT) <sup>35</sup>	32% LungCare vs 13% usual care	⊕○○○ Very low <sup>a,c</sup>	<b>The evidence is very uncertain on the effect of LungCare on receipt of lung cancer screening compared with usual care.</b>

Notes. GRADE Working Group grades of evidence:

High certainty: We are very confident that the true effect lies close to that of the estimate of the effect.

Moderate certainty: We are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low certainty: Our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.

Very low certainty: We have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations:

a. Downgraded 1 level for study limitations (rated some concerns, moderate, or high risk of bias).

b. Rated down 1 level for imprecision (event rate too low).

c. Rated down 2 levels for imprecision (OIS not met, sample size <150).

### Comparative Effectiveness Trials

Ten RCTs assessed comparative effectiveness<sup>19,27,31,37,41,45,46,48-50</sup>; 8 of the interventions were patient facing<sup>19,37,41,45,46,48-50</sup> and 2 were meant to be viewed by both the patient and health care provider.<sup>27,31</sup>

Very few of the RCTs utilized the same SDM intervention tools; only 2 RCTs included shouldiscreen.com as one of the tools (as an intervention or comparator). The remaining RCTs included a variety of tools, including author-derived tools. In the broadest sense, the trials compared author-defined decision aids to tools or activities described as educational materials/activities or to the decision aid delivered in a different modality or format. Three trials assessed mode of delivery by comparing the same decision aid delivered in a different mode or format.<sup>37,48,49</sup> The remaining 7 trials compared the decision aid to an educational tool/material/activity.<sup>19,27,31,41,45,46,50</sup> Study characteristics are provided in Table 17. Certainty of evidence ratings for selected outcomes are reported in Table 18.

### Trials Comparing Mode or Intensity of Delivery (Same Intervention)

Three trials compared the same tool but with changes to the intensity of the intervention or mode of delivery. Robichaux, 2023 investigated how the addition of additional outreach to a mailer and social media campaign would influence shared decision-making in an urban Native American clinic.<sup>48</sup> Webster, 2023 investigated differences in uptake and understanding when shouldiscreen.com was provided in an online or print format.<sup>37</sup> Finally, Sharma, 2018 investigated the impact of including in-depth messaging from quitline staff with a mailed brochure in comparison to just receiving the mailed brochure.<sup>49</sup> All 3 trials measured the receipt of lung cancer screening and all 3 found that there was no

significant increase in the receipt of lung cancer screening when comparing different modalities or intensity of the SDM tool.

Webster, 2023<sup>37</sup> also measured decisional conflict, distress/anxiety, quality of communication, satisfaction with decision, participant need for additional information, and knowledge and found no significant difference between those that viewed shouldiscreen.com virtually or in print form.

### *Trials Comparing Decision Aids to an Educational Tool or Another Decision Aid*

Six RCTs compared an author defined decision aid to a traditional educational tool for LCS.<sup>19,27,41,45,46,50</sup> Another RCT, by Sferra, 2021,<sup>31</sup> compared 2 different decision aids, Option Grid and shouldiscreen.com. Five of the 6 trials measured knowledge.<sup>19,41,45,46,50</sup> Of the 5 trials that compared a decision aid to an educational tool, the authors found a significant increase in knowledge scores among those that were exposed to the decision aid compared with those provided the educational tool. The single trial<sup>31</sup> that compared 2 decision aids found no difference in knowledge scores between the 2 groups.

Three RCTs comparing a decision aid with an educational tool measured receipt of LCS.<sup>19,27,41</sup> Two found no significant difference between those exposed to a decision aid versus those exposed to an educational tool and the proportion of participants that chose to undergo LCS.<sup>27,41</sup> The third trial by Shapira, 2023 found that those exposed to the decision aid (LCSDecTool) were more likely to undergo LCS than those exposed to general information on cancer screening and the United States Preventive Task Force screening guidelines for breast, colon, cervical, and lung cancer.<sup>19</sup>

Two trials measured decisional conflict or regret and both found no significant difference between the intervention and comparator arms.<sup>31,41</sup> Volk, 2020 compared Lung Cancer Screening: Is it Right for Me? with a standard educational tool from a lung cancer advocacy group,<sup>41</sup> while Sferra, 2021 compared exposure to shouldiscreen.com to exposure to Option Grids.<sup>31</sup>

Three of the trials assessed quality of communication using author-developed surveys; 2 of the trials reported 73% and 87.2% were satisfied with the information provided in the decision aid.<sup>41,46</sup> The third trial reported no significant difference in assessment of the quality of the decision aid when comparing shouldiscreen.com to Option Grids.<sup>31</sup>

**Table 17. Comparative Effectiveness RCTs Study Characteristics**

Author, Year Risk of Bias Follow-Up	Intervention	Comparator	Mode of Delivery Patient or Provider Facing	Tool Domains
<b>Robichaux, 2023<sup>48</sup></b> Low 6 months	Mailed Letter, face mask, LCS brochure, story about Native American traditional medicine, follow-up text message and second mailing	Mailed letter, face mask, LCS brochure & story about Native American traditional medicine	Print (mailed) and text message  Patient facing	Eligibility for LCS, what screening is, individual risk for LC, and where to get screening
<b>Webster, 2023<sup>37</sup></b> High 4 months	Shouldiscreen.com	Print version of shouldiscreen.com	Web  Patient facing	Eligibility for LCS, what screening is, individual risk for LC, cost, where to get screening, time commitment, harms, and other risk factors
<b>Schapira, 2023<sup>19</sup></b> Low 9 months	LCSDecTool	10-page general information on cancer prevention and the USPSTF screening guidelines for breast, colon, cervical, and lung cancer	Web  Patient facing	Eligibility for LCS, what screening is, individual risk for LC, cost, where to get screening, time commitment, harms, and other risk factors
<b>DiCarlo, 2022<sup>27</sup></b> Some concerns 280 days	Outreach contact plus LCS information plus telephone-administered decision counseling	Outreach contact plus with LCS information (no telephone-administered decision counseling)	Print (mailed)  Patient facing	Eligibility for LCS, what screening is, and harms
<b>Clark, 2022<sup>45</sup></b> Some concerns 0 days	4 5-minute video covering the benefits and harms of screening – including information on incidental findings	4-minute video covering the benefits and harms of screening – excluded the information on incidental findings	Video  Patient facing	What screening is, costs, and harms
<b>Sferra, 2021<sup>31</sup></b> Some concerns 6 months	Optiongrid.org	Shouldiscreen.com	Web  Patient facing	Eligibility for LCS, what screening is, individual risk for LC, cost, where to get screening, time commitment, harms, and other risk factors
<b>Carter-Harris, 2020<sup>46</sup></b> Some concerns 3 months	LungTalk (a computer tailored decision support tool (audio, video, and animation segments))	Generic information sheet online about LCS developed by the American Cancer Society	Web  Patient facing	What screening is and harms
<b>Volk, 2020<sup>41</sup></b> Some concerns 6 months	Lung Cancer Screening: Is it Right for Me?	Standard educational material brochure from a lung cancer advocacy group	Web  Patient facing	Eligibility for LCS, what screening is, harms, and other risk factors
<b>Sharma, 2018<sup>49</sup></b> High 4 months	LCS brochure with a tear-off feature to promote contact with their health care provider with phone-based in-depth messaging coupled with in-depth messaging from quitline staff	LCS brochure with a tear-off feature to promote contact with their health care provider	Print (mailed)  Patient facing	Eligibility for LCS, what screening is, and costs

Author, Year Risk of Bias Follow-Up	Intervention	Comparator	Mode of Delivery Patient or Provider Facing	Tool Domains
<b>Fraenkel, 2015<sup>50</sup></b> High 0 days	Numbers + a set of slides illustrating LDCT scans of 250 people in random order	Numbers + icon array or numbers only	Print  Patient facing	Harms

*Abbreviations.* LC=lung cancer; LCS=lung cancer screening; LCSDecTool=lung cancer screening decision tool; LDCT=low-dose computed tomography; SDM=shared decision-making.

**Table 18. Certainty of Evidence for SDM Tools versus SDM Tool/Educational Aid (Comparative Effectiveness RCTs)**

Outcome	Measurement Tool Follow-up	Total № of Participants (Studies)	Findings	Certainty	Importance
<i>Clinician Facing</i>					
<b>Decisional Conflict or Regret</b>	Ottawa Decision Regret Scale 6 months	<i>N</i> = 237 (1 RCT) <sup>31</sup>	Mean scores 6.0 (Option Grids) vs 10.2 (shouldiscreen.com), <i>p</i> = 0.02	⊕⊕○○ Low <sup>a,b</sup>	Option Grids may result in less decisional conflict or regret compared with shouldiscreen.com.
<b>Quality of Communication</b>	CollaboRATE 6 months	<i>N</i> = 237 (1 RCT) <sup>31</sup>	Mean scores 97.4% (Option Grids) vs. 98.6% (shouldiscreen.com), <i>p</i> = 0.6	⊕⊕○○ Low <sup>a,b</sup>	There may be little to no difference in quality of communication in SDM using Option Grids compared with shouldiscreen.com.
<i>Patient Facing During or Prior To Visit</i>					
<b>Receipt of Lung Cancer Screening</b>	% receiving screening 6 months	<i>N</i> = 140 (1 RCT) <sup>19</sup>	18% difference between LungCare and usual care	⊕⊕○○ Low <sup>c</sup>	LCSDecTool may result in increased lung cancer screening compared with usual care.
<b>Decisional Conflict/Regret</b>	Decisional Conflict Scale 3 months	<i>N</i> = 140 (1 RCT) <sup>19</sup>	LungCare 24.2 (20.8, 27.6) vs usual care 27.5 (23.3, 31.7) with a between group difference of -2.9 (-8.9, 3.0), <i>p</i> = 0.33)	⊕⊕○○ Low <sup>c</sup>	LCSDecTool may result in little to no difference in distress/anxiety compared with usual care.
<b>Distress/Anxiety</b>	Strate Trait Anxiety Index 3 months	<i>N</i> = 140 (1 RCT) <sup>19</sup>	No statistically significant difference between LungCare and usual care	⊕⊕○○ Low <sup>c</sup>	LCSDecTool may result in little to no difference in distress/anxiety compared with usual care.
<i>Patient Facing to Generate a Visit</i>					
<b>Receipt of Lung Cancer Screening</b>	% receiving screening 6 months	<i>N</i> = 516 (1 RCT) <sup>41</sup>	57/259 (22%) SDM tools vs 68/257 (26.5%) usual care	⊕⊕⊕⊕ High	“Lung Cancer Screening: Is It Right for Me?” video results in no difference in receipt of lung cancer screening compared with a 2-page brochure from a lung cancer advocacy group.
<b>Decisional Conflict / Regret</b>	Decisional Conflict Scale 1 week	<i>N</i> = 516 (1 RCT) <sup>41</sup>	Mean difference -14.1	⊕⊕⊕⊕ High	“Lung Cancer Screening: Is It Right for Me?” video results in less decisional conflict/regret compared with 2-page brochure from lung cancer advocacy group.
<b>Quality of Communication</b>	Author-developed 1 week	<i>N</i> = 60 (1 RCT) <sup>46</sup>	73% SDM tool very satisfied vs 28% usual care, no difference in preparedness	⊕⊕○○ Low <sup>a,e</sup>	LungTalk may result in little to no difference in quality of communication compared with nontailored LCS information sheet.

Outcome	Measurement Tool Follow-up	Total No of Participants (Studies)	Findings	Certainty	Importance
<i>Patient Facing to Generate a Visit</i>					
<b>Receipt of Lung Cancer Screening</b>	% receiving screening 6 months	N = 298 (1 RCT) <sup>37</sup>	11.0% SDM web vs 11.2% SDM print	⊕○○○ Very low <sup>b,c</sup>	The evidence is very uncertain on the effect of SDM web compared to SDM print on receipt of lung cancer screening.
<b>Decisional Conflict / Regret</b>	Health care Decisions Scale 4 months	N = 298 (1 RCT) <sup>37</sup>	2.9 SDM web vs 2.7 SDM print	⊕○○○ Very low <sup>b,d</sup>	The evidence is very uncertain on the effect of SDM web compared to SDM print on decisional conflict and regret.
<b>Distress/ Anxiety</b>	Author-developed 4 months	N = 298 (1 RCT) <sup>37</sup>	52.2% SDM web vs 54.4% print were distressed/anxious	⊕⊕○○ Low <sup>b</sup>	shouldiscreen.com web may cause little to no difference compared with shouldiscreen.com print on distress/anxiety.
<b>Quality of Communication</b>	Author-developed 4 months	N = 298 (1 RCT) <sup>37</sup>	25.6% SDM web vs 33.3% SDM print were confused by the material	⊕○○○ Very low <sup>b,e</sup>	The evidence is very uncertain on the effect of SDM web compared with SDM print on quality of communication.

Notes. GRADE Working Group grades of evidence:

High certainty: We are very confident that the true effect lies close to that of the estimate of the effect.

Moderate certainty: We are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low certainty: Our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.

Very low certainty: We have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations:

- a. Rated down 1 level for study limitations (study rated some concerns risk of bias).
- b. Rated down 2 levels for study limitations (study rated high risk of bias).
- c. Rated down 1 level for imprecision (low event rate [around 10%]).
- d. Rated down 1 level for imprecision (OIS not met, sample size <400).
- e. Rated down 1 level for indirectness (questions were not comprehensive of quality).

Abbreviations. LCSDecTool=lung cancer screening decision tool; RCT=randomize controlled trial; SDM=shared decision-making.

### KEY QUESTION 3: HARMS OF THE COMMUNICATION STRATEGIES, TOOLS, AND/OR APPROACHES

No studies reported on “author-defined harms.” Based on discussion with our operational partners and TEP, we categorized anxiety and decisional regret as harms. These findings are reported under KQ2.

### KEY QUESTION 4: BARRIERS AND FACILITATORS

Nine studies captured barriers and facilitators related to LCS SDM. Eight of these studies were qualitative study designs.<sup>21,22,55-60</sup> The ninth was a mixed-method design, employing a pre-post study design that investigated the impact of SDM and qualitative interviews to identify barriers and facilitators to implementing or maintaining SDM.<sup>18</sup> All but 1 study<sup>18</sup> interviewed health care providers, and 4 studies interviewed patients (Table 19).<sup>18,21,22,57</sup>

While all 9 studies assessed health care professionals’ or patients’ perceptions of SDM, not all authors assessed the implementation of a specific SDM tool. All included study populations had made use of an SDM tool; 5 studies<sup>18,21,56-58</sup> identified a specific tool and the remaining 4 assessed SDM as a concept, as multiple tools were in place.<sup>22,55,59,60</sup> Studies varied in their analytic approach to summarize themes identified from the interviews (see Appendix Table 11).

We provide the extracted qualitative themes grouped by CFIR domains and constructs. Table 20 provides a summary of the themes identified in the included studies coded to each CFIR domain. Two domains appeared repeatedly across the studies. The first domain was resource availability,<sup>55,56,58,60</sup> with time constraints frequently referenced as a barrier to implementing SDM. An example of this constraint from Lowery, et al follows: “Most PCPs reported needing 1 to 2 minutes to discuss LCS but frequently voiced not having 1 to 2 minutes during a visit because of patient-specific needs that were a higher priority.”<sup>56</sup> The second CFIR domain was innovation recipients, with a number of studies reporting a theme around patients’ reticence and lack of engagement with SDM<sup>22,55,57,59,60</sup> and patients’ negative response to the SDM.<sup>18,21,59,60</sup> Melzer, et al reported “Lack of patient engagement in the process of decision making was a barrier identified by all clinician types. A large number of patients, particularly older patients, requested a firm recommendation.”<sup>60</sup> Overall, barriers were reported with more frequency than facilitators, with themes related to facilitation often recommending or praising the inclusion of a decision aid during the SDM encounter.<sup>55,58,61</sup>

Of the included qualitative studies, 5 captured a VA patient population or VA health care providers.<sup>21,22,55,56,60</sup> Themes that emerged included a culture receptive to SDM to promote LCS screening: “The data supports so strongly that [LCS] is beneficial, that it doesn’t seem like there’s much of a decision.”<sup>55</sup> Barriers related to available resources (both clinicians and LCS navigators and tools), prioritization among other clinic demands and expectations, and innovation among both the deliverers and the recipients.



**Table 19. Summary Characteristics of Eligible Qualitative Studies**

Author, Year	ROB	Health Care Provider Interview	Patient Interview	N	Number of Sites	Qualitative Approach	SDM Implementation Evaluated
<b>Herbst*, 2023<sup>55</sup></b>	Low	✓		15	7	Ethnographic	Any SDM tool used currently in clinic
<b>Lowery*, 2022<sup>56</sup></b>	High	✓		33	8	Inductive thematic content analysis	SDM tool called Decision Precision
<b>Schapira*, 2022<sup>21</sup></b>	High	✓	✓	42	1	Thematic analysis	SDM tool called LCSDecTool
<b>Martinez, 2022<sup>57</sup></b>	Low	✓	✓	40	1	Grounded theory approach	LCS-LDCT Smart Set (a pre-programmed Epic tool)
<b>Reese, 2022<sup>58</sup></b>	Low	✓		14	1	Interviews coded using the Unified Theory of Acceptance and Use of Technology (UTAUT) and Social Cognitive Theory (SCT) models	Electronic decision aid
<b>Abubaker-Sharif, 2022<sup>59</sup></b>	High	✓		16	1	Thematic analysis	Any SDM tool (used Decision Counseling Program as an example)
<b>Melzer*, 2020<sup>60</sup></b>	Low	✓		24	3	Directed content analysis	Any SDM tool used currently in clinic
<b>Han, 2019<sup>18</sup></b>	Low		✓	17	1	Inductive qualitative methods	A lung cancer risk calculator
<b>Wiener*, 2018<sup>22</sup></b>	Moderate	✓	✓	52	4	Directed content analysis	Any SDM tool used currently in clinic

Notes. \*Included VA health care professionals or Veterans as part of the study population.

**Table 20. Barriers and Facilitators Identified in Qualitative Interviews of SDM Deliverers and Recipients**

CFIR Domain CFIR Construct	Barrier Facilitator	Barrier or Facilitator Description
<b>I. Innovation Domain</b>		
Adaptability	Barrier	3 studies reported that <b>tailoring of the information to the participant</b> was important, <sup>22,59,60</sup> including developing tools in <b>other languages</b> . <sup>59</sup>
Complexity	Barrier	1 study noted the <b>complexity of SDM</b> , and the multiple factors needed to know to guide the conversation (patient education, elicitation of personal values, knowing participant risk). <sup>59</sup>
Design	Barrier	2 studies reported the <b>design of the tool</b> was a barrier (difficult to navigate and medical terminology difficult for patient to understand, <sup>21</sup> inputting data during visit to calculate risk <sup>56</sup> ).
	Facilitator	1 study suggested the <b>use of any tool</b> prior to a visit would enable SDM. <sup>58</sup>
Evidence Base	Barrier	1 study reported clinicians were <b>surprised by low specificity of LDCT and frequency of false positives</b> resulting in unnecessary procedures and major complications. <sup>58</sup>
<b>II. Outer Setting Domain</b>		
External Pressure Performance Measurement	Barrier	2 studies reported <b>organizational priorities or pressure</b> to meet organizational goals influenced their decision to engage in SDM (some felt pressure to incorporate it, while others prioritized other organization goals over SDM). <sup>56,58</sup>
	Barrier	1 study reported clinicians felt <b>pressure to demonstrate the value of a dedicated LCS coordinator</b> . <sup>55</sup>
Local Attitudes	Barrier	2 studies reported clinicians felt <b>smoking history documentation in the EHR was inaccurate</b> . <sup>57,58</sup>
<b>III. Inner Setting Domain</b>		
Access to Knowledge and Information	Barrier	2 studies reported clinicians had <b>little or no knowledge of health care system initiatives</b> <sup>55</sup> or lacked knowledge about logistics of an LCS program. <sup>59</sup>
Available Resources	Barrier	4 studies reported that <b>time constraints</b> were a significant barrier. <sup>55,56,58,60</sup>
	Facilitator	1 study suggested <b>a decision aid would benefit patients and providers</b> . <sup>57</sup>
Communications	Barrier	1 study reported <b>lack of communication</b> about goals and structure led to confusion about how to implement elements of a lung cancer screening program. <sup>55</sup>
Culture	Barrier	1 study reported clinicians perceived the value of screening as high, therefore <b>limited information about harms and emphasized benefits</b> during SDM discussions. <sup>55</sup>
	Barrier	1 study noted the <b>difficulty in having screening conversations</b> with patients who are unlikely to be receptive. <sup>59</sup>
Relative Priority	Barrier	3 studies noted that SDM <b>may not be as high a priority</b> compared to competing demands such as other preventive screening or patient specific needs. <sup>55,56,58</sup>
Structural Characteristics IT Infrastructure	Facilitator	2 studies reported <b>integrating the SDM tool into the EHR</b> would be beneficial, to obtain patient information and facilitate reminders. <sup>55,58</sup>
	Barrier	1 reported difficulties in integration, especially regarding ordering LDCT. <sup>57</sup>
<b>IV. Individuals Domain</b>		
Capability	Barrier	3 studies reported on the clinicians' perceived capability to engage in SDM, including conflation of SDM with patient education, <sup>55</sup> difficulties with eligibility criteria, <sup>57</sup> and being unaware of insurance requirements or reimbursements. <sup>58</sup>
Innovation Deliverers	Barrier	1 study reported that <b>clinicians' personal experiences</b> led to promotion of screening, regardless of guidelines recommending screening. <sup>55</sup>

CFIR Domain	Barrier	Barrier or Facilitator Description
CFIR Construct	Facilitator	
	Barrier	1 study reported clinicians had <b>mixed feelings about using decision aids</b> (facilitated discussion but risk information served as a barrier to engaging patients). <sup>22</sup>
	Barrier	5 studies reported on <b>lack of patient engagement</b> in SDM, or readiness to accept clinicians' recommendation without discussion. <sup>22,55,57,59,60</sup>
	Barrier	4 studies reported <b>patients had negative affective responses to SDM and LCS</b> (eg, patients "didn't want to know"). <sup>18,21,59,60</sup>
	Barrier	3 studies reported that clinicians <b>perceived patients' awareness and knowledge</b> about LCS was limited. <sup>21,57,59</sup>
Innovation Recipients	Facilitator	1 study reported that clinicians agreed ensuring a screening decision in line with <b>patient's values was important</b> . <sup>60</sup>
	Barrier	1 study reported <b>patients had mixed feelings about use of decision aids</b> (some found them useful while other found information on harms off-putting). <sup>22</sup>
	Barrier	1 study reported on the frequency in which SDM for LCS should happen, and when patients may be receptive. <sup>57</sup>
	Barrier	1 study reported that patient accounts reflected a range of information received about LCS (eg, minimal information on harms given and then experienced an unexpected outcome vs comprehensive information given). <sup>22</sup>
Need	Barrier	1 study reported patients smoking history made LCS compulsory, and a rationale to bypass SDM. <sup>55</sup>

*Notes.* CFIR=Consolidated Framework for Implementation Research; EHR=electronic health record; IT=information technology; LCS=lung cancer screening; LDCT=low-dose computed tomography; SDM=shared decision-making.

## DISCUSSION

Lung cancer is the most common nondermatologic malignancy in adults and the leading cause of cancer-related death in the US. Screening with low-dose CT scanning reduces lung cancer mortality and is recommended by the USPSTF and the VA. However, LCS rates are low. Concerns remain that screening harms and burden, as well as referral of patients unlikely to adhere to initial or subsequent screening and follow-up for evaluation and treatment of abnormal findings, may limit net benefit. Thus, prior to LCS, clinicians are encouraged to provide patients with information about risks and benefits including the importance of screening and abnormal test evaluation adherence and smoking cessation and to solicit and support patient preferences and values in the decision-making process (*ie*, SDM). However, the effectiveness, harms, and burden of LCS SDM or the preferred approaches for SDM are not well understood. In particular, the harms and burden, including time, IT support, and resource allocation/usage of SDM for all potentially eligible individuals for LCS, were not reported. Additional author-defined harms were not reported. We categorized various measures of patient anxiety or decisional regret as harms. Our systematic review found that studies varied markedly in methodological characteristics and many had notable limitations to their rigor, replicability, and clinical applicability. Inconsistency in study designs (including sample sizes and duration), interventions, comparators, delivery modes and timing, and outcomes present important challenges to systematic reviewers, SDM researchers, clinicians, policymakers, and patients. Moreover, few studies provided information about whether their interventions met CMS criteria for SDM. Despite these limitations, the following observations and conclusions were possible:

### Key Findings

- ▶ A wide range of lung cancer screening communication strategies and information tools were studied across clinic settings/encounters, delivery approaches, and targeted individuals.
  - Authors often did not provide adequate information about the studied tools to determine if they met criteria for a patient decision aid rather than an “information tool.”
  - Strategies were characterized as health care professional-facing (used in clinic to guide discussion) or patient-facing (inform patient prior to or during visit but not guide discussion).
    - Within health care professional-facing: tools were meant to be used by a clinician or LCS navigator.
    - Within patient-facing: strategies were used prior to, or during a scheduled SDM visit, or to generate a SDM visit.
  - Some strategies combined SDM tools with care coordinators or navigators.
  - The most studied tool ( $k=7$ ) was a 5–15-minute decision aid available as print or web-based in English, Spanish, and Chinese language ([www.shouldiscreen.com](http://www.shouldiscreen.com)). The current tool includes the 2021 USPSTF recommendations and content.
- ▶ While most studies reported on knowledge, few addressed receipt of initial, or follow-up, LCS, adherence to evaluation and treatment of abnormal LCS findings, information quality, concordance of the screening decision with patient values, or patients’ decisional conflict, regret, or distress/anxiety.

- Studies did not report on many other outcomes of interest including smoking behaviors; resource allocations/usage (*eg*, clinician time, clinical staff/patient time, medical media support, IT support); cost or cost effectiveness.
- Studies did not report on fidelity (how well the intervention was delivered).
- ▶ SDM strategies and tools may increase LCS participation, may have acceptable information quality, and may not increase decisional conflict/regret. A decision aid may be superior to an educational tool, and the choice of decision aid may not impact uptake.
  - Decision aid selection should be guided by the population and setting of interest.
- ▶ Limitations and inconsistency in study design and aim, interventions, comparators, outcome measures, and risks of bias precluded synthesizing evidence or deriving conclusive statements on most interventions/outcomes, resulting in low to very low certainty of evidence.
  - There was little to no evidence on whether SDM effectiveness varied by patient (age, sex, race/ethnicity, smoking status, comorbidities, education) or clinic characteristics (primary care, prevention, smoking cessation clinics or public forums).
- ▶ Barriers to LCS SDM implementation include resource availability, particularly time constraints; patients' reticence and lack of engagement with SDM; and patients' negative response to SDM. Facilitators included use of a decision aid during the SDM encounter.
- ▶ Based on implementation studies conducted in VHA, implementation facilitators include: a clinical culture receptive to SDM; available resources including time and tools; prioritization among other clinic demands and expectations; and innovation among deliverers and recipients.
- ▶ Future research is needed to enhance LCS and SDM implementation. Areas include: developing methods for accurate, efficient, and effective detection of individuals eligible for LCS and follow-up; avoiding unnecessary or harmful referral of ineligible individuals and those unlikely to adhere to initial or follow-up LCS or subsequent evaluations; creating efficient, accurate, effective, and pragmatic SDM strategies that are adaptable to a variety of settings and patients while reducing patient, clinician, and health system burden; enhancing smoking cessation; and ensuring equity in LCS and communication strategies across patient and clinical settings.

### **Study Design Variation**

This review identified RCTs, CCTs, and pre-post and cohort studies. The degree to which efficacy or comparative effectiveness can be assessed with pre-post and cohort studies is limited. By its nature, the pre-post design does not allow for comparison between an intervention and comparator group for important outcomes such as receipt of LCS or adherence.

### **Included Interventions**

There are several tools that have been developed for SDM. Unfortunately, there was inconsistency in reporting/description of these tools in the literature, so classifying these tools into categories of patient decision aid or educational tool relied on author report or was not possible. A repository of published tools that SDM researchers could review and critique would be very helpful in understanding what has been tested in these at-risk populations. Access to the tools would also allow for accurate classification of the tool as a patient decision aid or educational tool. It would facilitate assessment of whether one tool is interchangeable with another and how applicable study findings are to SDM in general and not

specific to the tool utilized by the study. Some studies did not base their interventions on recognized criteria for SDM. Furthermore, some studies included additional outreach beyond SDM tools such as care coordinators or patient navigators to facilitate screening scheduling, attendance, and follow-up.

### **Comparators**

As there are a multitude of tools that have been developed for SDM, this further complicates synthesizing the available evidence as authors may choose to compare to any of these tools, the same tool, or no tool/usual care. Unless there is agreement that these tools are interchangeable—or a subset of tools is selected for further evaluation—identifying the most effective tool will remain challenging.

### **Primary Outcomes/Outcomes Of Interest**

Knowledge is the outcome most reported. However, outcomes ranked highest by our content experts and TEP were infrequently reported. Adherence to subsequent screening, an outcome of great interest, was only captured by a single study. This variation in outcome reporting is further compounded by authors' use of study-developed or unique methods of outcome measurement. Examples of this variation were the measures used to assess knowledge and quality of communication. Some studies used validated measures, whereas others used a single question to ascertain a participant's understanding of LCS and whether the participant felt the SDM tool was of good quality.

### **Mode of Delivery/Timing**

Studies varied widely in when and how SDM interventions were delivered, and as a result, the optimal timing and mode of administration of SDM remains unclear.

### **Applicability of Findings**

Many studies were conducted in research settings with a study coordinator, highly refined entry criteria, and filtering of many potentially eligible individuals and analysis of responders. Whether results from these studies will directly apply to most clinical settings is not well known, especially when including our findings evaluating SDM barriers and facilitators.

### **Policy Implications (VA Specific)**

A single study assessed a tool developed for the VA LCS demonstration project that began in 2013 and is referenced in [VA guidance for LCS](#).<sup>23</sup> That study was not conducted in a Veteran population. The 2 available studies that were conducted in Veteran populations examined different tools from the one referenced in the VA guidance.<sup>19,20</sup> Qualitative research suggested that Veterans and health care providers felt that VA culture was receptive to LCS SDM but that competing demands and time needed to conduct SDM were barriers to implementation.

Future research should be conducted in VHA to evaluate the effects, including the feasibility and barriers, of tools and strategies for LCS SDM. These tools and strategies, including the currently available VA tool, should be administered in various formats, clinical settings, and population targets. Studies should be designed with current clinical practice and procedures in mind so results are generalizable to primary care or prevention clinics, including those embedded in large medical centers as well as those in community-based outpatient clinics (CBOCs).

## **Barriers and Facilitators**

While implementation studies identified barriers, reducing these barriers could enhance SDM implementation into health care. Many of the identified barriers and facilitators pertained to available resources and time availability.

Given that LCS is recommended and underutilized among eligible individuals, the most important facilitator for LCS uptake may not be to define and refine the “best SDM” method. Rather, a critical facilitator is enhancing accurate and efficient identification, communication, and referral of eligible individuals for LCS, and ensuring LCS adherence and follow-up. As noted in a qualitative study conducted in VA: “The data supports so strongly that [LCS] is beneficial, that it doesn’t seem like there’s much of a decision.”<sup>55</sup> Reducing barriers related to available resources, prioritization among other clinic demands and expectations, and innovation among both the deliverers and the recipients are needed. As a corollary, strategies are needed to avoid unnecessary or even harmful referral of ineligible individuals or those unlikely to adhere or follow-up.

## **LIMITATIONS**

While the primary limitations to our findings are those inherent to the existing evidence, our review was limited to English language publications. However, the focus of this report is LCS SDM in the US. Potential differences in patients, disease etiology, and screening requirements from non-English language countries (and English language studies conducted outside the US) have lower applicability to US settings. Thus, limiting our inclusion to English language is unlikely to change findings.

## **FUTURE RESEARCH**

The current review highlights limitations of the LCS SDM evidence base. Standardization of outcome measures, greater transparency regarding tool domains and content, use of study designs that allow for assessment of efficacy and comparative effectiveness for all outcomes, and replicability of findings across populations, interventions, comparators, and settings would improve evidence certainty.<sup>62</sup>

Research is needed to enhance implementation by identifying and reducing barriers and encouraging facilitators to SDM and LCS. These can be targeted at several links in the screening chain including: 1) identifying individuals eligible and not eligible for screening; 2) efficiently and effectively communicating accurate information on LCS benefits and harms to patients in busy primary care settings; 3) understanding patient concerns about LCS and whether these vary by race/ethnicity, sex, geographic location, access to care, or social determinants of health; 4) facilitating scheduling of LCS appointments, tracking results, adherence to subsequent screening, and evaluation of abnormal findings; 5) evaluating when is the best time to present a decision support intervention (before or during the clinic visit) and whether patient versus clinician-based tools are most effective and feasible; 6) not referring or recommending LCS among individuals unlikely to benefit or adhere to LCS or follow-up evaluations; 7) improving tobacco cessation. Whether tools/strategies should be “patient facing” or “provider facing”; delivered by telehealth or in-person; print, or web-based; and whether they differ by patient characteristics (race/ethnicity, sex, education, sociodemographic factors) are largely unknown and may vary by feasibility, resource availability, and health care settings. Research could include determining knowledge elements most useful for informing screening decisions and ensuring SDM aids use validated instruments and include values/preference clarification components.



Finally, the requirement to conduct SDM for lung cancer screening remains unique among all cancer screening recommendations that receive an “A” or “B” recommendation by the USPSTF (*ie*, at least moderate certainty that implementing the recommended strategy results in at least moderate net benefit). Despite differences in specific screening strategies, benefits, and harms, other A/B recommendations do not require or strongly encourage that clinicians, health systems, and patients first engage in SDM rather than recommend screening. Lessons could be learned by examining screening implementation for other cancers with similar screening test frequency, adherence importance, and certainty of net benefit, such as mammography for breast cancer or stool-based testing or direct visualization testing for colorectal cancer (both have much higher screening rates while also noting the importance of requiring adherence to the full screening and follow-up cascade to be effective).<sup>63</sup> If a main goal of LCS is to increase LCS among eligible individuals, reducing barriers to the screening process is needed and may include reducing barriers inherent with formal SDM in eligible individuals. This includes improving efficiencies and reducing patient, clinician, and health system burden of SDM implementation.

Consistent with a USPSTF “B” recommendation, clinicians should generally recommend LCS in eligible individuals with a discussion of the rationale but understand that some patients will choose not to receive LCS. Additionally, the USPSTF and CMS raise concerns that the general US population eligible for lung cancer screening may be less likely to benefit from early detection compared with participants enrolled in LCS RCTs, mainly because they face a higher risk of death from competing causes such as heart disease and stroke.<sup>5-7</sup> Both the USPSTF and CMS emphasize the importance of adherence to the screening process including willingness to undergo curative treatment. However, these concerns are not unique to LCS and may reflect issues regarding resource requirements for low-dose CT scanning and tracking, follow-up, and treatment of abnormal findings not fully considered in the screening guideline net benefit calculations. Thus, future research should better assess competing risk and adherence in individuals deemed eligible for LCS based on age and smoking history.

## CONCLUSIONS

Strategies that include SDM tools, and possibly care coordinators or patient navigators, may increase LCS participation, have acceptable information quality, and do not increase decisional conflict/regret. A decision aid may be superior to an educational tool, and the choice of decision aid may not impact uptake. Variation in study design, LCS tools and strategies, comparator, delivery mode and timing, and outcomes presents challenges in evaluation and implementation. Few studies provided sufficient information about whether the tool or process met criteria to be classified as a decision aid or included information required by Medicare. While most studies reported on knowledge, comparatively few assessed receipt of initial or adherence to follow-up LCS, information quality, concordance of the screening decision with patient values, or patients’ decisional conflict, regret, or distress/anxiety. There was little to no evidence on whether effects varied by patient (age, sex, race/ethnicity, smoking status, comorbidities, education) or clinic characteristics (primary care, prevention, smoking cessation clinics or public forums).

Barriers to SDM include resource availability, especially time constraints, patients’ reticence and lack of engagement with SDM, and patients’ negative response to SDM. Facilitators include use of a decision aid during the SDM encounter. Research is needed to identify the most effective SDM tools and strategies, particularly those that are low burden and adaptable to different settings and patients, reduce barriers to identify individuals eligible for LCS, enhance LCS adherence and follow-up, promote smoking abstinence, and decrease referral of individuals ineligible or unlikely to adhere.



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# *Appendix*



## SEARCH STRATEGIES

Database Search Dates	Search Statement
<b>Embase</b>  01/01/2010- 12/06/2023	1 exp lung cancer/ or multiple pulmonary nodules/ or ((lung? or pulmonary) adj3 (adenocarcinoma* or benign or blastoma* or cancer* or carcinoma? or cyst? or hemangioma* or lesion? or malignan* or metasta* or neoplasm* or nodule? or non-malignan* or tumo?r*)).mp.
	2 cancer screening/ or early cancer diagnosis/ or (lung cancer* adj3 screen*).mp.
	3 (early detect* adj3 lung cancer*).mp.
	4 (lung adj5 (low dose computed tomograph* or low dose ct or LDCT)).mp.
	5 or/2-4
	6 1 and 5
	7 decision making/ or shared decision making/ or patient decision aid/ or patient preference/ or ((decision* or choice*) adj3 (aid* or behavio?r* or collaborat* or informed or make* or making or shared or support*)).mp.
	8 exp People by smoking status/ or cigarette smoking/ or vaping/ or electronic cigarette/ or Smoking cessation/ or (e-cigarette? or ever-smoker? or ex-smoker? or never-smoker? or nonsmoker? or non-smoker? or smoker? or smoking cessation or nicotine vaping).ti,ab,kf,kw.
	9 Counseling/ or Interviews/ or Patient education/ or patient participation/ or patient preference/ or ((participant? or patient?) adj3 (choice or counsel* or decide or decision* or discuss* or educat* or engage* or interview* or navigat* or participat* or prefer*)).ti,ab,kf,kw.
	10 or/7-9
	11 6 and 10
	12 case report/ or exp conference paper/ or consensus development/ or editorial/ or letter/ or note/
	13 11 not 12
	14 limit 13 to (books or chapter or conference abstract or conference paper or "conference review" or editorial or letter or note or "preprint (unpublished, non-peer reviewed)")
	15 13 not 14
	16 limit 15 to (english language and yr="2010 -Current")
<b>MEDLINE</b>  01/01/2010- 12/06/2023	1 exp Lung Neoplasms/ or Multiple Pulmonary Nodules/ or ((lung? or pulmonary) adj3 (adenocarcinoma* or benign or blastoma* or cancer* or carcinoma? or cyst? or hemangioma* or lesion? or malignan* or metasta* or neoplasm* or nodule? or non-malignan* or tumo?r*)).mp
	2 "Early Detection of Cancer"/ or (early detect* adj3 lung cancer*).mp.
	3 (lung cancer* adj3 screen*).mp.
	4 (lung adj5 (low dose computed tomograph* or low dose ct or LDCT)).mp
	5 Or/2-4
	6 1 and 5
	7 Choice Behavior/ or Decision Making/ or Decision Making, Shared/ or ((decision* or choice*) adj3 (aid* or behavio?r* or collaborat* or informed or make* or making or shared or support*)).mp.

	8	exp Tobacco Smoking/ or Ex-Smokers/ or Non-Smokers/ or Smoking Cessation/ or Smoking/ or Vaping/
	9	(e-cigarette? or ever-smoker? or ex-smoker? or never-smoker? or nonsmoker? or non-smoker? or smoker? or smoking cessation or nicotine vaping).mp.
	10	Health communication/ or Interviews as Topic/ or Patient Education Handout/ or "patient education as topic"/ or Patient Participation/ or Patient Preference/ or Patient Navigation/ or Counseling/
	11	((participant? or patient?) adj3 (choice or counsel* or decide or decision* or discuss* or educat* or engage* or interview* or navigat* or participat* or prefer*)).mp.
	12	Or/ 7-11
	13	6 and 12
	14	case reports/ or comment/ or exp congress/ or editorial/ or letter/ or legislation/ or preprint/ or news/ or festschrift/
	15	13 not 14
	16	Limit 15 to (English language and yr = "2010-current")
<b>CINAHL</b>	1	(MH "Lung Neoplasms+") OR (TI (lung N3 (adenocarcinoma* OR benign OR blastoma* OR cancer* OR carcinoma* OR cyst* OR hemangioma* OR lesion OR malignan* OR metasta* OR neoplasm* OR nodule OR non-malignan* OR tumor?r* ) OR AB ( lung N3 (adenocarcinoma* OR benign OR blastoma* OR cancer* OR carcinoma* OR cyst* OR hemangioma* OR lesion* OR malignan* OR metasta* OR neoplasm* OR nodule* OR non-malignan* OR tumor?r*)))
01/01/2010- 12/06/2023	2	(MH "Early Detection of Cancer") OR (MH "Cancer Screening")
	3	(TI lung N3 screen)* OR (AB lung N3 screen)*
	4	(TI early N3 detect* N3 "lung cancer*") OR (AB early N3 detect* N3 "lung cancer*")
	5	(TI lung N3 low dose computed tomograph*) OR (TI lung N3 low dose ct) OR (TI lung N3 LDCT) OR (AB lung N3 low dose computed tomograph*) OR (AB lung N3 low dose ct OR (AB lung N3 LDCT)
	6	S2 OR S3 OR S4 OR S5
	7	(MH "Consumer Participation") OR (MH "Counseling") OR (MH "Decision Making, Shared") OR (MH "Decision Making, Patient") OR (MH "Patient Education") OR (MH "Patient Preference") OR (MH "Patient Navigation")
	8	(TI "decision aid*" OR TI "patient choice" OR TI patient counsel* OR TI "patient decision*" OR TI "patient educat*" OR TI "patient interview*" OR TI "consumer participat*" OR TI "patient prefer*" OR TI "shared decision making" OR AB "decision aid*" OR AB "patient choice" OR AB patient counsel* OR AB "patient decision*" OR AB "patient educat*" OR AB "patient interview*" OR AB "consumer participat*" OR AB "patient prefer*" OR AB "shared decision making")
	9	(MH "Ex-Smokers") OR (MH "Non-Smokers") OR (MH "Smoking") OR (MH "Smoking Cessation") OR (MH "Vaping")
	10	S7 OR S8 OR S9
	11	S1 AND S6 AND S10
	12	(MH "Clinical Trials+") OR (MH "Controlled Before-After Studies") OR (MH "Pretest-Posttest Design+") OR (MH "Randomized Controlled Trials") OR (MH "Double-Blind Studies") OR (MH "Single-Blind Studies") OR (MH "Random Assignment") OR (MH "Cluster Sample") OR (MH "Crossover Design") OR (MH "Comparative Studies") OR (MH "Prospective Studies+") OR (MH "Quasi-Experimental Studies") OR (MH "Case Control Studies+") OR (MH "Placebos") OR (MH "Sample Size") OR (TI randomized) OR (TI randomized) OR (AB random*) OR (TI trial) OR (AB assigned) OR (AB



	allocated) OR (AB control W5 group) OR (AB cluster W3 RCT) OR (TI pre N3 post) OR (AB pre N3 post) OR (AB cohort N3 study OR (AB cohort N3 studies)
13	S11 AND S12



## STUDIES EXCLUDED DURING FULL-TEXT SCREENING

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15. Deros DE, Hagerman CJ, Kramer JA, et al, Change in amount smoked and readiness to quit among patients undergoing lung cancer screening. *Journal of thoracic disease*. 2021;13(8):4947-4955. *Ineligible intervention*.
16. Dharod A, Bellinger C, Foley K, Case LD, Miller D, The Reach and Feasibility of an Interactive Lung Cancer Screening Decision Aid Delivered by Patient Portal. *Applied clinical informatics*. 2019;10(1):19-27. *Ineligible comparison*.
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## UNDERWAY STUDIES

Study #	Study Title	Status	Total N*
1K08CA289097-01	A community health worker intervention to improve lung cancer screening uptake in community health centers serving Black and Hispanic communities	Active	NR
1U19MD020537-01	Lung Cancer Screening to Improve Equity in Tribal Communities in Oklahoma (Lung-Screen-Tribal OK)	Active	NR
5K08CA283304-02	Facilitation of Information Exchange for Shared Decision Making for Lung Cancer Screening	Active	NR
5R01CA237240-05	A Personalized Digital Outreach Intervention for Lung Cancer Screening	Active	NR
5R01CA251758-04	Addressing racial disparities in lung cancer screening	Active	NR
5R01CA258849-03	Provider Support and Patient Outreach in Lung Cancer Screening	Active	NR
5R01HL158850-03	TELEhealth Shared decision-making COaching for lung cancer screening in Primary care (TELESCOPE)	Active	NR
NCT02430948	Improving Compliance With Medical Testing Guidelines	Completed (no publication)	218
NCT02871739	A Trial Comparing Approaches to Shared Decision Making Skills Training for Clinicians	Completed (no publication)	23
NCT02914899	Informing the Adaptation of a CHW Model to Facilitate Lung Cancer Screening for the Chinese Community	Active, Not Yet Recruiting (no publication)	99
NCT03891602	DECIDE: Developing Tools for Lung Cancer Screening Discussion Improvement	Withdrawn (no publication)	0
NCT03929926	Proactive Outreach and Shared Decision Making in Improving Lung Cancer Screening Rates in Primary Care Patients	Completed (no publication)	2,355
NCT03958253	Lung Cancer Screening Protocol	Completed (no publication)	193
NCT04200534	Centralized Lung Cancer EARly Detection Among Smokers (CLEAR Study)	Recruiting (no publication)	520
NCT04498052	Evaluation of a Scalable Decision Support and Shared Decision Making Tool for Lung Cancer Screening	Active, Not Recruiting (no publication)	12,000
NCT04897568	Shared Decision Making in Rural Primary Care Lung Cancer Screening and Smoking Cessation	Completed (no publication)	118
NCT04940221	Testing Informed Decision Making in Lung Cancer Screening	Completed (no publication)	80
NCT05024955	Evaluating Shared Decision making for Lung Cancer Screening Among Chinese Populations in the United States	Withdrawn (no publication)	0
NCT05491213	TELESCOPE- TELEhealth Shared Decision making COaching	Recruiting (no publication)	420
NCT05679349	Support and Outreach to Increase Screening for Lung Cancer in Patients With a History of Smoking	Recruiting (no publication)	822
NCT05920850	The SHARED, Project, Lung Cancer Screening for African American Men (AAM)	Completed (no publication)	37
NCT06213532	CONNECTing to LungCare	Not Yet Recruiting (no publication)	147

\*Estimated enrollment

# CONSOLIDATED FRAMEWORK FOR IMPLEMENTATION RESEARCH (CFIR) DOMAINS\*

Domain Name Subdomain Name (If Applicable) Construct Name	Construct Definition
<b>I. Innovation Domain</b> <i>The “thing” being implemented, eg., a new clinical treatment, educational program, or city service</i>	
A. Innovation Source	The group that developed and/or visibly sponsored use of the innovation is reputable, credible, and/or trustable
B. Innovation Evidence Base	The innovation has robust evidence supporting its effectiveness
C. Innovation Relative Advantage	The innovation is better than other available innovations or current practice
D. Innovation Adaptability	The innovation can be modified, tailored, or refined to fit local context or needs
E. Innovation Trialability	The innovation can be tested or piloted on a small scale and undone
F. Innovation Complexity	The innovation is complicated, which may be reflected by its scope and/or the nature and number of connections and steps
G. Innovation Design	The innovation is well designed and packaged, including how it is assembled, bundled, and presented
H. Innovation Cost	The innovation purchase and operating costs are affordable
<b>II. Outer Setting Domain</b> <i>The setting in which the Inner Setting exists, eg, hospital system, school district, state. There may be multiple Outer Settings and/or multiple levels within the Outer Setting, eg, community, system, state</i>	
A. Critical Incidents	Large-scale and/or unanticipated events disrupt implementation and/or delivery of the innovation
B. Local Attitudes	Sociocultural values (eg, shared responsibility in helping recipients) and beliefs (eg, convictions about the worthiness of recipients) encourage the Outer Setting to support implementation and/or delivery of the innovation
C. Local Conditions	Economic, environmental, political, and/or technological conditions enable the Outer Setting to support implementation and/or delivery of the innovation
D. Partnerships & Connections	The Inner Setting is networked with external entities, including referral networks, academic affiliations, and professional organization networks
E. Policies & Laws	Legislation, regulations, professional group guidelines and recommendations, or accreditation standards support implementation and/or delivery of the innovation
F. Financing	Funding from external entities (eg, grants, reimbursement) is available to implement and/or deliver the innovation
G. External Pressure	External pressures drive implementation and/or delivery of the innovation <i>Use this construct to capture themes related to External Pressures that are not included in the subconstructs below</i>
1. Societal Pressure	Mass media campaigns, advocacy groups, or social movements or protests drive implementation and/or delivery of the innovation
2. Market Pressure	Competing with and/or imitating peer entities drives implementation and/or delivery of the innovation
3. Performance Measurement Pressure	Quality or benchmarking metrics or established service goals drive implementation and/or delivery of the innovation
<b>III. Inner Setting Domain</b> <i>The setting in which the innovation is implemented, eg, hospital, school, city. There may be multiple Inner Settings and/or multiple levels within the Inner Setting, eg, unit, classroom, team</i>	
A. Structural Characteristics	Infrastructure components support functional performance of the Inner Setting

Domain Name Subdomain Name (If Applicable) Construct Name	Construct Definition
	<i>Use this construct to capture themes related to Structural Characteristics that are not included in the subconstructs below</i>
1. Physical Infrastructure	Layout and configuration of space and other tangible material features support functional performance of the Inner Setting
2. Information Technology Infrastructure	Technological systems for tele-communication, electronic documentation, and data storage, management, reporting, and analysis support functional performance of the Inner Setting
3. Work Infrastructure	Organization of tasks and responsibilities within and between individuals and teams, and general staffing levels, support functional performance of the Inner Setting
B. Relational Connections	There are high quality formal and informal relationships, networks, and teams within and across Inner Setting boundaries (eg, structural, professional)
C. Communications	There are high quality formal and informal information sharing practices within and across Inner Setting boundaries (eg, structural, professional)
D. Culture	There are shared values, beliefs, and norms across the Inner Setting <i>Use this construct to capture themes related to Culture that are not included in the subconstructs below</i>
1. Human Equality-Centeredness	There are shared values, beliefs, and norms about the inherent equal worth and value of all human beings
2. Recipient-Centeredness	There are shared values, beliefs, and norms around caring, supporting, and addressing the needs and welfare of recipients
3. Deliverer-Centeredness	There are shared values, beliefs, and norms around caring, supporting, and addressing the needs and welfare of deliverers
4. Learning-Centeredness	There are shared values, beliefs, and norms around psychological safety, continual improvement, and using data to inform practice
<i>Note: Constructs E – K are specific to the implementation and/or delivery of the innovation</i>	
E. Tension for Change	The current situation is intolerable and needs to change
F. Compatibility	The innovation fits with workflows, systems, and processes
G. Relative Priority	Implementing and delivering the innovation is important compared to other initiatives
H. Incentive Systems	Tangible and/or intangible incentives and rewards and/or disincentives and punishments support implementation and delivery of the innovation
I. Mission Alignment	Implementing and delivering the innovation is in line with the overarching commitment, purpose, or goals in the Inner Setting
J. Available Resources	Resources are available to implement and deliver the innovation <i>Use this construct to capture themes related to Available Resources that are not included in the subconstructs below</i>
1. Funding	Funding is available to implement and deliver the innovation
2. Space	Physical space is available to implement and deliver the innovation
3. Materials & Equipment	Supplies are available to implement and deliver the innovation
K. Access to Knowledge & Information	Guidance and/or training is accessible to implement and deliver the innovation
<b>IV. Individuals Domain</b> <i>The roles and characteristics of individuals</i>	
<b>Roles Subdomain</b>	
A. High-level Leaders	Individuals with a high level of authority, including key decision-makers, executive leaders, or directors
B. Mid-level Leaders	Individuals with a moderate level of authority, including leaders supervised by a high-level leader and who supervise others

<b>Domain Name</b> <b>Subdomain Name (If Applicable)</b> <b>Construct Name</b>	<b>Construct Definition</b>
C. Opinion Leaders	Individuals with informal influence on the attitudes and behaviors of others
D. Implementation Facilitators	Individuals with subject matter expertise who assist, coach, or support implementation
E. Implementation Leads	Individuals who lead efforts to implement the innovation
F. Implementation Team Members	Individuals who collaborate with and support the Implementation Leads to implement the innovation, ideally including Innovation Deliverers and Recipients
G. Other Implementation Support	Individuals who support the Implementation Leads and/or Implementation Team Members to implement the innovation
H. Innovation Deliverers	Individuals who are directly or indirectly delivering the innovation
I. Innovation Recipients	Individuals who are directly or indirectly receiving the innovation
<b>Characteristics Subdomain</b>	
A. Need	The individual(s) has deficits related to survival, well-being, or personal fulfillment, which will be addressed by implementation and/or delivery of the innovation
B. Capability	The individual(s) has interpersonal competence, knowledge, and skills to fulfill Role
C. Opportunity	The individual(s) has availability, scope, and power to fulfill Role
D. Motivation	The individual(s) is committed to fulfilling Role
<b>V. Implementation Process Domain</b> <i>The activities and strategies used to implement the innovation</i>	
A. Teaming	Join together, intentionally coordinating and collaborating on interdependent tasks, to implement the innovation
B. Assessing Needs	Collect information about priorities, preferences, and needs of people <i>Use this construct to capture themes related to Assessing Needs that are not included in the subconstructs below</i>
1. Innovation Deliverers	Collect information about the priorities, preferences, and needs of deliverers to guide implementation and delivery of the innovation
2. Innovation Recipients	Collect information about the priorities, preferences, and needs of recipients to guide implementation and delivery of the innovation
C. Assessing Context	Collect information to identify and appraise barriers and facilitators to implementation and delivery of the innovation
D. Planning	Identify roles and responsibilities, outline specific steps and milestones, and define goals and measures for implementation success in advance
E. Tailoring Strategies	Choose and operationalize implementation strategies to address barriers, leverage facilitators, and fit context
F. Engaging	Attract and encourage participation in implementation and/or the innovation <i>Use this construct to capture themes related to Engaging that are not included in the subconstructs below</i>
1. Innovation Deliverers	Attract and encourage deliverers to serve on the implementation team and/or to deliver the innovation
2. Innovation Recipients	Attract and encourage recipients to serve on the implementation team and/or participate in the innovation
G. Doing	Implement in small steps, tests, or cycles of change to trial and cumulatively optimize delivery of the innovation
H. Reflecting & Evaluating	Collect and discuss quantitative and qualitative information about the success of implementation and/or the innovation <i>Use this construct to capture themes related to Reflecting &amp; Evaluating that are not included in the subconstructs below</i>

Domain Name Subdomain Name (If Applicable) Construct Name	Construct Definition
1. Implementation	Collect and discuss quantitative and qualitative information about the success of implementation
2. Innovation	Collect and discuss quantitative and qualitative information about the success of the innovation
I. Adapting	Modify the innovation and/or the Inner Setting for optimal fit and integration into work processes

Notes. \*Taken from Damschroder, L.J., Reardon, C.M., Widerquist, M.A.O. et al. The updated Consolidated Framework for Implementation Research based on user feedback. Implementation Sci 17, 75 (2022). <https://doi.org/10.1186/s13012-022-01245-0>.



## RISK OF BIAS ASSESSMENTS

### RANDOMIZED CONTROLLED TRIALS (ROB-2)

Author, Year	Bias from Randomization Process	Bias from Deviation from Intended Interventions (Assignment)	Bias from Deviation from Intended Interventions (Adherence)	Bias from Missing Outcome Data	Bias in Measurement of Outcome	Bias in Selection of Reported Result	Overall Risk of Bias (Low, Some Concerns, High)
Carter-Harris, 2020 <sup>46</sup>	Low	Low	Low	Low	Some concerns	Low	Some concerns
Clark, 2022 <sup>45</sup>	Low	Some concerns	Low	Low	Low	Low	Some concerns
DiCarlo, 2022 <sup>27</sup>	Low	Low	Low	Some concerns	Low	Low	Some concerns
Fraenkel, 2016 <sup>50</sup>	Some concerns	Low	Low	Low	Low	High	High
Percac-Lima, 2018 <sup>30</sup>	Some concerns	Low	Some concerns	Some concerns	Low	Low	Some concerns
Robichaux, 2023 <sup>48</sup>	Low	Low	Low	Low	Low	Low	Low
Schapira, 2023 <sup>19</sup>	Low	Low	Low	Low	Low	Low	Low
Sferra, 2021 <sup>31</sup>	Low	Low	Low	Some concerns	Low	Low	Some concerns
Sharma, 2018 <sup>49</sup>	High	High	Some concerns	High	Low	Low	High
Volk, 2020 <sup>41</sup>	Low	Low	Low	Low	Low	Low	Low
Walsh, 2023 <sup>35</sup>	Some concerns	Some concerns	Low	Low	Low	Low	Some concerns
Webster, 2023 <sup>37</sup>	Low	Low	High	Some concerns	Low	Low	High

### NONRANDOMIZED PRE-POST COMPARISON STUDIES (JBI QUASI-EXPERIMENTAL)

Author, Year	Is It Clear in the Study What Is the 'Cause' And What Is The 'Effect' (ie, There Is No Confusion About Which Variable Comes First)?	Were the Participants Included in Any Comparisons Similar?	Were the Participants Included in Any Comparisons Receiving Similar Treatment/Care, Other Than the Exposure or Intervention of Interest?	Were There Multiple Measurements of the Outcome Both Pre and Post the Intervention/Exposure?	Was Follow-Up Complete and If Not, Were Differences Between Groups in Terms of Their Follow-Up Adequately Described and Analyzed?	Were the Outcomes of Participants Included in Any Comparisons Measured in the Same Way?	Were Outcomes Measured in a Reliable Way?	Was Appropriate Statistical Analysis Used?	Overall Risk of Bias (Low, Moderate, High)
Bittner Fagan, 2020 <sup>25</sup>	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Moderate
Crothers, 2016 <sup>23</sup>	Yes	Yes	No	Yes	Unclear	Yes	Yes	Yes	Moderate
Flores, 2021 <sup>32</sup>	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Moderate



Author, Year	Is It Clear in the Study What Is the 'Cause' And What Is The 'Effect' (ie, There Is No Confusion About Which Variable Comes First)?	Were the Participants Included in Any Comparisons Similar?	Were the Participants Included in Any Comparisons Receiving Similar Treatment/Care, Other Than the Exposure or Intervention of Interest?	Were There Multiple Measurements of the Outcome Both Pre and Post the Intervention/Exposure?	Was Follow-Up Complete and If Not, Were Differences Between Groups in Terms of Their Follow-Up Adequately Described and Analyzed?	Were the Outcomes of Participants Included in Any Comparisons Measured in the Same Way?	Were Outcomes Measured in a Reliable Way?	Was Appropriate Statistical Analysis Used?	Overall Risk of Bias (Low, Moderate, High)
Hoffman, 2018 <sup>40</sup>	Yes	Yes	Yes	Yes	Yes	Yes	Unclear	Yes	Moderate
Ito Fukunaga, 2022 <sup>28</sup>	Yes	Yes	Yes	Unclear	Yes	Yes	Yes	Yes	Moderate
Kukhareva, 2023 <sup>29</sup>	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Low
Lau, 2015 <sup>39</sup>	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Low
Lau, 2021 <sup>38</sup>	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Low
Mazzone, 2017 <sup>33</sup>	Yes	Yes	Yes	Yes	Unclear	Yes	Yes	Yes	Moderate
Reuland, 2018 <sup>47</sup>	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Low
Sakoda, 2020 <sup>34</sup>	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Moderate
Strong, 2020 <sup>43</sup>	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Low
Studts, 2020 <sup>44</sup>	Yes	Yes	Yes	Yes	Unclear	Yes	Yes	Yes	Moderate
Volk, 2014 <sup>42</sup>	Yes	Yes	Yes	Yes	Unclear	Yes	Yes	Yes	Moderate

**NONRANDOMIZED COHORT STUDIES (JBI COHORT)**

Author, Year	Were the Two Groups Similar and Recruited From The Same Population?	Were the Exposures Measured Similarly to Assign People to Both Exposed and Unexposed Groups?	Was The Exposure Measured in a Valid and Reliable Way?	Were Confounding Factors Identified?	Were Strategies to Deal With Confounding Factors Stated?	Were the Groups/Participants Free of the Outcome At the Start of the Study (Or at the Moment of Exposure)?	Were the Outcomes Measured in a Valid and Reliable Way?	Was The Follow-Up Time Reported and Sufficient to Be Long Enough for Outcomes to Occur?	Was Follow-Up Complete, and if Not, Were the Reasons to Loss to Follow-Up Described and Explored?	Were Strategies to Address Incomplete Follow-Up Utilized?	Was Appropriate Statistical Analysis Used?	Overall Risk of Bias (Low, Moderate, High)
Bittner Fagan, 2023 <sup>26</sup>	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Unclear	Unclear	Moderate
Goodwin, 2020 <sup>54</sup>	Unclear	Yes	Yes	Yes	Yes	Unclear	Yes	Yes	Yes	Unclear	Unclear	High
Tanner, 2019 <sup>20</sup>	Yes	Yes	Yes	Yes	Unclear	Unclear	Yes	Yes	Yes	Yes	Yes	Moderate
Studts, 2023 <sup>53</sup>	Yes	Yes	Yes	Yes	Yes	Unclear	Yes	Yes	Yes	Unclear	Yes	Moderate

Abbreviations. NA=not applicable.

**QUALITATIVE STUDIES (CASP)**

Author, Year	Was There a Clear Statement of the Aims of the Research?	Is Qualitative Methodology Appropriate?	Was the Research Design Appropriate to Address the Aims of the Research?	Was the Recruitment Strategy Appropriate to the Aims of the Research?	Was the Data Collected in a Way That Addressed the Research Issue?	Has the Relationship Between Researcher and Participants Been Adequately Considered?	Have Ethical Issues Been Taken Into Consideration?	Was the Data Analysis Sufficiently Rigorous?	Is There a Clear Statement of Findings?	Overall Risk of Bias (Low, Moderate, High)
Abubaker-Sharif, 2022 <sup>59</sup>	Yes	Yes	Yes	Yes	Yes	No	Yes	No	Yes	High
Han, 2019 <sup>18</sup>	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Low
Herbst, 2023 <sup>55</sup>	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Low
Lowery, 2022 <sup>56</sup>	Yes	Yes	Can't Tell	Yes	Can't Tell	No	Yes	Can't Tell	Yes	High

Author, Year	Was There a Clear Statement of the Aims of the Research?	Is Qualitative Methodology Appropriate?	Was the Research Design Appropriate to Address the Aims of the Research?	Was the Recruitment Strategy Appropriate to the Aims of the Research?	Was the Data Collected in a Way That Addressed the Research Issue?	Has the Relationship Between Researcher and Participants Been Adequately Considered?	Have Ethical Issues Been Taken Into Consideration?	Was the Data Analysis Sufficiently Rigorous?	Is There a Clear Statement of Findings?	Overall Risk of Bias (Low, Moderate, High)
Martinez, 2022 <sup>57</sup>	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Low
Melzer, 2020 <sup>60</sup>	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Low
Reese, 2022 <sup>58</sup>	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Low
Schapira, 2022 <sup>21</sup>	Yes	Yes	Can't Tell	Can't Tell	Yes	Yes	Yes	Yes	Yes	High
Wiener, 2018 <sup>22</sup>	Yes	Yes	Yes	Yes	Yes	No	Yes	Can't Tell	Yes	Moderate

## HEALTH CARE PROFESSIONAL-FACING TOOLS OR MATERIALS

### TOOLS FOR CLINICIAN USE DURING SDM CLINIC VISIT TO HELP GUIDE DISCUSSION WITH THE PATIENT

Appendix Table 1. Detailed Characteristics for Studies Evaluating Tools for Clinician Use

Author, Year Risk of Bias Study Design Follow-Up Duration Trial ID Funding source	Inclusion/Exclusion Criteria	Intervention: Detailed Intervention Characteristics  Participants Randomized Demographics Setting	Comparator(s): Detailed Comparator Characteristics  Participants Randomized Demographics Setting	Eligible Outcomes & Measures Reported (Time Points)
Han, 2019 <sup>18</sup>  Low  Pre-post  3 months  NR  Maine Cancer Foundation, & the Maine Lung Cancer Coalition, an initiative jointly supported by the Bristol Myers Squibb Foundation, Maine Cancer Foundation, and Maine Economic Improvement Fund	<b>Inclusion:</b> Ages 55–80 with ≥30-pack- year smoking history, who either currently smoke or quit ≤15 years ago  <b>Exclusion:</b> NR	The prescreening SDM counseling was provided by 2 pulmonary physicians during 40-minute consultation visits, guided by a brief 1-page decision aid. The decision aid was modeled on the “Option Grid” approach and utilized a “Frequently Asked Questions” format. Used PLCOM2012 risk calculator.  N = 60  <b>Age</b> Mean (SD): 63.2 (5.2) <b>Gender</b> Female: 41% <b>Race/Ethnicity:</b> NR <b>Education:</b> NR <b>Insurance Status:</b> NR <b>Smoking Status</b> Currently smoke: 51% Pack years, mean (SD): NR <b>Clinic</b>	NA	<b>Receipt of lung cancer screening (3 mo)</b> Count (%)
Ito Fukunaga, 2022 <sup>28</sup>  Moderate	<b>Inclusion:</b> Age 55–80, ≥ 30 pack-year smoking history, currently smoking, or else non-smoking for ≤ 15 years	A single-page, paper-based, encounter decision aid with a FAQ format designed to guide a structured conversation between	NA	<b>Decisional conflict/regret (0 days)</b> DCS

Author, Year Risk of Bias Study Design Follow-Up Duration Trial ID Funding source	Inclusion/Exclusion Criteria	Intervention: Detailed Intervention Characteristics  Participants Randomized Demographics Setting	Comparator(s): Detailed Comparator Characteristics  Participants Randomized Demographics Setting	Eligible Outcomes & Measures Reported (Time Points)
Pre-post  0 days  NR  Outcomes Research Grant from the Maine Cancer Foundation; the Maine Lung Cancer Coalition (jointly supported by the Bristol Myers Squibb Foundation, Maine Cancer Foundation, and the Maine Economic Improvement Fund); the National Heart, Lung, and Blood Institute through Grant 1K12HK138049-01	<b>Exclusion:</b> NR	the patient and clinician, which focused on explaining key benefits and harms of LDCT screening, using data from the National Lung Screening Trial (NLST).  N = 23  <b>Age</b> Mean (SD): 65.8 (NR) <b>Gender:</b> Female: 43% <b>Race/Ethnicity</b> Black/African American: 1.6% White: 86.6% Hispanic: 6.2% <b>Education:</b> NR <b>Insurance Status:</b> NR <b>Smoking Status:</b> NR <b>Clinic</b>		<b>Knowledge of screening benefits &amp; harms (0 days)</b> Author-developed questionnaire
Kukhareva, 2023 <sup>29</sup>  Moderate  Controlled clinical trial  120 days  NCT04498052  Agency for Healthcare Research and Quality [Grants R18HS026198 and R18HS028791]; VA HSR&D Career Development Award [Grant CDA 16-151]	<b>Inclusion:</b> Patients who completed at least one primary care office visit during the study period, met 2013 USPSTF criteria for LCS (55-80 years of age, ≥30-pack-year smoking history, current tobacco use or quit smoking in the last 15 years), had not undergone chest CT scan imaging (low dose or otherwise) in the past year, and had not declined screening in the past 3 years  <b>Exclusion:</b> History of lung cancer before the visit date, chest CT scan imaging carried out in the past year, or structured EHR data from the past 3 years indicating the patient decided against screening	Pre-implementation of a clinician-facing EHR prompts and an EHR-integrated SDM tool  N = 1090  <b>Age</b> Mean (SD): 65.2 (6.6) <b>Gender</b> Female: 42% <b>Race/Ethnicity</b> Black/African American: 1.6% White: 86.6% Hispanic: 6.2% <b>Education:</b> NR <b>Insurance Status</b> Private: 30.3	Post-implementation of a clinician-facing EHR prompts and an EHR-integrated SDM tool  N = 1026  <b>Age</b> Mean (SD): 65.3 (6.6) <b>Gender</b> Female: 43% <b>Race/Ethnicity</b> Black/African American: 1.7% White: 87.9% Hispanic: 5.6% <b>Education:</b> NR <b>Insurance Status</b>	<b>Receipt of lung cancer screening (120 days)</b> Stratified by race/ethnicity & gender

Author, Year Risk of Bias Study Design Follow-Up Duration Trial ID Funding source	Inclusion/Exclusion Criteria	Intervention: Detailed Intervention Characteristics  Participants Randomized Demographics Setting	Comparator(s): Detailed Comparator Characteristics  Participants Randomized Demographics Setting	Eligible Outcomes & Measures Reported (Time Points)
		Public: 65.2 None: 4.5 <b>Smoking Status</b> Currently smoke: 52.7% Pack years, mean (SD): NR <b>Clinic</b>	Private: 29.3 Public: 67.6 None: 3 <b>Smoking Status</b> Currently smoke: 54.1% Pack years, mean (SD): NR <b>Clinic</b>	
Sferra, 2021 <sup>31</sup>  Some concerns  RCT  6 months  NR  Temple University Fox Chase Cancer Center/HC Regional Comprehensive Cancer Health Disparity Partnership, Award #U54 CA221704 from the National Cancer Institute of National Institutes of Health	<b>Inclusion:</b> Ages 55 and 80, smoking history of at least 30 pack years, actively smoking or quit smoking within the past 15 years, at least a sixth-grade reading level, as assessed by the Rapid Estimate of Adult Literacy in Medicine criteria  <b>Exclusion:</b> Symptoms suggestive of lung cancer, such as hemoptysis or unexplained weight loss, previous lung cancer, previous cancer of any origin with active treatment within the past 5 years or any comorbidity or condition that precluded them from lung cancer treatment	A directed SDM discussion utilizing Option Grids (www.optiongrid.org), an information sheet to guide a physician–patient encounter to compare lung cancer screening options.  N = 128  <b>Age</b> Mean (SD): 64.0 (NR) <b>Gender</b> Female: 71% <b>Race/Ethnicity</b> Black/African American: 55.5% White: 35.9% Hispanic: 6.3% <b>Education</b> High school or greater: 68% <b>Insurance Status:</b> NR <b>Smoking Status:</b> NR <b>Clinic</b>	A directed SDM discussion utilizing shouldscreen.com; the physician navigated the patient through the website  N = 109  <b>Age</b> Mean (SD): 64.0 (NR) <b>Gender</b> Female: 51% <b>Race/Ethnicity</b> Black/African American: 68.8% White: 21.1% Hispanic: 8.3% <b>Education</b> High school or greater: 57.8% <b>Insurance Status:</b> NR <b>Smoking Status:</b> NR <b>Clinic</b>	<b>Quality of communication (6 mo)</b> CollaboRATE  <b>Knowledge of screening benefits &amp; harms (6 mo)</b> Author-developed 14-question survey based on Lau et al. knowledge questionnaire  <b>Decisional conflict/regret (6 mo)</b> Ottawa Decision Regret Scale
Tanner, 2019 <sup>20</sup>  Moderate  Cohort	<b>Inclusion:</b> Eligibility for LCS based on the USPST 2014 screening recommendations; identified via EMR  <b>Exclusion:</b> NR	In-person SDM visit using a paper decision aid and a personalized risk assessment for developing lung cancer over the next 6 years using the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial modified	Telephone-based SDM appointment, including the same counseling and risk assessment provided to intervention group	Receipt of lung cancer screening (1 mo) Proportion of participants  Decisional conflict/regret (1 mo) DCS

Author, Year Risk of Bias Study Design Follow-Up Duration Trial ID Funding source	Inclusion/Exclusion Criteria	Intervention: Detailed Intervention Characteristics  Participants Randomized Demographics Setting	Comparator(s): Detailed Comparator Characteristics  Participants Randomized Demographics Setting	Eligible Outcomes & Measures Reported (Time Points)
1 month  NR  Veterans Affairs Health Services Research and Development Pilot Grant and an American Cancer Society Institutional Research Grant		2012 calculator + shouldiscreen.com  N = 69  <b>Age</b> Mean (SD): 64.1 (6) <b>Gender</b> Female: 52.2% <b>Race/Ethnicity</b> Black/African American: 28.5% White: 64.2% Native American or Alaska Native: 0% Hispanic: 5.1% <b>Education</b> High school or greater: 86.9% <b>Insurance Status:</b> NR <b>Smoking Status:</b> NR <b>Clinic</b>	N = 68  <b>Age</b> Mean (SD): 65.2 (6.2) <b>Gender</b> Female: 5.9% <b>Race/Ethnicity</b> Black/African American: 27.9% White: 63.2% Native American or Alaska Native: 2.9% Hispanic: 5.9% <b>Education</b> High school or greater: 92.6% <b>Insurance Status:</b> NR <b>Smoking Status:</b> NR <b>Home</b>	Satisfaction with decision (1 mo) Satisfaction With Decisions scale

**Abbreviations.** CT=computed tomography; DCS=Decisional Conflict Scale; EHR=electronic health record; EMR=electronic medical record; FAQ=frequently asked questions; LCS=lung cancer screening; LDCT=low-dose computed tomography; Mo=month; NA=not applicable; NR=not reported; PLCO=Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial; RCT=randomized controlled trial; SD=standard deviation; SDM=shared decision making; USPSTF=United States Preventative Services Task Force.

**Appendix Table 2. Detailed Results for Studies Evaluating Tools for Clinician Use**

Author, Year Study Design Risk of Bias	Measurement Instrument	Intervention	Comparator	Results
<i>Quality of Communication</i>				
Sferra, 2021 <sup>31</sup> RCT Some concerns	CollaboRATE	Baseline mean (SD): NR Follow-up: 97.4	Baseline mean (SD): NR Follow-up: 98.6	P = 0.6
<i>Decisional Conflict/Regret</i>				
Ito Fukunaga, 2022 <sup>28</sup> Pre-post Moderate	DCS (0=no decisional conflict to 100=extremely high decisional conflict)	Baseline mean (SD): 35.0 (25.8) Follow-up: 0.2 (1.0)	NA	"All changes in DCS total & subscale scores were significant ( $p < 0.001$ )."
Sferra, 2021 <sup>31</sup> RCT Some concerns	Ottawa Decision Regret Scale (0=no decisional regret to 100=extremely high decisional regret)	Baseline mean (SD): NR Follow-up: 6.0	Baseline mean (SD): NR Follow-up: 10.0	P = 0.02
Tanner, 2019 <sup>20</sup> Cohort Moderate	DCS (0=no decisional conflict to 100=extremely high decisional conflict)	Baseline mean (SD): NR Follow-up: 11.3 (3.4)	Baseline mean (SD): NR Follow-up: 12.1 (3.4)	NR
<i>Receipt of Lung Cancer Screening</i>				
Han, 2019 <sup>18</sup> Pre-post Low	Count (%) of recipients	60/60 (100)	NA	NR
Kukhareva, 2023 <sup>29</sup> CCT Moderate	Overall count (%) of recipients	48/1090 (4.4)	182/1026 (17.7)	OR (95% CI): 4.7 (3.1, 7.1) P < 0.001
	Count (%) of recipients, stratified by race/ethnicity	Non-Hispanic White - 43/944 (4.6) Non-Hispanic Black - 1/17 (5.9) Hispanic - 2/68 (2.9) Other - 2/61 (3.3)	Non-Hispanic White - 159/902 (17.6) Non-Hispanic Black - 5/17 (29.4) Hispanic - 9/57 (15.8) Other - 9/50 (18.0)	NR
	Count (%) of recipients, stratified by gender	Female 18/458 (3.9) Male 30/632 (4.7)	Female 74/441 (16.8) Male 108/585 (18.5)	NR
Tanner, 2019 <sup>20</sup>	Count (%) of recipients	61/69 (88.4)	60/68 (88.2)	NR



Cohort				
Moderate				
<i>Knowledge of Screening Benefits and Harms</i>				
Ito Fukunaga, 2022 <sup>28</sup> Pre-post Moderate	2 author-developed questionnaires	"Five out of eighteen respondents (28%) correctly identified the absolute mortality reduction from lung cancer screening as 1%, while 18 out of 22 respondents (82%) correctly identified the rate of abnormal LDCT as 25%. Among all participants, four (17%) answered both questions correctly, and three (13%) answered both incorrectly or did not answer."	NA	NR
Sferra, 2021 <sup>31</sup> RCT Some concerns	Author-developed 14-question survey based on Lau et al. knowledge questionnaire	Baseline mean (SD): NR Follow-up: 67.4	Baseline mean (SD): NR Follow-up: 62.4	NR
<i>Satisfaction With Decision</i>				
Tanner, 2019 <sup>20</sup> Cohort Moderate	Satisfaction with Decisions scale	Baseline mean (SD): NR Follow-up: 26.7 (2.8)	Baseline mean (SD): NR Follow-up: 24.6 (5.6)	NR

*Abbreviations.* CI=confidence interval; DCS=Decisional Conflict Scale; LDCT=low-dose computed tomography; NA=not applicable; NR=not reported; OR=odds ratio; RCT=randomized controlled trial; SD=standard deviation.

## TOOLS FOR LCS NAVIGATOR USE TO HELP GUIDE SDM DISCUSSION

**Appendix Table 3. Detailed Characteristics for Studies Evaluating Tools for LCS Navigator Use**

Author, Year Risk of Bias Study Design Follow-Up Duration Trial ID Funding Source	Inclusion/Exclusion Criteria	Intervention: Detailed Intervention Characteristics  Participants Randomized Demographics Setting	Comparator(s): Detailed Comparator Characteristics  Participants Randomized Demographics Setting	Eligible Outcomes & Measures Reported (Time Points)
Bittner Fagan, 2020 <sup>25</sup>  Moderate  Pre-post  90 days  NR  Institutional Development Award (IDeA) from the National Institute of General Medical Sciences of the National Institutes of Health under grant number U54-GM104941 and the Physician's Professionalism Council of Christiana Care Health System	<b>Inclusion:</b> Ages 55-80, currently or formerly smoked with at least a 30 pack-year history, has not quit smoking for more than 15 years, and has not have received a LDCT scan within the last year  <b>Exclusion:</b> NR	A phone-based appointment with a decision counselor who reviewed the educational materials that were mailed and guided the patient through decision counseling session using an online software application, the Decision Counseling Program© (DCP).  N = 20  <b>Age:</b> NR <b>Gender</b> Female: 45% <b>Race/Ethnicity</b> Black/African American: 20% White: 75% Hispanic: 5.3% <b>Education:</b> NR <b>Insurance Status</b> Private: 35% Public: 60% None: 5% <b>Smoking Status</b> Currently smoke: 55% Pack years, mean (SD): 49.7 (21.4) <b>Clinic; Community</b>	No DCP        N = 8  <b>Age:</b> NR <b>Gender</b> Female: 75% <b>Race/Ethnicity</b> Black/African American: 12.5% White: 87.5% Hispanic: 0% <b>Education:</b> NR <b>Insurance Status</b> Private: 37.5% Public: 62.5% None: 0% <b>Smoking Status</b> Currently smoke: 100% Pack years, mean (SD): 21.4 (7.9) <b>NA</b>	<b>Receipt of lung cancer screening (90 days)</b> Proportion  <b>Decisional conflict/regret (30 days)</b> Author Developed 5-point Likert scale (0 = "strongly agree" to 4 = "strongly disagree"); stratified by people who currently smoked

Author, Year Risk of Bias Study Design Follow-Up Duration Trial ID Funding Source	Inclusion/Exclusion Criteria	Intervention: Detailed Intervention Characteristics  Participants Randomized Demographics Setting	Comparator(s): Detailed Comparator Characteristics  Participants Randomized Demographics Setting	Eligible Outcomes & Measures Reported (Time Points)
Bittner Fagan, 2023 <sup>26</sup>  Moderate  Cohort  1 year  NR  NIH, State of Delaware, University of Delaware, Christiana Care Health System, Nemours, Delaware State University, and Medical University of South Carolina	<b>Inclusion:</b> Between 55-80 years of age, had at least a 30-pack year smoking history, had no symptoms consistent with cancer, and had not undergone an LDCT scan of the lungs within the last year.  <b>Exclusion:</b> Those with limited life expectancy or prohibitive comorbid conditions, had participated in prior studies on lung cancer screening, were already enrolled in the health system screening program, or had had a CT scan of the chest in the last year.	Telephone-delivered SDM with a decision counselor (not a physician, nurse practitioner, or physician assistant) using Decision Counseling Program ®, an online interactive decision aid; and a second SDM conversation at a visit either with their PCP or with the centralized lung cancer screening program.  N = 64  <b>Age</b> Mean (SD): 64.2 (6.1) <b>Gender</b> Female: 50% <b>Race/Ethnicity</b> Asian: 1.6% Black/African American: 17.2% White: 79.6% Hispanic: 1.6% <b>Education:</b> NR <b>Insurance Status</b> Private: 42.2% Public: 54.7% None: 3.1% <b>Smoking Status</b> Currently smoke: NR Pack years, mean (SD): 44.2 (15.9) <b>Clinic</b>	The control group, who had declined study participation, represents usual care and therefore SDM for lung cancer screening may or may not have occurred with a provider.  N = 16  <b>Age</b> Mean (SD): 63.3 (5.9) <b>Gender</b> Female: 50% <b>Race/Ethnicity</b> Asian: 0% Black/African American: 6.3% White: 93.7% Hispanic: 0% <b>Education:</b> NR <b>Insurance Status</b> Private: 25% Public: 68.7% None: 6.3% <b>Smoking Status</b> Currently smoke: NR Pack years, mean (SD): 51.1 (16.2) <b>NA</b>	<b>Receipt of lung cancer screening (1 year)</b> Count
DiCarlo, 2022 <sup>27</sup>  Some concerns  RCT	<b>Inclusion:</b> Patients in participating practices who had not been screened with LDCT and were potentially eligible for LCS, using basic eligibility criteria consistent with the USPSTF, CMS, and National	Outreach contact + decision counseling  N = 302	Outreach contact only  N = 297	<b>Receipt of lung cancer screening (280 days)</b> Count (%)

Author, Year Risk of Bias Study Design Follow-Up Duration Trial ID Funding Source	Inclusion/Exclusion Criteria	Intervention: Detailed Intervention Characteristics  Participants Randomized Demographics Setting	Comparator(s): Detailed Comparator Characteristics  Participants Randomized Demographics Setting	Eligible Outcomes & Measures Reported (Time Points)
280 days  NR  A grant from Bristol-Myers Squibb Foundation entitled, "Engaging a Learning Community to Increase Lung Cancer Screening in Vulnerable Populations," and by the Cancer Center Support Grant 5P30CA056036–17 of the Sidney Kimmel Cancer Center	Comprehensive Cancer Center Network guidelines  <b>Exclusion:</b> NR	<b>Age:</b> NR <b>Gender</b> Female: 49% <b>Race/Ethnicity</b> Asian: 17% Black/African American: 28% White: 50% Native American or Alaska Native: 0% Hispanic: 3% <b>Education:</b> NR <b>Insurance Status:</b> NR <b>Smoking Status</b> Currently smoke: 23% Pack years, mean (SD): NR <b>Clinic</b>	<b>Age:</b> NR <b>Gender</b> Female: 46% <b>Race/Ethnicity</b> Asian: 17% Black/African American: 30% White: 46% Native American or Alaska Native: 0% Hispanic: 4% <b>Education:</b> NR <b>Insurance Status:</b> NR <b>Smoking Status</b> Currently smoke: 22% Pack years, mean (SD): NR <b>Clinic</b> <hr/> Usual care  N = 1748  <b>Age:</b> NR <b>Gender</b> Female: 55% <b>Race/Ethnicity</b> Asian: 8% Black/African American: 32% White: 56% Native American or Alaska Native: <1% Hispanic: 2% <b>Education:</b> NR <b>Insurance Status</b> Private: 35% Public: 60% None: 5% <b>Smoking Status</b>	

Author, Year Risk of Bias Study Design Follow-Up Duration Trial ID Funding Source	Inclusion/Exclusion Criteria	Intervention: Detailed Intervention Characteristics  Participants Randomized Demographics Setting	Comparator(s): Detailed Comparator Characteristics  Participants Randomized Demographics Setting	Eligible Outcomes & Measures Reported (Time Points)
			Currently smoke: 21% Pack years, mean (SD): NR <b>Clinic</b>	
Percac-Lima, 2018 <sup>30</sup>  Some concerns  RCT  1 year  NCT02705365  American Cancer Society: Cancer Control Career Development Award for Primary Care Physicians (CCCDAA-14- 012-01-CCCDAA) and Lazarex Cancer Foundation	<b>Inclusion:</b> Ages 55–77 years old who were identified as people who currently smoke in the EMR  <b>Exclusion:</b> Patients who had any chest CT performed in the previous 18 months and those not receiving care in one of the 5 community health centers	A patient navigation program - navigators contacted patients to determine LCS eligibility, introduce SDM, schedule appointments with primary care physicians, and help overcome barriers to obtaining screening and follow-up.  N = 400  <b>Age</b> Mean (SD): 61.8 (5.4) <b>Gender</b> Female: 47% <b>Race/Ethnicity</b> Asian: 4.5% Black/African American: 4.5% White: 77.8% Hispanic: 6.5% <b>Education</b> High school or greater: 80.8% <b>Insurance Status</b> Private: 32% Public: 67.9% None: 0.3% <b>Smoking Status</b> Currently smoke: 100% Pack years, mean (SD): NR <b>Clinic</b>	Usual care  N = 800  <b>Age</b> Mean (SD): 62.4 (5.7) <b>Gender</b> Female: 55.3% <b>Race/Ethnicity</b> Asian: 2.8% Black/African American: 3.1% White: 83.3% Hispanic: 5.1% <b>Education</b> High school or greater: 80% <b>Insurance Status</b> Private: 35% Public: 65% None: 0% <b>Smoking Status</b> Currently smoke: 100% Pack years, mean (SD): NR <b>Clinic</b>	<b>Receipt of lung cancer screening (1 yr)</b> Count (%)  <b>Receipt of additional tests/procedures for identified findings (1 yr)</b> Count (%)

**Abbreviations.** CMS=Centers for Medicare & Medicaid Services; CT=computed tomography; EMR=electronic medical record; LCS=lung cancer screening; LDCT=low-dose computed tomography; NR=not reported; PCP=primary care provider; RCT=randomized controlled trial SD=standard deviation; SDM=shared decision-making; USPSTF=United States Preventative Services Task Force; Yr=year.

**Appendix Table 4. Detailed Results for Studies Evaluating Tools for LCS Navigator Use**

Author, Year Study Design Risk of Bias	Measurement Instrument	Intervention	Comparator	Results
<i>Decisional Conflict/Regret</i>				
Bittner Fagan, 2020 <sup>25</sup> Pre-post	Author-developed 5-point Likert scale (0 = "strongly agree" to 4 = "strongly disagree")	-0.57 (18.2)	NA	P = 0.69
	Author-developed 5-point Likert scale (0 = "strongly agree" to 4 = "strongly disagree"), stratified by current smoking status	Currently smoke: -7.55 Formerly smoke: 7.81	NA	Currently smoke: $p = 0.25$ Formerly smoke: $p = 0.75$
<i>Receipt of Lung Cancer Screening</i>				
Bittner Fagan, 2020 <sup>25</sup> Pre-post	Count (%) of recipients	9/20	0/8	NR
Bittner Fagan, 2023 <sup>26</sup> Cohort Moderate	Count (%) of recipients within 1 year of SDM appointment	29/64 (45.3)	0/16 (0)	NR
DiCarlo, 2022 <sup>27</sup> RCT Some concerns	Count (%) of recipients	33/599 (5.5)	31/1748 (1.8)	HR (95% CI): 3.28 (1.98, 5.41) $p = 0.001$
Percac-Lima, 2018 <sup>30</sup> RCT Some concerns	Count (%) of recipients	94/400 (23.5)	69/800 (8.6)	P < 0.001
<i>Receipt of Additional Tests/Procedures for Identified Findings</i>				
Percac-Lima, 2018 <sup>30</sup> RCT Some concerns	Count (%) of recipients	<p><i>"In the intervention group, 12 (12.8%) patients had Lung-RADS 3 findings and required a 6-month follow up compared to 6 (8.7%) in the control group. Seven (7.4%) in the intervention group and 6 (9.6%) in control patients had Lung-RADS 4 finding and required immediate follow-up...The number of additional diagnostic tests post-screening was similar in both groups: in the navigated group 2 patients had a PET CT, 3 repeat chest CT, 1 an abdominal CT, 1 brain MRI, and 1 patient had a mediastinoscopic biopsy. Among screened patients in the usual care group 4 had a PET CT, 5 repeat chest CT, and 1 an abdominal CT. Eight lung cancers were diagnosed in intervention patients (2%) compared to 4 in control patients (0.5%). Three patients (2 in the intervention group and 1 in the control group) were diagnosed with lung cancer after a screening CT and had surgical resection. One patient with stage 1 disease had only a surgical resection. Two patients with stage 3</i></p>		

Author, Year Study Design Risk of Bias	Measurement Instrument	Intervention	Comparator	Results
<i>disease received surgery followed by chemotherapy and chemotherapy with radiation. Six of nine cancers identified after a diagnostic chest CT were stage 4."</i>				

*Abbreviations.* CI=confidence interval; CT=computed tomography; HR=hazard ratio; MRI=magnetic resonance imaging; NA=not applicable; NR=not reported; PET=positron emission tomography; RADS=Reporting and Data System; RCT=randomized controlled trial.





## PATIENT-FACING TOOLS OR MATERIALS

### TOOLS FOR PATIENT USE DURING OR PRIOR TO A SDM CLINIC VISIT

**Appendix Table 5. Detailed Characteristics for Studies Evaluating Tools for Use During or Prior to an SDM Clinic Visit**

Author, Year Risk of Bias Study Design Follow-Up Duration Trial ID Funding Source	Inclusion/Exclusion Criteria	Intervention: Detailed Intervention Characteristics  Participants Randomized Demographics Setting	Comparator(s): Detailed Comparator Characteristics  Participants Randomized Demographics Setting	Eligible Outcomes & Measures Reported (Time Points)
Flores, 2021 <sup>32</sup>  Moderate  Pre-post  0 days  NR  American Cancer Society Institutional Research Grant Award 128592-IRG-15-171-04	<b>Inclusion:</b> Ages 55 to 77 years, smoking history of $\geq 30$ pack-years, or diagnosis of schizophrenia spectrum disorder or bipolar disorder  <b>Exclusion:</b> Cognitive deficits severe enough to preclude a participant's ability to provide consent, presence of a guardian for medical decision making, history of lung cancer, or already enrolled in an LCS program	Two 30-minute educational sessions, one led by a radiologist focused on LCS, and one led by a mental health clinician focused on smoking cessation (later adapted into a single session)  N = 15  <b>Age</b> Mean (SD): 61.3 (3.7) <b>Gender</b> Female: 40% <b>Race/Ethnicity</b> White: 86% Native American or Alaska Native: 14% Hispanic: 7% <b>Education</b> High school or greater: 53% <b>Insurance Status</b> Private: NR Public: 86% None: NR <b>Smoking Status</b> Current Smoker: 67% Pack years, mean (SD): NR <b>Clinic</b>	NA	<b>Distress/anxiety (0 days)</b> Author-developed question about their lung cancer worry  <b>Quality of communication (0 days)</b> Author-developed question: "Overall, I was satisfied with the education sessions."

Author, Year Risk of Bias Study Design Follow-Up Duration Trial ID Funding Source	Inclusion/Exclusion Criteria	Intervention: Detailed Intervention Characteristics  Participants Randomized Demographics Setting	Comparator(s): Detailed Comparator Characteristics  Participants Randomized Demographics Setting	Eligible Outcomes & Measures Reported (Time Points)
Mazzone, 2017 <sup>33</sup>  Moderate  Pre-post  1 month  NR  None	<b>Inclusion:</b> Patients referred to lung cancer screening program by primary care or specialty provider  <b>Exclusion:</b> NR; authors state that 7 patients were excluded for smoking history, 1 for their age, & 1 had undergone a CT scan in the past 12 months	Counselling and SDM visit including an author developed 6-min narrated video slideshow describing the benefits and harms of lung cancer screening with the use of a decision aid ( <a href="http://www.shouldiscreen.com">http://www.shouldiscreen.com</a> )  N = 423  <b>Age</b> Mean (SD): 64.4 (NR) <b>Gender</b> Female: 33.9% <b>Race/Ethnicity:</b> NR <b>Education</b> High school or greater: 89.5% <b>Insurance Status:</b> NR <b>Smoking Status</b> Current Smoker: 45.2% Pack years, mean (SD): 53 (NR) <b>Clinic</b>	NA	<b>Receipt of lung cancer screening (1 mo)</b> Count  <b>Quality of communication (1 mo)</b> Author-developed survey  <b>Knowledge of screening benefits &amp; harms (1 mo)</b> Author-developed survey
Sakoda, 2020 <sup>34</sup>  Moderate  Pre-post  14 months  NR  National Cancer Institute (K07 CA188142)	<b>Inclusion:</b> Participants were class attendees from June 2017 to August 2018, who completed surveys administered immediately before and after the class  <b>Exclusion:</b> NR	Patients attend a group education class led by clinician specialists before a personal shared decision making visit is scheduled. Key aspects, including the eligibility criteria and potential benefits and harms, are presented. A risk assessment is personalized and discussed at the SDM visit if a patient chooses to continue with screening. The importance of smoking abstinence is stressed to encourage current smokers to quit. Patient education materials and a decision worksheet handout are provided to support the learning process.  N = 680	Screening eligible participants from the education class	<b>Knowledge of screening benefits &amp; harms (14 mo)</b> Author-developed survey

Author, Year Risk of Bias Study Design Follow-Up Duration Trial ID Funding Source	Inclusion/Exclusion Criteria	Intervention: Detailed Intervention Characteristics  Participants Randomized Demographics Setting	Comparator(s): Detailed Comparator Characteristics  Participants Randomized Demographics Setting	Eligible Outcomes & Measures Reported (Time Points)
		<b>Age</b> Median (IQR): 64.3 (59, 69) <b>Gender</b> Female: 40.2% <b>Race/Ethnicity</b> Asian: 10.7% Black or African American: 3.9% White: 75.9% Hispanic: 6.9% <b>Education:</b> NR <b>Insurance Status:</b> NR <b>Smoking Status</b> Current Smoker: 54.7% Pack years, mean (SD): NR <b>Community</b>	N = 269  <b>Age</b> Median (IQR): 64 (60, 69) <b>Gender</b> Female: 40.2% <b>Race/Ethnicity</b> Asian: 7.8 % Black or African American: 2.3% White: 82.9% Hispanic: 6.2% <b>Education:</b> NR <b>Insurance Status:</b> NR <b>Smoking Status</b> Current Smoker: 50.9% Pack years, mean (SD): NR <b>Community</b>	
Schapira, 2023 <sup>19</sup>  Low  RCT  9 months  NCT02899754  Veteran's Affairs HSR&D (HX001898-01A2)	<b>Inclusion:</b> Age 55 to 80 years, active smokers or those who quit smoking within the past 15 years, history of at least 30 pack-years of smoking, and an upcoming appointment in primary care within 3 weeks  <b>Exclusion:</b> A cancer diagnosis, except for nonmelanoma skin cancer or prostate cancer not requiring active treatment, and a primary care clinician assessment of life expectancy less than 2 years	Lung Cancer Screening Decision Tool (LCSDecTool) is an online tool that provides an overview of LCS using a simulated patient-clinician dialogue, interactive knowledge boxes, a pictograph representing LCS outcomes, a value elicitation exercise, smoking cessation advice, mental health resources, and the option to request a referral to a smoking cessation clinic or to a behavioral health clinician to support smoking cessation efforts  N = 69	Web-based 10-page guide that provided general information on cancer prevention and the USPSTF screening guidelines for breast, colon, cervical, and lung cancer	<b>Receipt of lung cancer screening (9 mo)</b> Count (%)  <b>Decisional conflict/regret (3 mo)</b> DCS total, decisional conflict scale developed by Brehaut et al. (stratified by race/ethnicity)  <b>Distress/anxiety (3 mo)</b> State Trait Anxiety Index (stratified by race/ethnicity)

Author, Year Risk of Bias Study Design Follow-Up Duration Trial ID Funding Source	Inclusion/Exclusion Criteria	Intervention: Detailed Intervention Characteristics  Participants Randomized Demographics Setting	Comparator(s): Detailed Comparator Characteristics  Participants Randomized Demographics Setting	Eligible Outcomes & Measures Reported (Time Points)
		<b>Age</b> Median (IQR): 64 (61, 69) <b>Gender</b> Female: 11.6% <b>Race/Ethnicity</b> Black or African American: 60.9% White: 37.7% Hispanic: 1.4% <b>Education</b> High school or greater: 95.7% <b>Insurance Status:</b> NR <b>Smoking Status</b> Current Smoker: 73.9% Pack years, median (IQR): 40.5 (35, 50) <b>Clinic</b>	N = 71  <b>Age</b> Median (IQR): 64 (62, 70) <b>Gender</b> Female: 4.2% <b>Race/Ethnicity</b> Black or African American: 46.5% White: 50.7% Hispanic: 4.2% <b>Education</b> High school or greater: 98.4% <b>Insurance Status:</b> NR <b>Smoking Status</b> Current Smoker: 57.7% Pack years, median (IQR): 45 (39, 54) <b>Clinic</b>	<b>Knowledge of screening benefits &amp; harms (3 mo)</b> NR
Walsh, 2023 <sup>35</sup>  Some concerns  RCT  2 months  NCT03862001  Tobacco Related Diseases Research Program 26IR-0006; National Institute on Aging of the NIH award no. P30AG015272	<b>Inclusion:</b> Age 55-80, smoked at least 30 pack-years in lifetime, quit smoking within the last 15 years if a former smoker, English speaker, no prior history of lung cancer, did not have a lung cancer screening test within the last year, PCP does not object to patient's participation, and have a scheduled visit at University of California, San Francisco (UCSF) internal medicine clinics  <b>Exclusion:</b> Speaking a language other than English, has a history of lung cancer, had a lung cancer screening test within the last year, and PCP objects to patient's participation (taken from clinicaltrials.gov)	LungCare was administered on a touch tablet in waiting room prior to primary care appt. The product includes a 5-minute animated video and a risk and preference assessment... After completion, the patient was provided 2 printed reports, 1) an individualized patient report and 2) an individualized report to hand to their physician designed to efficiently prompt patient-physician discussion  N = 34  <b>Age</b> Mean (SD): 66.7 (6.3) <b>Gender</b> Female: 47% <b>Race/Ethnicity</b>	Usual care          N = 32  <b>Age</b>	<b>Receipt of lung cancer screening (1 wk)</b> Count (%)  <b>Knowledge of screening benefits &amp; harms (1 wk)</b> Author-developed set of 10 true/false questions

Author, Year Risk of Bias Study Design Follow-Up Duration Trial ID Funding Source	Inclusion/Exclusion Criteria	Intervention: Detailed Intervention Characteristics  Participants Randomized Demographics Setting	Comparator(s): Detailed Comparator Characteristics  Participants Randomized Demographics Setting	Eligible Outcomes & Measures Reported (Time Points)
		Asian: 3% Black or African American: 29% White: 65% <b>Education</b> High school or greater: 89.5% <b>Insurance Status:</b> NR <b>Smoking Status</b> Current Smoker: 27% Pack years, mean (SD): NR  <b>Clinic</b>	Mean (SD): 64.9 (5.7) <b>Gender</b> Female: 56% <b>Race/Ethnicity</b> Asian: 6% Black or African American: 31% White: 59% <b>Education</b> High school or greater: 94% <b>Insurance Status:</b> NR <b>Smoking Status</b> Current Smoker: 28% Pack years, mean (SD): NR  <b>Clinic</b>	

**Abbreviations.** CT=computed tomography; DCS=Decisional Conflict Scale; EHR=electronic health record; HSR&D=Health Services Research & Development; IQR=interquartile range; LCS=lung cancer screening; Mo=month; NA=not applicable; NIH=National Institute of Health; NR=not reported; PCP=primary care provider; RCT=randomized controlled trial; SD=standard deviation; SDM=shared decision-making; USPSTF=United States Preventative Services Task Force; Wk=week.

**Appendix Table 6. Detailed Results for Studies Evaluating Tools for Use During or Prior to an SDM Clinic Visit**

Author, Year Study Design Risk of Bias	Measurement Instrument	Intervention	Comparator	Results
<i>Quality of Communication</i>				
Flores, 2021 <sup>32</sup> Pre-post Moderate	Count (%) of participants who responded to the question: "Overall, I was satisfied with the education sessions."	Strongly agree or agree: 14/15 (93) Neither agree nor disagree: 1/15 (7)	NA	NR
Mazzone, 2017 <sup>33</sup> Pre-post Moderate	Author-developed questionnaire	"Of the 66 patients who provided comments about the visit, 57 were positive (eg, "good presentation helped me to make an informed choice"; "Excellent! No unnecessary pressure—honest, highly intelligent, and sensitive to needs of my whole life"), and nine comments were negative (eg, "information regarding harms of screening is confusing"; "boring")."	NA	NR
<i>Decisional Conflict/Regret</i>				
Schapira, 2023 <sup>19</sup> RCT Low	DCS overall	Baseline mean (95% CI): NR Follow-up: 24.2 (20.8, 27.6)	Baseline mean (95% CI): NR Follow-up: 27.5 (23.3, 31.7)	-2.9 (-8.9, 3.0) P = 0.33
	DCS overall, stratified by race/ethnicity	Baseline mean (95% CI): NR Follow-up: 25.3 (20.5, 30.0)	Baseline mean (95% CI): NR Follow-up: 25.9 (19.5, 32.3)	-1.0 (-9.0, 7.1)
	A decisional conflict scale developed by Brehaut et al.	Baseline mean (95% CI): NR Follow-up: 32.5 (30.1, 35.0)	Baseline mean (95% CI): NR Follow-up: 34.3 (31.9, 36.7)	-2.0 (-5.6, 1.5) P = 0.26
	A decisional conflict scale developed by Brehaut et al., stratified by race/ethnicity	Baseline mean (95% CI): NR Follow-up: 32.9 (29.5, 36.2)	Baseline mean (95% CI): NR Follow-up: 32.7 (29.0, 36.3)	-0.5 (-5.5, 4.4) P = 0.83
<i>Distress/Anxiety</i>				
Flores, 2021 <sup>32</sup> Pre-post Moderate	State Trait Anxiety Index	Baseline mean (SD): 1.8 (0.9) Follow-up: 2.4 (1.2)	NA	0.57 P = 0.03
Schapira, 2023 <sup>19</sup> RCT Low	State Trait Anxiety Index	Baseline mean (95% CI): NR Follow-up: 36.6 (33.6, 39.7)	Baseline mean (95% CI): NR Follow-up: 38.2 (33.9, 42.4)	-0.7 (-5.1, 3.6) P = 0.74
	State Trait Anxiety Index, stratified by race/ethnicity	Baseline mean (95% CI): NR Follow-up: 36.5 (32.2, 40.8)	Baseline mean (95% CI): NR Follow-up: 36.0 (29.1, 43.0)	1.3 (-5.1, 7.6) P = 0.69
<i>Receipt of Lung Cancer Screening</i>				
Mazzone, 2017 <sup>33</sup> Pre-post Moderate	Count (%) of recipients	400/423 (94.6)	NA	NR
Schapira, 2023 <sup>19</sup> RCT Low	Count (%) of recipients	31/69 (44.9)	18/71 (25.4)	Between-group difference (95% CI): 18.8 (4.4, 33.2) P = 0.02
Walsh, 2023 <sup>35</sup> RCT	Count (%) of recipients	11/34 (32)	4/32 (13)	P = 0.01

Author, Year Study Design Risk of Bias	Measurement Instrument	Intervention	Comparator	Results
Some concerns				
<i>Knowledge of Screening Benefits and Harms</i>				
Mazzone, 2017 <sup>33</sup> Pre-post Moderate	Author-designed questionnaire	Authors do not report a composite knowledge score but instead report change in knowledge for age range, smoking, and benefits & harms of screening. They also report these results stratified by education level.	NA	NR
Sakoda, 2020 <sup>34</sup> Pre-post Moderate	Author-designed questionnaire	"Response patterns were similar for those identified as screening-eligible, with slightly larger pre-post increases in the proportion of correct responses to most statements."		
Schapira, 2023 <sup>19</sup> RCT Low	NR	Baseline mean (95% CI): NR Follow-up: 6.2 (5.6, 6.8)	Baseline mean (95% CI): NR Follow-up: 5.1 (4.4, 5.8)	1.1 (0.1, 2.0) P = 0.01
Walsh, 2023 <sup>35</sup> RCT Some concerns	Author-developed questionnaire of 10 true/false questions	Baseline mean (SD): NR Follow-up: 6.5 (1.7)	Baseline mean (SD): NR Follow-up: 5.5 (1.4)	P < 0.01

**Abbreviations.** CI=confidence interval; DCS=Decisional Conflict Scale; NA=not applicable; NR=not reported; RCT=randomized controlled trial; SD=standard deviation; SDM=shared decision-making.



## TOOLS OR MATERIALS FOR PATIENT EDUCATION ABOUT SCREENING AND TO POTENTIALLY GENERATE SDM VISITS

**Appendix Table 7. Detailed Characteristics for Studies Evaluating Tools for Patient Education to Generate SDM**

Author, Year Risk of Bias Study Design Follow-Up Duration Trial ID Funding source	Inclusion/Exclusion Criteria	Intervention: Detailed Intervention Characteristics  Participants Randomized Demographics Setting	Comparator(s): Detailed Comparator Characteristics  Participants Randomized Demographics Setting	Eligible Outcomes & Measures Reported (Time Points)
Carter-Harris, 2020 <sup>46</sup>  Some concerns  RCT  3 months  NR  Indiana University Purdue University at Indianapolis Developing Diverse Researchers with Investigative Expertise Pilot Grant, American Cancer Society Institutional Research Grant, and Indiana University School of Nursing Pilot Grant	<b>Inclusion:</b> Ages 55-80 years, 30 pack-year tobacco smoking history, current smoker or former smoker who quit within the past 15 years, not diagnosed with a condition that would be contraindicated for lung cancer screening, and not diagnosed with lung cancer  <b>Exclusion:</b> NR	LungTalk is a computer-tailored decision support tool (audio, video, and animation segments) that is designed to increase knowledge and awareness about the option to screen, or not, for lung cancer and to prepare screening-eligible individuals to engage in shared decision making about lung cancer screening with their clinician. Messages are tailored by smoking status.  N = 31  <b>Age</b> Mean (SD): 61.2 (4.8) <b>Gender</b> Female: 52% <b>Race/Ethnicity</b> Black or African American: 19% White: 77% <b>Education</b> High school or greater: 97% <b>Insurance Status</b> Private: 37% Public: 50% None: NR <b>Smoking Status</b> Current Smoker: 51.6% Pack years, mean (SD): 47.6 (21.9) <b>Community</b>	Viewed generic information sheet online about lung cancer screening developed by the American Cancer Society          N = 29  <b>Age</b> Mean (SD): 63.2 (5.5) <b>Gender</b> Female: 52% <b>Race/Ethnicity</b> Black or African American: 14% White: 88% <b>Education</b> High school or greater: 100% <b>Insurance Status</b> Private: 25% Public: 53% None: NR <b>Smoking Status</b> Current Smoker: 55.2% Pack years, mean (SD): 49.9 (16.6) <b>Community</b>	<b>Quality of communication (1 wk)</b> Author-developed questionnaire      <b>Knowledge of screening benefits &amp; harms (1 wk)</b> Knowledge of Lung Cancer and Lung Cancer Screening scale

Author, Year Risk of Bias Study Design Follow-Up Duration Trial ID Funding source	Inclusion/Exclusion Criteria	Intervention: Detailed Intervention Characteristics  Participants Randomized Demographics Setting	Comparator(s): Detailed Comparator Characteristics  Participants Randomized Demographics Setting	Eligible Outcomes & Measures Reported (Time Points)
Clark, 2022 <sup>45</sup>  Some concerns  RCT  0 days  NCT04432753  Health Resources & Services Administration-funded primary care research fellowship at the University of North Carolina at Chapel Hill (T32- HP14001)	<b>Inclusion:</b> 55–80-year- old current and former smokers who quit within the last 15 years with a 30 pack year minimum  <b>Exclusion:</b> NR	A four-and-a-half-minute video decision aid, covering the benefit and harms of screening, including information on incidental findings which was 31 seconds in length  N = 173  <b>Age</b> Mean (SD): 64.5 (6.5) <b>Gender</b> Female: 49.7% <b>Race/Ethnicity</b> Black or African American: 20.2% White: 69.4% Hispanic: 7.5% <b>Education</b> High school or greater: 96% <b>Insurance Status</b> Private: 29% Public: 71% None: 6.4% <b>Smoking Status</b> Current Smoker: 72.3% Pack years, mean (SD): NR <b>Community</b>	The control group viewed the same decision aid as the intervention arm however the information regarding incidental findings was not included  N = 175  <b>Age</b> Mean (SD): 64.4 (6.1) <b>Gender</b> Female: 53.1% <b>Race/Ethnicity</b> Black or African American: 14.9% White: 76.6% Hispanic: 8% <b>Education</b> High school or greater: 96% <b>Insurance Status</b> Private: 34.1% Public: 60.9% None: 6.9% <b>Smoking Status</b> Current Smoker: 68.6% Pack years, mean (SD): NR <b>Community</b>	<b>Knowledge of screening benefits &amp; harms (0 days)</b> Author-developed questionnaire
Crothers, 2016 <sup>23</sup>  Moderate  Pre-post  0 days  NR	<b>Inclusion:</b> Ages 50–74, current or former smokers for at least 20 pack-years  <b>Exclusion:</b> Cognitive or language limitations (eg, expressive language limitations, non-English speaking) or known malignancy (except nonmelanoma skin cancers)	1) A web-based tool ( <a href="http://www.shouldiscreen.com">www.shouldiscreen.com</a> ) and 2) an educational paper pamphlet ( <a href="http://www.prevention.va.gov/preventing_diseases/screening_for_lung_cancer.asp">http://www.prevention.va.gov/preventing_diseases/screening_for_lung_cancer.asp</a> )  N = 45  <b>Age</b> Median (IQR): 61 (57, 61)	NA	<b>Knowledge of screening benefits &amp; harms (0 days)</b> Author-developed questionnaire

Author, Year Risk of Bias Study Design Follow-Up Duration Trial ID Funding source	Inclusion/Exclusion Criteria	Intervention: Detailed Intervention Characteristics  Participants Randomized Demographics Setting	Comparator(s): Detailed Comparator Characteristics  Participants Randomized Demographics Setting	Eligible Outcomes & Measures Reported (Time Points)
Lung Cancer Discovery Grant from the American Lung Association, K05 CA104699, and by resources from the Veteran's Affairs Portland Health Care System		<b>Gender</b> Female: 29% <b>Race/Ethnicity</b> Asian: 4% Black or African American: 31% White: 58% Native American or Alaska Native: 2% Native Hawaiian or Other Pacific Islander: 4% Hispanic: 2% <b>Education</b> High school or greater: 73% <b>Insurance Status</b> Private: 11% Medicare: 67% Medicaid: 42% None: 2% <b>Smoking Status</b> Current Smoker: 76% Pack years, median (IQR): 37 (23, 54) <b>Clinic</b>		

Author, Year Risk of Bias Study Design Follow-Up Duration Trial ID Funding source	Inclusion/Exclusion Criteria	Intervention: Detailed Intervention Characteristics  Participants Randomized Demographics Setting	Comparator(s): Detailed Comparator Characteristics  Participants Randomized Demographics Setting	Eligible Outcomes & Measures Reported (Time Points)
Fraenkel, 2016 <sup>50</sup>  High  RCT  0 days  NR  The National Science Foundation NSF SES-1047757; the National Institute of Arthritis and Musculoskeletal and Skin Diseases, part of the National Institutes of Health, under award number AR060231-01	<b>Inclusion:</b> English- speaking, not scheduled for follow-up of a pulmonary nodule, did not have a history of lung cancer  <b>Exclusion:</b> NR	Numbers only  N = 84  <b>Age</b> Mean (SD): 61.2 (9.4) <b>Gender</b> Female: 58.3% <b>Race/Ethnicity</b> White: 90.5% Hispanic: 4.8% <b>Education:</b> NR <b>Insurance Status:</b> NR <b>Smoking Status</b> Current Smoker: 11.9% Pack years, mean (SD): NR <b>Clinic</b>	Numbers + icon arrays  N = 86  <b>Age</b> Mean (SD): 59.6 (8.7) <b>Gender</b> Female: 52.3% <b>Race/Ethnicity</b> White: 93% Hispanic: 5.8% <b>Education:</b> NR <b>Insurance Status:</b> NR <b>Smoking Status</b> Current Smoker: 5.8% Pack years, mean (SD): NR <b>Clinic</b>  Numbers + a set of slides illustrating LDCT scans of 250 people in random order that displayed the number of normal scans, false-positive lung nodules, cancers found leading to a life saved, and cancers found leading to death despite treatment  N = 83  <b>Age</b> Mean (SD): 61.8 (8.1) <b>Gender</b> Female: 51.8% <b>Race/Ethnicity</b> White: 92.8% Hispanic: 4.8% <b>Education</b> High school or greater: 73%	<b>Knowledge of screening benefits &amp; harms (0 days)</b> Author-developed questionnaire

Author, Year Risk of Bias Study Design Follow-Up Duration Trial ID Funding source	Inclusion/Exclusion Criteria	Intervention: Detailed Intervention Characteristics  Participants Randomized Demographics Setting	Comparator(s): Detailed Comparator Characteristics  Participants Randomized Demographics Setting	Eligible Outcomes & Measures Reported (Time Points)
			<b>Insurance Status:</b> NR <b>Smoking Status</b> Current Smoker: 7.1% Pack years, mean (SD): NR <b>Clinic</b>	
Hoffman, 2018 <sup>40</sup>  Moderate  Pre-post  0 days  NCT02282969  Patient-Centered Outcomes Research Institute (PCORI) Award (CER-1306-03385) and The University of Texas MD Anderson Cancer Center Duncan Family Institute for Cancer Prevention and Risk Assessment, National Cancer Institute of the National Institutes of Health under Award Number R25CA057730, and by a Cancer Center Support Grant CA016672	<b>Inclusion:</b> English-speaking men and women aged 55 to 80 years with no history of lung cancer, who were current smokers or had quit within the past 15 years  <b>Exclusion:</b> NR	A patient decision aid video, "Lung Cancer Screening: Is It Right for Me?" viewed online  N = 31  <b>Age</b> Mean (SD): 61.5 (4.7) <b>Gender</b> Female: 50% <b>Race/Ethnicity</b> Black or African American: 30% White: 63.3% Hispanic: 3.3% <b>Education</b> High school or greater: 100% <b>Insurance Status</b> Private: 36.7% Public: 46.6% None: NR <b>Smoking Status</b> Current Smoker: 60.7% Pack years, mean (SD): 30.4 (18.9) <b>Clinic</b>	NA	<b>Decisional conflict/regret (0 days)</b> DCS – Values Clarity subscale  <b>Participant need for additional information (0 days)</b> 10-point VAS – "How informed about lung cancer screening?"  <b>Knowledge of screening benefits &amp; harms (0 days)</b> 12-item measure
Lau, 2015 <sup>39</sup>  Low  Pre-post	<b>Inclusion:</b> Current or former smokers, aged 45–80, with no previous history of lung cancer and no chest CT in the previous year at the time of recruitment	www.shouldiscreen.com (initial development study)  N = 60  <b>Age</b>	NA	<b>Concordance of decision (0 days)</b> Ottawa Decision Support Framework

Author, Year Risk of Bias Study Design Follow-Up Duration Trial ID Funding source	Inclusion/Exclusion Criteria	Intervention: Detailed Intervention Characteristics  Participants Randomized Demographics Setting	Comparator(s): Detailed Comparator Characteristics  Participants Randomized Demographics Setting	Eligible Outcomes & Measures Reported (Time Points)
0 days  NR  Elizabeth A. Crary Fund of the University of Michigan Comprehensive Cancer Center	<b>Exclusion:</b> NR	Mean (SD): 60.6 (7.3) <b>Gender</b> Female: 50% <b>Race/Ethnicity</b> Black or African American: 12% White: 88% <b>Education</b> High school or greater: 98% <b>Insurance Status:</b> NR <b>Smoking Status</b> Current Smoker: 27% Pack years, mean (SD): 24.1 (23.9) <b>Community</b>		<b>Decisional conflict/regret (0 days)</b> DCS  <b>Knowledge of screening benefits &amp; harms (0 days)</b> Ottawa Decision Support Framework
Lau, 2021 <sup>38</sup>  Low  Pre-post  6 months  NR  The National Cancer Institute under award no. P30CA046592; the University of Michigan Rogel Cancer Center, Cancer Control and Population Sciences Research Program: Outreach and Health Disparities Grant; Career Development Award from Veterans Affairs' Health Services Research and Development Service (CDA 16- 151)	<b>Inclusion:</b> African American community members from the east side of Detroit, MI, current/former smokers, aged 45-77 years, did not have a history of lung cancer, and did not participate in any prior testing of the tool  <b>Exclusion:</b> NR	A modified version of shouldscreen.com, NA a web-based decision aid, was used to include the following: basic information about low-dose computed tomography screening, education about lung cancer risk factors, and a lung cancer risk calculator that computes a personalized risk based on the PLCOm2012 model  N = 74  <b>Age</b> Mean (SD): 62.7 (6.8) <b>Gender</b> Female: 48.6% <b>Race/Ethnicity</b> Black or African American: 100% <b>Education</b> High school or greater: 80.9% <b>Insurance Status:</b> NR <b>Smoking Status</b> Current Smoker: 68.9% Pack years, mean (SD): NR		<b>Concordance of decision (0 days)</b> Determined by the first question from the DCS: Which option do you prefer? A) I prefer to screen; B) I prefer not to screen; C) Unsure  <b>Decisional conflict/regret (0 days)</b> DCS  <b>Knowledge of screening benefits &amp; harms (0 days)</b> Derived from the 10-item Ottawa Decision Support Framework

Author, Year Risk of Bias Study Design Follow-Up Duration Trial ID Funding source	Inclusion/Exclusion Criteria	Intervention: Detailed Intervention Characteristics  Participants Randomized Demographics Setting	Comparator(s): Detailed Comparator Characteristics  Participants Randomized Demographics Setting	Eligible Outcomes & Measures Reported (Time Points)
Reuland, 2018 <sup>47</sup>  Low  Pre-post  3 months  NCT03077230  Grant from NCI (P30-CA16086) to the Lineberger Comprehensive Cancer Center, and the Cancer Prevention and Control Intervention Research, an initiative of the University Cancer Research Fund and the UNC Lineberger Comprehensive Cancer Center, the North Carolina Translational and Clinical Sciences Institute at the University of North Carolina (Grant No. 1UL1TR001111; UNC IRB#s 14–1813 and 14–2012)	<b>Inclusion:</b> Active patients at an academic internal medicine practice ages 55–80 who were current or former smokers  <b>Exclusion:</b> Patients with lung cancer, cancer treatment with chemotherapy or radiation within 18 months; recent hemoptysis or unexplained weight loss, or any chest CT within 18 months; those who clearly did not meet USPSTF smoking history requirements; & those deemed inappropriate for screening based on comorbidities	SAILS Decision Aid ( <a href="https://vimeo.com/192026567/77541728">https://vimeo.com/192026567/77541728</a> ) - Participants viewed the 6-min video at the clinic on a tablet computer  N = 50  <b>Age</b> Mean (SD): 63 (NR) <b>Gender</b> Female: 48% <b>Race/Ethnicity</b> Black or African American: 30% White: 58% <b>Education</b> High school or greater: 50% <b>Insurance Status</b> Private: 28% Public: 38% None: 8 % <b>Smoking Status</b> Current Smoker: 46% Pack years, mean (SD): 52 (NR) <b>Clinic</b>	NA	<b>Receipt of lung cancer screening (3 mo)</b> Count  <b>Receipt of additional tests/procedures for identified findings (3 mo)</b> Count  <b>Knowledge of screening benefits &amp; harms (0 days)</b> Author-developed questionnaire
Robichaux, 2023 <sup>48</sup>  Low  RCT  6 months  NR  National Institutes of Health's National Heart, Lung, and Blood Institute grant T32 HL007741 23	<b>Inclusion:</b> Age 50-80 years old with current or past commercial tobacco smoking documented in the electronic health record  <b>Exclusion:</b> Received a CT (low dose or otherwise) of the chest in the last 12 months	All participants were mailed a letter from the clinic indicating they may be eligible for a new health service along with instructions for scheduling an appointment, a clinic-logo branded facemask, and a LCS brochure. Posts were also made on existing social media accounts for the clinic about LCS. Patients in the intensive outreach group also receiving a follow-up text message and a second mailing that contained a bundle of traditional medicine and a story book about traditional tobacco that had been developed by the Great Lakes Inter-Tribal Council	All participants were mailed a letter from the clinic indicating they may be eligible for a new health service along with instructions for scheduling an appointment, a clinic-logo branded facemask, and a LCS brochure. Posts were also made on existing social media accounts for the clinic about LCS	<b>Receipt of lung cancer screening (6 mo)</b> Count of scans ordered and completed



Author, Year Risk of Bias Study Design Follow-Up Duration Trial ID Funding source	Inclusion/Exclusion Criteria	Intervention: Detailed Intervention Characteristics  Participants Randomized Demographics Setting	Comparator(s): Detailed Comparator Characteristics  Participants Randomized Demographics Setting	Eligible Outcomes & Measures Reported (Time Points)
(CR), the National Center for Advancing Translational Science grant UL1TR002494 (AB), and the University of Minnesota Program in Health Disparities Research		N = 234  <b>Age</b> Mean (SD): 61.3 (7.6) Median (IQR): 60 (44, 79) <b>Gender</b> Female: 57.3% <b>Race/Ethnicity</b> Native American or Alaska Native: 100% <b>Education: NR</b> <b>Insurance Status</b> Private: 0% Public: 70.5% None: NR <b>Smoking Status</b> Current Smoker: 62.4% Pack years, mean (SD): NR <b>Locality</b> Rural: 3% <b>Clinic</b>	N = 235  <b>Age</b> Mean (SD): 60.5 (7.2) Median (IQR): 59 (50, 78) <b>Gender</b> Female: 57.4% <b>Race/Ethnicity</b> Native American or Alaska Native: 100% <b>Education: NR</b> <b>Insurance Status</b> Private: 0% Public: 71.1% None: NR <b>Smoking Status</b> Current Smoker: 62.6% Pack years, mean (SD): NR <b>Locality</b> Rural: 2.5% <b>Clinic</b>	
Sharma, 2018 <sup>49</sup>  High  RCT  4 months  NR  A fellowship by the Cancer Prevention and Research Institute of Texas grant award, RP170259; and by the MD Anderson Cancer Center	<b>Inclusion:</b> Callers to the New York State Smokers Quitline (NYSSQL) who resided in New York state but outside of Erie and Niagara counties, current/former smokers, ages of 55-79, had a smoking history of at least 30-pack-years or quit smoking within the past 15 years, agreed to be re-contacted for a 4-month follow-up survey, and able to communicate in English	A brochure about LCS with a tear-off feature to promote contact with their health care provider, along with in-depth messaging regarding LCS over the telephone from quit line staff  N = 500  <b>Age</b> Mean (SD): NR (6.3) Median (IQR): 62 (NR) <b>Gender</b> Female: 54.2% <b>Race/Ethnicity</b>	The same brochure about LCS with a tear-off feature to promote contact with their health care provider  N = 500  <b>Age</b> Mean (SD): NR (5.6) Median (IQR): 61 (NR) <b>Gender</b> Female: 53.2%	<b>Receipt of lung cancer screening (4 mo)</b> Count

Author, Year Risk of Bias Study Design Follow-Up Duration Trial ID Funding source	Inclusion/Exclusion Criteria	Intervention: Detailed Intervention Characteristics  Participants Randomized Demographics Setting	Comparator(s): Detailed Comparator Characteristics  Participants Randomized Demographics Setting	Eligible Outcomes & Measures Reported (Time Points)
Support Grant, CA016672, funded by the National Cancer Institute	<b>Exclusion:</b> NR	Black or African American: 12% White: 67.6% Hispanic: 7.4% <b>Education:</b> NR <b>Insurance Status</b> Private: 17.4% Public: 77.8% None: NR <b>Smoking Status</b> Current Smoker: 72.2% Pack years, median (SD): 45.0 (20.1) <b>Community</b>	<b>Race/Ethnicity</b> Black or African American: 12% White: 68.8% Hispanic: 5.2% <b>Education:</b> NR <b>Insurance Status</b> Private: 18.4% Public: 72.2% None: NR <b>Smoking Status</b> Current Smoker: 72.2% Pack years, median (SD): 45.0 (21.4) <b>Community</b>	
Strong, 2020 <sup>43</sup>  Low  Pre-post  0 days  NR  NR	<b>Inclusion:</b> Adults living in the Commonwealth of Virginia, ages of 55-77, current smokers or former smokers who quit in the past 15 years     <b>Exclusion:</b> People who were never smokers, underwent lung cancer screening with LDCT, or had been diagnosed and/or treated for lung cancer	A Youtube educational video on lung cancer screening. Participants engaged in a single independent viewing.  N = 31  <b>Age</b> Mean (SD): 60.9 (NR) Median (IQR): 59 (NR) <b>Gender</b> Female: 61.3% <b>Race/Ethnicity</b> Black or African American: 3.2% White: 93.5% <b>Education</b> High school or greater: 100% <b>Insurance Status</b> Private: NR Public: 35.5% None: NR <b>Smoking Status</b> Current Smoker: 35.5% Pack years, mean (SD): NR	NA	<b>Knowledge of screening benefits &amp; harms (0 days)</b> LCS-12

Author, Year Risk of Bias Study Design Follow-Up Duration Trial ID Funding source	Inclusion/Exclusion Criteria	Intervention: Detailed Intervention Characteristics  Participants Randomized Demographics Setting Community	Comparator(s): Detailed Comparator Characteristics  Participants Randomized Demographics Setting	Eligible Outcomes & Measures Reported (Time Points)
<p>Stutts, 2020<sup>44</sup></p> <p>Moderate</p> <p>Pre-post</p> <p>0 days</p> <p>NR</p> <p>Grant from the National Institutes of Health (R21CA139371) as well as assistance from the Behavioral and Community-Based Research Shared Resource Facility of the University of Kentucky Markey Cancer Center (P30CA177558)</p>	<p><b>Inclusion:</b> English-speaking individuals 45 years of age or older who were former or current smokers with at least a 20 pack-year history and without a history of lung cancer</p> <p><b>Exclusion:</b> NR</p>	<p>A brief educational narrative coupled with an exercise on decisional regret administered through a website</p> <p>N = 210</p> <p><b>Age</b> Mean (SD): 61.7 (8.46)</p> <p><b>Gender</b> Female: 52%</p> <p><b>Race/Ethnicity</b> Black or African American: 24% White: 46% Hispanic: 28%</p> <p><b>Education</b> High school or greater: 88%</p> <p><b>Insurance Status</b> Private: 67% Public: 59% None: NR</p> <p><b>Smoking Status</b> Current Smoker: NR Pack years, mean (SD): 40.0 (20.1)</p> <p><b>Community</b></p>	<p>NA</p>	<p><b>Decisional conflict/regret (0 days)</b> Modified DCS – LL Overall (stratified by age, race/ethnicity, SES/education, &amp; current smoking status)</p> <p><b>Participant need for additional information (0 days)</b> Modified DCS – LL Informed subscale</p>

Author, Year Risk of Bias Study Design Follow-Up Duration Trial ID Funding source	Inclusion/Exclusion Criteria	Intervention: Detailed Intervention Characteristics  Participants Randomized Demographics Setting	Comparator(s): Detailed Comparator Characteristics  Participants Randomized Demographics Setting	Eligible Outcomes & Measures Reported (Time Points)
Volk, 2014 <sup>42</sup>  Moderate  Pre-post  0 days  NR  NR	<b>Inclusion:</b> Patients from a tobacco treatment program at a large cancer center who had no history of lung cancer  <b>Exclusion:</b> History of lung cancer	A 6-minute video "Lung Cancer Screening: Is It Right for Me?" intended to be used in the primary care setting.  N = 52  <b>Age</b> Mean (SD): 58.5 (NR) <b>Gender</b> Female: 65.4% <b>Race/Ethnicity</b> Black or African American: 19.2% White: 74.8% Hispanic: 6% <b>Education:</b> NR <b>Insurance Status:</b> NR <b>Smoking Status</b> Current Smoker: 44.2% Pack years, mean (SD): 30.0 (NR) <b>Clinic</b>	NA	<b>Quality of communication (0 days)</b> Author-developed questionnaire  <b>Knowledge of screening benefits &amp; harms (0 days)</b> Author-developed knowledge questionnaire

Author, Year Risk of Bias Study Design Follow-Up Duration Trial ID Funding source	Inclusion/Exclusion Criteria	Intervention: Detailed Intervention Characteristics  Participants Randomized Demographics Setting	Comparator(s): Detailed Comparator Characteristics  Participants Randomized Demographics Setting	Eligible Outcomes & Measures Reported (Time Points)
Volk, 2020 <sup>41</sup>  Low  RCT  6 months  NCT02286713  Award CER-1306-03385 from the Patient-Centered Outcomes Research Institute; award P30CA016672 from the National Institutes of Health, National Cancer	<b>Inclusion:</b> Tobacco quit line clients from 13 states (ages 55-77 years) who reported a 30-plus pack-year smoking history  <b>Exclusion:</b> Clients with a history of lung cancer	A 9.5-minute narrated video, Lung Cancer Screening: Is It Right for Me? It included information about eligibility and smoking history, lung cancer epidemiology and risk factors, undergoing a CT scan, depictions of the magnitude of mortality reduction, harms, and smoking cessation  N = 259  <b>Age:</b> NR <b>Gender</b> Female: 60.6% <b>Race/Ethnicity</b> Black or African American: 23.9% White: 71.4% Native Hawaiian or Other Pacific Islander: 0% Hispanic: 2.7% <b>Education</b> High school or greater: 84.2% <b>Insurance Status</b> Private: NR Public: NR None: 7.7% <b>Smoking Status</b> Current Smoker: NR Pack years, mean (SD): 47.0 (NR) <b>Community</b>	Standard education  N = 257  <b>Age:</b> NR <b>Gender</b> Female: 63.4% <b>Race/Ethnicity</b> Black or African American: 29.6% White: 68.9% Native Hawaiian or Other Pacific Islander: 0.4% Hispanic: 0.4% <b>Education</b> High school or greater: 86.1% <b>Insurance Status</b> Private: NR Public: NR None: 7.7% <b>Smoking Status</b> Current Smoker: NR Pack years, mean (SD): 49.0 (NR) <b>Community</b>	<b>Receipt of lung cancer screening (6 mo)</b> Count  <b>Quality of communication (1 wk)</b> Author-developed questionnaire adapted from the Ottawa Acceptability Measure  <b>Decisional conflict/regret (1 wk)</b> DCS – Informed & Values Clarity subscales  <b>Knowledge of screening benefits &amp; harms (6 mo)</b> Questionnaire developed by Lowenstein et al.
Webster, 2023 <sup>37</sup>  High  RCT  4 months	<b>Inclusion:</b> 50–80 years old, a 20+ pack-year smoking history, English-speaking, never screened or screened $\geq 12$ months ago for lung cancer, no history of lung cancer, no household members enrolled in the study, and	Patients were provided with a link to shouldscreen.com (via text, email or mail) when they contacted the quit line for smoking cessation  N = 146  <b>Age</b>	Patients were provided with a print LCS brochure (via mail or email) when they contacted the quit line for smoking cessation  N = 152  <b>Age</b>	<b>Receipt of lung cancer screening (4 mo)</b> Count  <b>Quality of communication (NR)</b> Author-developed measure

Author, Year Risk of Bias Study Design Follow-Up Duration Trial ID Funding source	Inclusion/Exclusion Criteria	Intervention: Detailed Intervention Characteristics  Participants Randomized Demographics Setting	Comparator(s): Detailed Comparator Characteristics  Participants Randomized Demographics Setting	Eligible Outcomes & Measures Reported (Time Points)
NCT05046951  American Lung Association, #686977	willing to be contacted by research staff about trial participation  <b>Exclusion:</b> NR	Mean (SD): 61.6 (6.8) <b>Gender</b> Female: 64.4% <b>Race/Ethnicity</b> Black or African American: 52.1% White: 40.4% Hispanic: 1.4% <b>Education</b> High school or greater: 78.7% <b>Insurance Status</b> Private: 30.9% Public: 55.4% None: 1.4% <b>Smoking Status</b> Current Smoker: 100% Pack years, mean (SD): 64.0 (37.4) <b>Community</b>	Mean (SD): 61.8 (5.8) <b>Gender</b> Female: 67.8% <b>Race/Ethnicity</b> Black or African American: 56.3% White: 41.7% Hispanic: 2% <b>Education</b> High school or greater: 75% <b>Insurance Status</b> Private: 22.1% Public: 52.3% None: 7.4% <b>Smoking Status</b> Current Smoker: 100% Pack years, mean (SD): 63.0 (34.7) <b>Community</b>	<b>Decisional conflict/ regret (1 mo, 4 mo)</b> Health Care Decisions scale  <b>Satisfaction with decision (1 mo, 4 mo)</b> 5-point Likert scale  <b>Participant need for additional information (NR)</b> Author-developed measure  <b>Distress/anxiety (NR)</b> Author-developed measure  <b>Knowledge of screening benefits &amp; harms (1 mo, 4 mo)</b> Author-developed measure with 9 true/false questions

**Abbreviations.** CT=computed tomography; DCS=Decisional Conflict Scale; DCS-LL=Decisional Conflict Scale – Low Literacy; IQR=interquartile range; LCS=lung cancer screening; LDCT=low-dose computed tomography; Mo=month; NA=not applicable; NCI=National Cancer Institute; NR=not reported; RCT=randomized controlled trial; SD=standard deviation; SES=socioeconomic status; UNC=University of North Carolina; USPSTF=United States Preventative Services Task Force; VAS=visual analog scale; Wk=week.

**Appendix Table 8. Detailed Results for Studies Evaluating Tools for Patient Education to Generate SDM**

Author, Year Study Design Risk of Bias	Measurement Instrument	Intervention	Comparator	Results
<i>Quality of Communication</i>				
Carter-Harris, 2020 <sup>46</sup> RCT Some concerns	Author-developed questionnaire	<u>Satisfaction n (%)</u> Not at all satisfied: 0 (0) Somewhat satisfied: 1 (3) Satisfied: 7 (23) Very satisfied: 22 (73)  <u>Preparedness n (%)</u> Somewhat prepared: 4 (13) Prepared: 10 (33) Very prepared: 16 (53)	<u>Satisfaction n (%)</u> Not at all satisfied: 1 (3) Somewhat satisfied: 4 (14) Satisfied: 16 (55) Very satisfied: 8 (28)  <u>Preparedness n (%)</u> Somewhat prepared: 6 (21) Prepared: 6 (21) Very prepared: 17 (59)	"Satisfaction with the LungTalk intervention was significantly higher than with the nontailored lung screening information sheet. Individuals in both groups felt "prepared" or "very prepared" to have a discussion with their clinician about lung screening, with no significant differences between the 2 intervention groups on preparedness ( $p=0.52$ )."
Volk, 2014 <sup>42</sup> Pre-post Moderate	Author-developed questionnaire	"More than 94% of patients viewed the entire video, would recommend it to others, felt it held their interest, and wanted to view similar videos about health care decisions. Ratings of the amount of information in the aid, length, and clarity were highly favorable. Most patients (78.8%) believed that people would be more interested in screening after viewing the decision aid."	NA	--
Volk, 2020 <sup>41</sup> RCT Low	Author-developed questionnaire adapted from the Ottawa Acceptability Measure	"Only 10 of 228 participants (4.4%) felt that the PDA was too long, whereas 53 of 228 (23.2%) wanted more information. In addition, 198 of 227 participants (87.2%) indicated that the PDA included enough information to help a person make a decision about lung cancer screening."	--	NR
Webster, 2023 <sup>37</sup> RCT High	Author-developed questionnaire	"Did you find that any parts of the materials were confusing or difficult to understand?" n (%) A little bit: 34 (29.8) Moderately: 4 (3.5) Extremely: 0 (0)  "Did the materials prepare you to talk to your doctor about what matters most to you?" n (%) Not at all: 9 (5)	"Did you find that any parts of the materials were confusing or difficult to understand?" n (%) A little bit: 19 (21.1) Moderately: 4 (4.4) Extremely: 0 (0)  "Did the materials prepare you to talk to your doctor about what matters most to you?" n (%) Not at all: 10 (4.4)	"No significant group differences"



Author, Year Study Design Risk of Bias	Measurement Instrument	Intervention	Comparator	Results
<i>Decisional Conflict/Regret</i>				
Hoffman, 2018 <sup>40</sup> Pre-post Moderate	DCS - Values Clarity Subscale (0="feels extremely clear about personal values" to 100="feels extremely unclear about personal values")	Baseline mean (SD): NR Follow-up: 3.9 (NR)	NA	NR
Lau, 2015 <sup>39</sup> Pre-post Low	DCS (0=no decisional conflict to 100=extremely high decisional conflict)	Baseline mean (SD): 46.3 (29.7) Follow-up: 15.1 (25.8)	NA	P < 0.001
Lau, 2021 <sup>38</sup> Pre-post Low	DCS (0=no decisional conflict to 100=extremely high decisional conflict)	Baseline mean (SD): 17.5 (11.4) Follow-up: 8.9 (9.6)	NA	8.6 P < 0.001
Studts, 2020 <sup>44</sup> Pre-post Moderate	Modified DCS-LL Overall	Baseline mean (SD): 47.6 (27.2) Follow-up: 18.3 (22.2)	NA	29.3 P < 0.0001
Volk, 2020 <sup>41</sup> RCT Low	DCS: Informed Subscale (0=feels extremely informed to 100=feels extremely uninformed)	Baseline mean (95% CI): NR Follow-up: 27.1 (23.8, 30.4)	Baseline mean (95% CI): NR 42.1 (38.1, 46.0)	-14.9 (-20.1, -9.7) P < 0.001
	DCS - Values Clarity Subscale (0="feels extremely clear about personal values" to 100="feels extremely unclear about personal values")	Baseline mean (95% CI): NR Follow-up: 17.6 (14.2, 21.0)	Baseline mean (95% CI): NR Follow-up: 31.7 (27.4, 35.9)	-14.1 (-19.5, -8.7) P < 0.001
Webster, 2023 <sup>37</sup> RCT High	Satisfaction with Decisions scale (1=low satisfaction to 5=high satisfaction)	Baseline mean (SD): 2.9 (1.1) 1 mo follow-up: 3.2 (1.0) 4 mo follow-up: 3.2 (0.9)	Baseline mean (SD): 2.7 (1.1) 1 mo follow-up: 3.2 (1.1) 4 mo follow-up: 3.2 (1.1)	"No significant group differences"
<i>Concordance of Decision With Patients' Values &amp; Preferences</i>				
Lau, 2015 <sup>39</sup> Pre-post Low	Ottawa Decision Support Framework – Participants who preferred to be screened & were eligible for screening + participants who did not wish to be screened & not eligible for screening	Baseline n (%): 14 (23.7) Follow-up: 35 (59.3)	NA	P < 0.001
Lau, 2021 <sup>38</sup> Pre-post Low	Determined by the first question from the Decisional Conflict Scale: Which option do you prefer? A) I	Baseline mean (SD): 0.21 (0.41) Follow-up: 0.33 (0.47)	NA	0.12 P < 0.016

Author, Year Study Design Risk of Bias	Measurement Instrument	Intervention	Comparator	Results
	prefer to screen; B) I prefer not to screen; C) Unsure			
<i>Distress/Anxiety</i>				
Webster, 2023 <sup>37</sup> RCT High	Author-developed question: "Did the materials make you nervous or fearful about either LCS or about lung cancer?"	N (%) Only a little: 26 (22.8) Somewhat: 18 (15.8) Very much: 18 (15.8)	N (%) Only a little: 28 (31.1) Somewhat: 9 (10) Very much: 10 (11.1)	"No significant group differences"
<i>Receipt of Lung Cancer Screening</i>				
Reuland, 2018 <sup>47</sup> Pre-post Low	Count (%) of recipients	10/50 (20)	NA	NR
Robichaux, 2023 <sup>48</sup> RCT Low	Count (%) of scans ordered and completed	18/234 (7.7)	22/235 (9.4)	P = 0.63
Sharma, 2018 <sup>49</sup> RCT High	Count (%) of participants who received LCS	23/500 (4.6)	18/500 (3.6)	P = 0.68
Volk, 2020 <sup>41</sup> RCT Low	Count (%) of participants who received LCS	57/259 (22)	68/257 (26.5)	NR
Webster, 2023 <sup>37</sup> RCT High	Completed LDCT	11.0%	11.2%	P > 0.8
<i>Receipt of Additional Tests/Procedures for Identified Findings</i>				
Reuland, 2018 <sup>47</sup> Pre-post Low	Count of recipients	"One [LungRADS] was category 4a... [and] the recommended 3-month follow-up scan showed resolution of the nodule."	NA	NR
<i>Knowledge of Screening Benefits and Harms</i>				
Carter-Harris, 2020 <sup>46</sup> RCT Some concerns	Knowledge of Lung Cancer and Lung Cancer Screening scale (higher score=higher knowledge)	Baseline mean (SD): 3.9 (1.5) Follow-up: 6.3 (1.3) Within-group difference: 2.4 (1.5), P < 0.01	Baseline mean (SD): 3.7 (1.5) Follow-up: 4.8 (1.3) Within-group difference: 1.1 (1.2), P < 0.01	NR
Clark, 2022 <sup>45</sup> RCT Some concerns	Author-developed questionnaire (5 true/false questions & 1 multiple choice question)	Baseline mean (SD): NR Follow-up: 5.3 (NR) Difference: 2.8	Baseline mean (SD): NR Follow-up: 5.1 (NR) Difference: 2.6	NR

Author, Year Study Design Risk of Bias	Measurement Instrument	Intervention	Comparator	Results
		N (%) of participants who answered questions correctly 164/173 (94.8)	N (%) of participants who answered questions correctly 129/175 (73.5)	95% CI: -28.4, -13.8% P < 0.01
Crothers, 2016 <sup>23</sup> Pre-post Moderate	Author-developed questionnaire (20 true/false questions)	--	NA	"Most notable was improvement in knowledge about possible harms associated with screening: the proportion answering these items correctly increased from 69 to 93% overall (P = 0.002)... However, knowledge of benefits did not change as much. More participants endorsed that screening lowered one's chances of "getting lung cancer" at the end of the focus group discussions, increasing from 25% before to 50% after focus group attendance."
Fraenkel, 2015 <sup>50</sup> RCT High	Author-developed questionnaire (3 multiple choice questions)	Numbers only  Within-group difference in model-estimated mean (SE): 0.7 (0.01)	Numbers + icon array  Within-group difference in model-estimated mean (SE): 1.2 (0.01)  Numbers + slides  Within-group difference in model-estimated mean (SE): 1.0 (0.01)	"Average knowledge differed between the 3 formats (overall difference between means, P = 0.001). Knowledge was greater in the numbers + icon array and the numbers + experience formats when compared with the numbers-only format (difference between means [95% CI]= 0.5 [0.2–0.7] and 0.3 [0.01–0.6], respectively)."
Hoffman, 2018 <sup>40</sup> Pre-post Moderate	LCS-12 (12 true/false questions; overall maximum score=12)	Baseline mean (SD): 5.7 (NR) Follow-up: 9.6 (NR)	NA	3.9 (2.9) P < 0.001
Lau, 2015 <sup>39</sup> Pre-post Low	Ottawa Decision Support Framework (overall maximum score=14)	Baseline mean (SD): 7.5 (1.9) Follow-up: 10.9 (2.2)	NA	NR
Lau, 2021 <sup>38</sup> Pre-post Low	Derived from the 10-item Ottawa Decision Support Framework (overall maximum score=13)	Baseline mean (SD): 5.7 (1.9) Follow-up: 7.1 (2.3)	NA	1.4 P < 0.001
Reuland, 2018 <sup>47</sup> Pre-post Low	9-item author-developed questionnaire (overall maximum score=9)	Baseline mean (SD): 2.6 (NR) Follow-up: 5.5 (NR)	NA	2.8 (95% CI 2.1, 2.6) P < 0.001
Strong, 2020 <sup>43</sup> Pre-post Low	LCS-12 (12 true/false questions; overall maximum score=12)	Baseline mean (SD): 5.3 (2.9) Follow-up: 8.2 (2.0)	NA	-2.9 (96% CI -3.9, -1.9) t-test score: -5.96

Author, Year Study Design Risk of Bias	Measurement Instrument	Intervention	Comparator	Results
Volk, 2014 <sup>42</sup> Pre-post Moderate	11-item author-developed knowledge measure	Baseline mean (SD) % of correct responses: 25.5% (20.7) Follow-up: 74.8% (20.2)	NA	Authors do not report an overall p-value, but do report p-values at the individual question level ( $p < 0.01$ for each question)
Volk, 2020 <sup>41</sup> RCT Low	16-item questionnaire developed by Lowenstein et al.	Mean (95% CI) no. of correct responses: 49.9 (47.5, 52.3)	Mean (95% CI) no. of correct responses: 40.0 (37.6, 42.4)	9.9 (95% CI 6.5, 13.3) $P < 0.001$
Webster, 2023 <sup>37</sup> RCT High	Author-developed questionnaire (based on literature; 9 true/false questions)	Baseline mean (SD) percent correct: 62.7 (14.3) 1 mo follow-up: 67.0 (15.0) 4 mo follow-up: 66.4 (12.9)	Baseline mean (SD) percent correct: 63.4 (14.3) 1 mo follow-up: 64.5 (14.4) 4 mo follow-up: 65.7 (12.4)	NR
<i>Satisfaction With Decision</i>				
Webster, 2023 <sup>37</sup> RCT High	5-point Likert – “To what extent is this statement true for you at this time: ‘I am satisfied with my decision about whether to undergo screening or not.’”	<p>“Strongly agree or agree”</p> <p>Baseline n (%): NR 1 mo follow-up: 110 (93.2) 4 mo follow-up: 99 (90.8)</p> <p>“Neither agree/disagree, disagree, or strongly disagree”</p> <p>Baseline n (%): NR 1 mo follow-up: 8 (6.8) 4 mo follow-up: 7 (6.6)</p>	<p>“Strongly agree or agree”</p> <p>Baseline n (%): NR 1 mo follow-up: 96 (85.7) 4 mo follow-up: 93 (86.1)</p> <p>“Neither agree/disagree, disagree, or strongly disagree”</p> <p>Baseline n (%): NR 1 mo follow-up: 16 (14.3) 4 mo follow-up: 15 (13.9)</p>	$p < 0.10$ at 4 months print vs. web
<i>Participant Need for Additional Information</i>				
Hoffman, 2018 <sup>40</sup> Pre-post Moderate	10-point VAS, “How informed do you feel about lung cancer screening?”	Baseline mean (SD): NR Follow-up: 8.7 (1.6)	NA	NR
Studts, 2020 <sup>44</sup> Pre-post Moderate	Modified DCS-LL Informed (2 questions; lower scores = more informed)	Baseline mean (SD): 52.2 (30.5) Follow-up: 16.9 (24.5)	NA	35.3 $P < 0.0001$
Webster, 2023 <sup>37</sup> RCT High	Count (%) of participants who answered the question, “Would you say that the materials contained...” with the response ‘too little information’	5 (5.6)	6 (5.3)	“No significant group differences”

Notes. \*Percentages may not add to 100% due to rounding.

Abbreviations. CI=confidence interval; DCS=Decisional Conflict Scale; DCS-LL=Decisional Conflict Scale – Low Literacy; LCS=lung cancer screening; LDCT=low-dose computed tomography; Lung-RADS=Lung CT Screening Reporting & Data System; NA=not applicable; NR=not reported; PDA=patient decision aid; RCT=randomized controlled trial; SD=standard deviation; SE=standard error; VAS=visual analog scale.

## OTHER STUDIES EVALUATING SDM FOR LUNG CANCER SCREENING

**Appendix Table 9. Detailed Characteristics for Other Studies Evaluating SDM for Lung Cancer**

Author, Year Risk of Bias Study Design Follow-Up Duration Trial ID Funding Source	Inclusion/Exclusion Criteria	Intervention: Detailed Intervention Characteristics  Participants Randomized Demographics Setting	Comparator(s): Detailed Comparator Characteristics  Participants Randomized Demographics Setting	Eligible Outcomes & Measures Reported (Time Points)
Goodwin, 2020 <sup>54</sup>  High  Cohort  3 months  NR  Cancer Prevention and Treatment Institute of Texas grant RP160674	<b>Inclusion:</b> A 20% random sample of national Medicare data to determine enrollees aged 55 to 80 years who had a separate visit for SDM (Current Procedural Terminology [CPT] code G0296) from January 1, 2016, to September 30, 2018, with complete insurance enrollment 1 year prior  <b>Exclusion:</b> NR	SDM conversation (with different types of clinician specialties (family practice, internal medicine, pulmonary radiologist, nurse practitioner, physician assistant, other)  N = 11,699  <b>Age:</b> NR <b>Gender</b> Female: 46.9% <b>Race/Ethnicity</b> Black or African American: 6% White: 90.9% Hispanic: 2% <b>Education:</b> NR <b>Insurance Status</b> Private: NR Public: 78.5% None: NR <b>Smoking Status:</b> NR <b>Clinic</b>	LDCT scan only  N = 7522  <b>Age:</b> NR <b>Gender</b> Female: 48.4% <b>Race/Ethnicity</b> Black or African American: 6% White: 88.4% Hispanic: 2% <b>Education:</b> NR <b>Insurance Status</b> Private: NR Public: 79.3% None: NR <b>Smoking Status:</b> NR <b>Clinic</b>	<b>Receipt of lung cancer screening (3 mo)</b> Count (%) (stratified by race/ethnicity & clinical setting)

Author, Year Risk of Bias Study Design Follow-Up Duration Trial ID Funding Source	Inclusion/Exclusion Criteria	Intervention: Detailed Intervention Characteristics  Participants Randomized Demographics Setting	Comparator(s): Detailed Comparator Characteristics  Participants Randomized Demographics Setting	Eligible Outcomes & Measures Reported (Time Points)
Studts, 2023 <sup>53</sup>  Moderate  Cohort  15 months  NR  NR	<b>Inclusion:</b> "The extracted Colorado All Payer Claims Database (APCD) dataset included all health claims, procedural codes, and dates of services from January 1, 2012, to December 31, 2018, for individuals with claims for a LCS specific low-dose computed tomography scan (LDCT), with the use of International Classification of Diseases (ICD) codes S8032 and G0297... This analysis was limited to individuals who had an index LDCT prior to October 1, 2017, with a complete 15 months of follow-up time available in the Colorado APCD dataset. Individuals with a SDM claim within 90 days preceding the index LDCT, identified with an ICD code of G0296, were classified as having had a SDM consultation."  <b>Exclusion:</b> NR	Documentation of a SDM consultation (ICD code G0296)  N = 2476  <b>Age:</b> NR <b>Gender</b> Female: 45% <b>Race/Ethnicity:</b> NR <b>Education:</b> NR <b>Insurance Status</b> Private: 30% Public: 70% None: NR <b>Smoking Status:</b> NR <b>Locality</b> Rural: 3% <b>Clinic</b>	No documentation of a SDM consultation  N = 4717  <b>Age:</b> NR <b>Gender</b> Female: 48% <b>Race/Ethnicity:</b> NR <b>Education:</b> NR <b>Insurance Status</b> Private: 22% Public: 78% None: NR <b>Smoking Status:</b> NR <b>Locality</b> Rural: 8% <b>Clinic</b>	<b>Adherence to subsequent screening (15 mo)</b>  Count (%) of participants with complete follow-up who had an SDM claim

*Abbreviations.* LDCT=low-dose computed tomography; Mo=month; NR=not reported; SDM=shared decision-making..

**Appendix Table 10. Detailed Results for Included Other Studies Evaluating SDM for Lung Cancer**

Author, Year Study Design Risk of Bias	Measurement Instrument	Intervention	Comparator	Results
<i>Receipt of Lung Cancer Screening</i>				
Goodwin, 2020 <sup>54</sup> Cohort High	Count (%) of recipients	7522/11699 (64.3)	NA	NR
	Count (%) of Black/African American recipients	710/11699 (6.1)	447/7522 (5.9)	LDCT rate (95% CI): 63.0 (59.3, 66.5) OR (95% CI): 0.87 (0.72, 1.06)
	Count (%) of Hispanic recipients	229/11699 (2)	144/7522 (1.9)	LDCT rate (95% CI): 62.9 (56.3, 69.2) OR (95% CI): 0.86 (0.62, 1.20)
	Adjusted odds ratios (95% CI) for receipt of LDCT by type of clinician conducting the SDM (vs family practice)	--	--	Internal medicine: 1.18 (1.01-1.36) Pulmonary: 0.84 (0.70-1.01) Radiologist: 9.09 (4.16-19.85) Nurse practitioner: 1.70 (1.42-2.05) Physician assistant: 1.40 (1.08-1.80) Other: 1.27 (0.97-1.66)
<i>Adherence to Subsequent Screening</i>				
Studts, 2023 <sup>53</sup> Cohort Moderate	Count (%) of participants with complete 15-months follow-up who had an SDM claim	178/2476 (7)	245/4717 (5)	"Individuals with a documented SDM consultation had 25% higher odds of adherence to annual LCS than those without SDM documentation (OR, 1.25; 95% CI, 1.01-1.54)."

*Abbreviations.* LCS=lung cancer screening; LDCT=low-dose computed tomography; NA=not applicable; NR=not reported; OR=odds ratio; SDM=shared decision-making.

## STUDIES ASSESSING BARRIERS AND FACILITATORS

**Appendix Table 11. Study Characteristics and Outcomes for Included Studies Evaluating Barriers and Facilitators of SDM and LCS**

Sample Size Study Description	CFIR Domain → Construct	Barrier/Facilitator
<i>Abubaker-Sharif, 2022<sup>59</sup> (High RoB)</i>		
N=16 Physicians	Innovation → Adaptability	"...crucial to take <b>patient health literacy</b> levels into account, having meaningful conversations with patients can be challenging...explaining downstream repercussions and risk of radiation, you really need to change and <b>tailor to somebody's understanding</b> of those effects."
Qualitative interviews about SDM in general, used DCP to serve as an example decision aid to facilitate SDM	Innovation → Complexity	Suggestion that <b>tools should be available in multiple languages</b>  Understanding the <b>importance of shared decision making and it's complexity</b> (involves patient education, the elicitation of personal values, and clarification of preference, knowing participant risk to help guide conversation)  "Many interviewees felt that the <b>decision counseling process represents a standardized approach</b> to having a conversation about LCS that would help to ensure LCS information is presented and discussed with all patients."
	Inner Setting → Access to Knowledge and Information	<b>Physician knowledge:</b> increased education about LCS, more information about how to assess patient eligibility for LCS and refer eligible patients for screening services, who was responsible for contacting referred patients to schedule a screening appointment, and how patients could manage costs associated with screening.
	Inner Setting → Culture	"SDM about LCS is <b>challenging to implement in practice</b> with certain patients...it is not productive to suggest screening to some patients who have not been adherent to other cancer screening recommendations. For [receptive] patients...physicians realize that it is necessary to make time to address the need for annual screening, the safety of the screening exam, and the cost of LDCT."
	Individuals → Innovation Recipients	Perceived patient knowledge: <b>belief that patient awareness of LCS and screening guidelines is limited.</b>  Patient Barriers to the Uptake of Lung Cancer Screening: <b>patient worries and concerns</b> about undergoing LCS (eg, they may not want to know); <b>engaging current smokers is especially challenging</b> ("the fear of finding lung cancer seems to be enough to prevent smokers from undergoing screening, but not enough to motivate them to stop smoking.")
<i>Han, 2019<sup>18</sup> (Low RoB)</i>		
N=17 Patients	Individuals → Innovation Recipients	<b>Patients perceptions about personalized risk calculators</b> used in SDM tools: Disbelief of personalized cancer risk information; Uncertainty about personalized cancer risk information; Lack of influence of personalized risk information
Pre-post study of SDM decision aid, interviews conducted on content		
<i>Herbst, 2023<sup>55</sup> (Low RoB)</i>		
N=15 Clinicians/ Leadership	Outer Setting → External Pressure → Performance Measurement Pressure	" <b>Perceived pressure</b> to demonstrate the value of the LCS coordinator role"
	Inner Setting → Access to Knowledge and Information	"Participants had <b>little or no knowledge</b> of VA's whole health initiative"



Sample Size Study Description	CFIR Domain → Construct	Barrier/Facilitator
Qualitative interviews conducted to inform SDM implementation plan	Inner Setting → Available Resources	"Time constraints in primary care"
	Inner Setting → Communications	"Lack of communication about LCS goals or structure...flexibility led to confusion about how to implement elements of the LCS program, including SDM"
	Inner Setting → Culture → Recipient Centeredness	Limiting information about the harms of screening ("Clinicians...emphasized the benefits of LCS and were careful not to share information that might make patients hesitant about screening.") Perceived value of LCS limiting need for SDM ("The data supports so strongly that [LCS] is beneficial, that it doesn't seem like there's much of a decision.") "Perception that SDM is already happening"
	Inner Setting → Relative Priority	Comparison to other preventive screenings ("...unaware of SDM being recommended for other screenings; therefore, participants questioned its value for LCS.") "Insufficient priority of LCS in relation to competing demands"
	Inner Setting → Structural Characteristics → IT Infrastructure	"No systematic prompts to trigger LCS discussions"
	Individuals → Capability	"Conflation of SDM and patient education"
	Individuals → Innovation Deliverers	"Personal experiences that influence their thinking about LCS" (ie, promote screening)
	Individuals → Innovation Recipients	Patients not actively engaging in the LCS conversation ("patients generally agree to LCS")
	Individuals → Need	Patient's smoking history making LCS compulsory ("patients' smoking history as the rationale to bypass SDM and proceed directly to LCS, despite guidelines recommending SDM for all patients eligible for LCS.")
<i>Lowery, 2022<sup>56</sup> (High RoB)</i>		
N=33 Physicians	Innovation → Design	"Having to input clinical data on risk factors into the tool was seen as a significant barrier to tool use as it added more time to the visit."
Investigating 2 different implementation strategies of Decision Precision	Outer Setting → External Pressure → Performance Measurement Pressure	"Most PCPs reported needing 1 to 2 minutes to discuss LCS but frequently voiced not having even 1 to 2 minutes during a visit because of...organizational priorities (eg, performance measures)."
	Inner Setting → Available Resources	"Limited time in the clinic was perceived as a key barrier by almost all the PCPs."
	Inner Setting → Relative Priority	"Most PCPs reported needing 1 to 2 minutes to discuss LCS but frequently voiced not having even 1 to 2 minutes during a visit because of patient-specific needs that were a higher priority (eg, acute complaints) ..."
<i>Martinez, 2022<sup>57</sup> (Low RoB)</i>		
N=10/30 Providers/ Patients	Outer Setting → Local Attitudes	"...difficulties with the integration of LCS-LDCT ordering into the current EHR system noting that key variables, eg, smoking history, are often missing or inaccurate."
Qualitative interviews to understand how attitudes	Inner Setting → Available Resources	"Use of a decision aid handout would benefit providers and patients"
	Inner Setting → Structural Characteristics → IT Infrastructure	"...difficulties with the integration of LCS-LDCT ordering into the current EHR system..."

Sample Size Study Description	CFIR Domain → Construct	Barrier/Facilitator
and barriers impact effective implementation and uptake of screening	Individuals → Capability	<b>Provider difficulties with eligibility criteria:</b> "Because of the multiple criteria for LCS-LDCT, providers noted that they frequently had to take the time to look up eligibility criteria before recommending LCS-LDCT to patients."
	Individuals → Innovation Recipients	"Half of respondents felt strongly that the <b>most important factor</b> influencing their decision to do the screening was a <b>physician recommendation</b> ."
		"A family medicine provider admitted that <b>patient's "probably [did] not" understand</b> all the pros and cons of screening."
		<b>Frequency in which SDM about LSC should be attempted;</b> which patients may be most receptive to screening.
<i>Melzer, 2020<sup>60</sup> (Low RoB)</i>		
N=24 Clinicians  Qualitative interviews to examine current communication practices and barriers to SDM for LCS at facilities with established LCS programs	Innovation → Adaptability	Tailoring of information: "All clinicians agreed that <b>some degree of tailoring of information</b> was necessary but interpreted the idea of tailoring in different ways. The judgments that contributed to how clinicians tailored the communication were implicit; no clinician indicated that they ask a patient how much or what kind of information they preferred."
		Information exchange: All clinicians agreed that "adequate" information was a necessary part of the process and that <b>this information should be provided at the patient's level of health literacy</b> .
	Inner Setting → Available Resources	"Providers in all roles indicated that <b>time was a significant issue</b> , as SDM was perceived to be a lengthy process."
	Individuals → Innovation Recipients	Patient Values: Clinicians of all roles agreed that <b>ensuring a screening decision in line with a patient's values</b> is key <b>"Lack of patient engagement</b> in the process of decision making was a barrier identified by all clinician types. A large number of patients, particularly older patients, requested a firm recommendation."  "All clinicians indicated that the screening decision rests with the patient and felt they made it clear that screening was optional. However, some clinicians noted a <b>perception that many patients "don't want a choice."</b> Despite PCPs indicating that LCS is offered as a choice, LCS-Cs felt that many patients did not perceive it that way and <b>felt obligated to follow their PCP's recommendation</b> ."  Screening Decision and Anxiety: All but one PCP reported that <b>nearly all patients accept screening readily when offered</b> . PCPs felt that "decliners" were in two groups: decliners of screening tests in general and those who felt anxious or "(didn't want) to know" about lung cancer.
<i>Reese, 2022<sup>58</sup> (Low RoB)</i>		
N=14 Physicians  Qualitative interviews conducted after physician-facing decision aid integrated into the EHR	Innovation → Evidence Base	"While many participants believed screening was important, several were <b>surprised by the low specificity of low-dose CT scans</b> and the <b>frequency with which false positive</b> findings result in unnecessary procedures and major complications."
	Innovation → Design	"Most participants thought <b>providing patients with access to an educational module</b> , possibly outside the encounter, <b>would enable shared decision making</b> ."
	Outer Setting → External Pressure → Performance Measurement Pressure	"The <b>incentives and outcomes</b> of shared decision making were <b>conflicting</b> , due primarily to clinic <b>performance measures for screening</b> ."
	Outer Setting → Local Attitudes	"Most participants perceived <b>smoking history documentation in the EHR as inaccurate</b> or insufficient for documenting and ordering low-dose CTs."
	Inner Setting → Available Resources	"While most participants believed that shared decision making should be used more often for a variety of cancer screenings, the <b>time required to have this type of conversation</b> during an encounter <b>was a primary barrier</b> ."

Sample Size Study Description	CFIR Domain → Construct	Barrier/Facilitator
	Inner Setting → Relative Priority	"Most participants believed that <b>screening would not be the primary reason for the encounter</b> and that reminders would be needed to use the decision aid."
	Inner Setting → Structural Characteristics → IT Infrastructure	"Most participants thought they would use the decision aid to support shared decision making, if it was <b>integrated with the EHR</b> to obtain patient information. Furthermore, integrating the decision aid in the EHR would facilitate reminders, documentation, and patient education."
		"Most participants believed that screening would not be the primary reason for the encounter and that <b>reminders would be needed to use the decision aid.</b> "
	Individuals → Capability	"A majority of participants were <b>unaware of reimbursement requirements</b> and were <b>concerned of insurance issues</b> with ordering a low dose CT."
<i>Schapira, 2022<sup>21</sup> (High RoB)</i>		
N=42 Veteran patients  Usability study of the LCSDecTool, qualitative outcomes to implementation of this tool in VA clinics	Innovation → Design	"the LCSDecTool was generally easy to use; however, <b>specific navigation challenges</b> remained"
		"users sought <b>more detailed descriptions</b> about the LCS process, some noted <b>difficulty understanding medical terms</b> used in the LCSDecTool"
	Individuals → Innovation Recipients	<b>Negative affective responses</b> of using the tool (worry about cancer risk or learning about harms is scary), ease of understanding, genuineness of tool (scripted dialog), tool <b>evoked Veteran struggles with prior efforts at smoking cessation</b>  " <b>Low baseline awareness and knowledge about LCS</b> that increased after use of the LCS decision support tool"
<i>Wiener, 2018<sup>22</sup> (Moderate RoB)</i>		
N=36/49 Clinicians/ Patients  Qualitative interviews to characterize experiences of patients and clinicians from early adopting LCS programs	Innovation → Adaptability	Clinicians reported <b>variable degrees of information sharing with patients</b> , some offering comprehensive description while other provided limited information. Those who provided limited information did so for varying reasons: uncertain of patients comprehension; worried patients might be overwhelmed; some clinicians didn't provide harms information because of their own personal beliefs
	Individuals → Innovation Deliverers	Clinicians reported <b>mixed experiences with decision aids</b> . Some found that they facilitated discussion and improved patient comprehension, others believed decision aids with specific risk information served as a barrier to engaging patients.
	Individuals → Innovation Recipients	Clinicians discussed the <b>challenges of engaging patients in deliberation</b>  Information Sharing, Patients: Echoing clinician reports, <b>patient accounts reflected a range of information received about LCS</b> . Some reported receiving minimal information (not told indication for CT, not told about harms and then experienced an unexpected outcome), while other reported successful information sharing.  <b>Patients also noted barriers to deliberation</b> . Mirroring clinician accounts, some patients reported simply accepting their clinician's strong recommendation without significant deliberation, for some it evoked an emotional response, hindering engaging in deliberation. Others recalled successful deliberation, and felt questions and concerns were addressed.  Many <b>patients did not mention decision aids</b> when recounting communication and decision-making about LCS. <b>Those who did reported mixed impressions</b> , some were positive and found decision aids useful while others found them excessively detailed and information on harms off-putting

**Abbreviations.** CFIR=Consolidated Framework for Implementation Research; CT=computed tomography DCP=Decision Counseling Program; EHR=electronic health record; IT=information technology; LCS=lung cancer screening; LCS-C=lung cancer screening coordinators; LDCT=low-dose computed tomography; PCP=primary care physicians; RoB=Risk of Bias; SDM=shared decision-making; VA=Veterans Affairs.

## PEER REVIEW COMMENTS AND RESPONSES

Comment #	Reviewer #	Comment	Author Response
<i>Are the objectives, scope, and methods for this review clearly described?</i>			
1	1	Yes	
2	2	Yes	
3	3	Yes	
4	5	Yes	
5	6	Yes	
6	7	Yes	
7	8	Yes	
<i>Is there any indication of bias in our synthesis of the evidence?</i>			
8	1	No	
9	2	No	
10	3	No	
11	5	No	
12	6	No	
13	7	No	
14	8	No	
<i>Are there any published or unpublished studies that we may have overlooked?</i>			
15	1	No	
16	2	No	
17	3	No	
18	5	<p>Yes - I'm aware of other studies related to barriers/facilitors for SDM</p> <ol style="list-style-type: none"> <li>1. Crothers K, Kross E, Reisch LM, et al. Patients' Attitudes Regarding Lung Cancer Screening and Decision Aids: A Survey and Focus Group Study. Ann Am Thorac Soc. Sep 21 2016;doi:10.1513/AnnalsATS.201604-289OC</li> <li>2. Eberth JM, McDonnell KK, Sercy E, et al. A national survey of primary care physicians: Perceptions and practices of low-dose CT lung cancer screening. Prev Med Rep. Sep 2018;11:93-99. doi:10.1016/j.pmedr.2018.05.013</li> <li>3. Henderson LM, Benefield TS, Bearden SC, et al. Changes in Physician Knowledge, Attitudes, Beliefs, and Practices regarding Lung Cancer Screening. Ann Am Thorac Soc. Aug 2019;16(8):1065-1069. doi:10.1513/AnnalsATS.201812-867RL</li> <li>4. Hoffman RM, Sussman AL, Getrich CM, et al. Attitudes and Beliefs of Primary Care Providers in New Mexico About Lung Cancer Screening Using Low-Dose</li> </ol>	<p>Thank you for the list of articles. Our search identified 8 of these articles, 2 of which (Crothers and Wiener) are detailed in our report. The remaining 6 were excluded at abstract screening as they addressed LCS as a whole and not specifically SDM for LCS, therefore were out of scope. One article (Henderson) was not captured by our search and we have reviewed. Similar to the other articles, it is outside of scope as it is focused on LCS as a whole and not SDM for LCS.</p>

Comment #	Reviewer #	Comment	Author Response
		<p>Computed Tomography. Prev Chronic Dis. Jul 09 2015;12:E108. doi:10.5888/pcd12.150112</p> <p>5. Kanodra NM, Pope C, Halbert CH, Silvestri GA, Rice LJ, Tanner NT. Primary Care Provider and Patient Perspectives on Lung Cancer Screening. A Qualitative Study. Ann Am Thorac Soc. Nov 2016;13(11):1977-1982. doi:10.1513/AnnalsATS.201604-286OC</p> <p>6. Simmons VN, Gray JE, Schabath MB, Wilson LE, Quinn GP. High-risk community and primary care providers knowledge about and barriers to low-dose computed topography lung cancer screening. Lung Cancer. Apr 2017;106:42-49. doi:10.1016/j.lungcan.2017.01.012</p> <p>7. Triplette M, Kross EK, Mann BA, et al. An Assessment of Primary Care and Pulmonary Provider Perspectives on Lung Cancer Screening. Ann Am Thorac Soc. Jan 2018;15(1):69-75. doi:10.1513/AnnalsATS.201705-392OC</p> <p>8. Volk RJ, Foxhall LE. Readiness of primary care clinicians to implement lung cancer screening programs. Prev Med Rep. 2015;2:717-9. doi:10.1016/j.pmedr.2015.08.014</p> <p>9. Wiener RS, Koppelman E, Bolton R, et al. Patient and Clinician Perspectives on Shared Decision-making in Early Adopting Lung Cancer Screening Programs: a Qualitative Study. J Gen Intern Med. Jul 2018;33(7):1035-1042. doi:10.1007/s11606-018-4350-9</p>	
19	6	No	Thank you.
20	7	No	Thank you.
21	8	Yes - <a href="https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2819704">https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2819704</a>	Thank you, this article was published after our initial search dates. We have reviewed the article, and while it may meet our inclusion criteria, we do not feel it would change our overall conclusions. Additionally, SDM is only one component of a multi-faceted intervention, it may be difficult to determine what effect (if any) SDM had in the results reported.
<i>Additional suggestions or comments can be provided below.</i>			
22	1	Page 1, Line 21: SDM acronym should be spelled out prior to first use (Shared Decision Making)	Thank you.
23	1	Page 4, Line 31: should Veterans' Affairs simply be Veterans Affairs, without the apostrophe?	Thank you.
24	1	Page 5, Lines 21-27: This reads like a complicated run on sentence, especially the last part of the sentence...should this be broken into two sentences?	Thank you, we have updated.
25	1	Page 5, Line 52: recommend comma after "process"	Thank you.
26	1	Page 6, Line 16 vs. 17: recommend Oxford comma after "screening"	Thank you.
27	1	Page 6, Lines 36-38: it may be helpful to explain why this estimate of 1-1.5M Veterans is larger than the 900,000 estimate listed earlier on this page from the	The difference is most likely due to revised and expanded population eligibility in the 2021 USPSTF

Comment #	Reviewer #	Comment	Author Response
		2016 study...changes in Veteran enrollment? Aging of the Veteran population such that more established enrollees from 2016 now meet USPSTF criteria for LCS? We are left to speculate on this disparity as written.	recommendations compared with the 2013 recommendations. We clarified that the 1-15M Veterans eligible is related to the 2021 expanded recommendations.
28	1	Page 14, Lines 37-38: Recommend adding a descriptor for length of time of the YouTube video (as all other listed videos have a length of time descriptor)	Study authors simply state the intervention was a YouTube video, no link or run time were provided.
29	1	Pages 14-15, Table 2 Overall: if allowed, and available, could web URL links be provided to as many of the tools listed here? Why is ShouldIScreen the only link provided? Are the others proprietary such that there are rights management issues with providing web links, or are these simply not available?	As not all authors provided links or access to their tools we were unable to provide links to all tools. To underscore this issue, we have added a sentence in the report to note that web URL links are provided when available.
30	1	Page 16, Lines 28-37: There is a significant discovery here, that is not highlighted in the Executive Summary Conclusions or elsewhere. Essentially, when a SMD tool is integrated into the EHR, the impact on LCS adoption is quite significant...this reinforces Human Centered Design Principles that we see in so many other aspects of clinical work...namely, if something is integrated into EHR workflows, it is completed/used by busy, overburdened clinicians. If it is not, is it not completed/used to nearly the same amount. This is a really important discovery that seemingly is buried in page 16 of the ESP report...recommend more emphasis on this finding in other aspects of the report.	We agree that this is one of many important findings. Rather than selecting a single finding or providing a lengthy text list of findings in the executive summary we elected to report all certainty of evidence ratings in a single table. This table includes the mode of delivery, outcome, study design and number of enrollees and a summary statement.
31	1	Page 20, Lines 25-49: Also here are some very important discoveries on enhanced LCS adoption using these specific tools for non-clinicians...may warrant more emphasis within discussion section of report as the findings were quite significant...food for thought	We plan to leave as written. The report focuses on SDM. The studies noted that SDM tools plus care coordination may result in increased receipt of LCS compared with usual care. (low COE). It is not clear about the independent effect of SDM tools on LCS rates given the additional roles of care coordinators to facilitate LCS beyond what would occur in usual care. The findings are also summarized in Table 1 in the Executive Summary and the section specific Certainty of Evidence ratings tables.
32	1	Page 28, Lines 13-14: should highlighted yellow section be removed?	Thank you.
33	1	Pages 28-29, Table 9: as with Table 2, could length of time descriptors be added where appropriate, as well as web URLs for any of these tools, if available and allowed to be shared within the ESP document? Just trying to help readers navigate to these tools if they wish to explore in more detail.	Thank you for the comment. When made available by authors we have included the tool URLs.
34	1	Page 29, Line 32: should the bolded text section be removed?	Thank you.
35	1	Page 58, Lines 51-52. I believe the acronym for CBOC is Community Based Outpatient Clinic, not Community Based Outreach Clinic	Thank you. We have corrected.
36	2	Page 1, line 16: the use of "health care provider" to categorize strategies, that is further divided into clinician and non-clinician categories, is confusing. It seems like a non-clinician should not be categorized as a health care provider? Later in	We have updated to "professional", rather than provider for consistency. We also changed non-clinicians to read: "LCS navigators" to help

Comment #	Reviewer #	Comment	Author Response
		the document (Table 1) it categorizes tools as Health care Professional-Facing. Suggest using health care professional instead of health care provider when referring to strategies as well as tools.	differentiate a less specific and potentially confusing term of "non-clinicians".
37	2	Page 1, line 21: define SDM. May want to introduce SDM earlier--in line 12, "Shared decision making (SDM) strategies..."	Thank you.
38	2	Page 1, line 23: How are care coordinators or navigators distinct from non-clinicians? Suggest clarifying how these strategies are different from healthcare provider-facing strategies.	Please see explanation for item 36.
39	2	Page 12, line 51: If the authors did not report a tool as a decision aid, was it classified as an educational tool? Or were those tools not identified as decision aids all identified by authors as educational tools?	To be considered a decision aid the authors were required to specifically state that. If they did not we classified the tools as educational tools. We rarely had access to the listed tools and could not evaluate whether any noted tool met decision aid standards, relying on author definition.
40	2	Page 13, line 40, footnote: why are the IPDAS standards only for RCTs? Is this because all RCTs that were included used IPDAS standards?	Thank you for noticing this. We reviewed and determined that this was placed in error and have removed the footnote.
41	2	Page 19, line 21: Would highlight the Importance column in Table 4 and also in subsequent tables (Tables 8, 11, 12, 13, 16). This Importance column contains summary information that is useful for readers.	Importance column "bolded" as suggested.
42	2	Page 28, line 21: Recommend highlighting the Importance column	Done in bold.
43	2	Page 36, line 21: Recommend highlighting the Importance column	Done in bold.
44	2	Page 38, line 28: Recommend highlighting the Importance column	Done in bold.
45	2	Page 39, line 32: Typo: should be (3.9%), not (3/9%)	Thank you.
46	2	Page 40, line 21: Recommend highlighting the Importance column	Done in bold.
47	2	Page 46, line 5: Recommend highlighting the Importance column	Done in bold.
48	2	Page 47, line 32: should be United States "Preventive," not "Preventative"	Thank you. Corrected.
49	2	Page 59, line 45 - page 60, line 12: Important points about being consistent in shared decision making expectations across screening recommendations and the need for systems-level approaches to refine who may benefit from LCS.	Thank you. We do not believe changes are requested/needed.
50	3	Great job!!!!!!!!!!!!!!!!!!!!!!	Thank you.
51	3	1. Please do not use the term "smoker" as it is pejorative and stigmatizing. Please consider using "people who currently/formerly used cigarettes" or other patient-centered language.	Thank you. We have changed this throughout to read: "people who currently/formerly smoked."
52	3	2. In the Key Findings and other relevant areas, please note how many times shouldscreen.com was studied. I believe it's the "most" but still a minority of studies evaluated it.	Thank you. Done.



Comment #	Reviewer #	Comment	Author Response
53	3	3. Re the Conclusion in the Exec Summary statement, "While most studies reported on knowledge, few .....". Please consider changing "reported on knowledge" to a more quantitative statement, if possible. For example, "While most studies found small/medium/large improvements in LCS knowledge, few....".	We did not have any established minimally important differences to reference and how to define a small/medium/large improvement in decisional conflict is a large undertaking that would require expert consensus. Furthermore, knowledge was not ranked by partners and TEP members as a "critical" or "important" outcome for decision making. Finally, studies varied widely in how they assessed knowledge and the range of possible scores. It would be extremely challenging and potentially misleading to summarize effect magnitude across these studies and scales. The sentence used is also meant as a lead-in to the more clinically relevant outcomes of interest that we did assess for certainty of evidence and desired to highlight. We thus leave unchanged.
54	3	4. In Table 1 Exec Summary, is it possible to include references for the studies?	As part of the ESP report template and brand we do not include references in the executive summary. All references can be found in the full report.
55	3	5. In Table 1 Exec Summary, is it possible to include a quantitative statement re the magnitude of an effect for the "high certainty" studies if there was an effect? For example, re Decisional Conflict for the "Lung Cancer Screening: Is It Right for Me?" study, instead of "less", can you say, "...results in a small/medium/large improvement in decisional conflict/regret"?	We can only provide the direction of effect in our GRADE certainty of evidence statements. We did not have any established minimally important differences to reference and how to define a small/medium/large improvement in decisional conflict is a large undertaking that would require expert consensus.
56	3	6. For suggestions #2 through #5, please consider changing in the full summary as well.	We have carried out any changes in the Executive Summary to the full report.
57	3	7. In Table in the Main Report, can you clarify what "not described as meeting IPDAS standards" means? Does it mean the authors reported, it did NOT meet IPDAS standards" or "the authors did not report whether it met IPDAS standards"? Also, add IPDAS and a reference to the abbreviations at the bottom of the Table.	The original writing is accurate. To be considered meeting IPDAS standards the authors were required to specifically state that. If they did not we noted that the tools were "not described as meeting IPDAS standards". We rarely had access to the listed tools and did not evaluate whether any noted tool met IPDAS standards, relying on author definition.
58	3	8. In the Results section and Tables in the Main Report, is there a way to include the magnitude of change in knowledge, decision conflict/regret, etc.? Do some of the instruments report the minimally clinically important difference? Alternatively, is there a way to include the total score in the report? For example, in Table 4, it says the Ottawa decision regret was better by 4 points for shouldscreen.com. However, this difference would be important to contextualize that there are 100 points available.	<p>Please see our response to comment #55 regarding minimally important differences.</p> <p>Where possible we updated in the text to include the total possible scale score.</p>



Comment #	Reviewer #	Comment	Author Response
59	5	General comments The authors should be commended for drafting a comprehensive, well-written, and thoughtful assessment of SDM for LCS. They appropriately highlight the rationale for conducting SDM, characterize the various approaches to implementing SDM, and identify many important gaps in the literature.	Thank you.
60	5	A striking finding to me is that apparently only one study (Percac-Lima) addressed follow-up of an abnormal LDCT. I think this is critical omission in current studies and an issue for future research. While adherence with annual screening is necessary for a successful screening program, cancer mortality will be reduced only if abnormal findings are fully evaluated—and patients with early-stage cancers receive curative treatment. I think the importance of tracking adherence with these downstream processes should be further emphasized in the report. Adherence with diagnostic evaluations and treatment are outcomes that may well be impacted by SDM.	Thank you. We note this in the key messages. It is also listed in the summary certainty of evidence ratings table where we conclude: “the evidence is very uncertain on the effect of SDM on LCS adherence”. Of note, studies were not designed or intended to evaluate longer term LCS adherence (or follow-up of abnormal findings including adherence with diagnostic evaluations and treatment on an initial or subsequent LCS). We added a phrase in the results section and conclusion emphasizing this issue.
61	5	Given the most recent CMS determination that telehealth is an acceptable delivery strategy (and can be delivered by “auxiliary” personnel), a future research issue should be to compare clinic-based vs. telehealth SDM interventions, particularly those delivered by non-clinicians. Although this may be considered part of creating better SDM strategies, I suggest that the research agenda also include determining what knowledge elements are most useful for informing screening decisions and to encourage investigators to use validated instruments to measure this outcome.	Thank you. We have added these suggestions to the future research issue section (though as per above we have changed the term “non-clinician”).
62	5	Specific comments 8.31: I think readers would like to know what the report authors consider to be harms from SDM; possibilities could include increasing anxiety/distress or decisional conflict, or regret. The discussion (56.15) mentions that the harms of SDM are not well known. However, I did not find any previous comments about harms in the combined KQ2 and KQ3 results sections explicitly supporting that statement.	Thank you. We have revised the document to provide a separate section for KQ3: “Harms of the communication strategies, tools, and/or approaches. Our protocol defined outcome for this was: “author defined harms”. No studies reported this. Based on discussion with our operational partners and TEP we defined additional harms as anxiety and decisional regret. These results are listed in KQ2. We note both of these points in our KQ3 very brief summary. One could also include outcomes such as resource allocation, time, and cost. These outcomes were listed under KQ2. We have now included a statement in the beginning of the KQ2 section to note that no studies reported on these (and some other outcomes). This is also noted in the discussion and a future research need. We revised the discussion to note that harms and burden (patient as well as clinician/health system) burden .... Are not well understood. Harms and burden of SDM for all

Comment #	Reviewer #	Comment	Author Response
			potentially eligible individuals for LCS was not reported beyond measures of patient anxiety or decisional regret. We added to our key findings bullets: As noted above, studies did not report on many other outcomes of interest including: smoking behaviors; resource allocations/usage (eg, clinician time, clinical staff/patient time, medical media support, IT support); cost or cost effectiveness.
63	5	2.27: LCS is meant to identify—and treat—lung cancer early to reduce mortality.	Thank you. We revised the sentence to read: Lung cancer screening (LCS) is meant to reduce lung cancer mortality through early identification and treatment of lung cancer.
64	5	2.30: I think the comment about “adherence to initial and follow-up screening (including evaluation of abnormal findings on LCS)” could be more clearly stated. I interpret “follow-up screening” as referring to annual screening. Evaluation of abnormal findings is part of the screening process, though distinct from “screenings.”	Thank you. We clarified to read: “... adherence to initial and subsequent screening as well as evaluation and treatment of abnormal findings on LCS...”
65	5	3.21: Harms particularly arise from invasive diagnostic testing.	We add “invasive diagnostic testing”. Harms come from multiple sources as we note in the sentence.
66	5	4.57: Consider explaining the difference between decision aid and educational tool.	Thank you, we have added.
67	5	5:59. References 6 and 7 should be for the 2015 and 2022 CMS determinations, respectively. I think the report should note that the 2015 determination expected licensed independent practitioners to conduct a clinic-based visit while the 2022 determination allows non-clinicians to deliver SDM and supports telehealth.	Thank you. We added this.
68	5	8:6. As above, I think receipt of additional tests/procedures following abnormal scans are also important adherence outcomes. The discussion does mention “or subsequent evaluations” in the context of adherence; I suggest using this more complete description throughout the report.	We agree that receipt of additional tests/procedures (and subsequent evaluations) is an important outcome and a measure of overall adherence to LCS. In this report, LCS adherence was defined as “adherence to subsequent screening”. We also had as an outcome of interest: “receipt of additional tests/procedures for identified findings” though these were not reported. We have also included determining if patients adherence to subsequent evaluations as an important outcome.
69	5	11.28: I may have missed this, but I did not find the disqualifying factors for excluding the 2,683 citations based on title/abstract review.	We do not capture the reason for exclusion at the abstract triage level. We exclude if the population, intervention, setting, or time frame do not meet the inclusion criteria.
70	5	12.17: Missing period after “...included studies”	Thank you.

Comment #	Reviewer #	Comment	Author Response
71	5	12.29; 58.37: The 2016 Crothers study decision aid did not use the current VA decision (which I helped develop in 2023). They likely used the patient decision aid ("Screening for Lung Cancer") that was developed for VA demonstration project that began in 2013. I did confirm with Dr. Slatore that the current VA decision aid is available.	Thank you. We have revised to state in the Policy implications (VA Specific) section: A single study (Crothers) assessed a tool developed by VA and referenced in VA guidance for LCS. However, that study was not conducted in a Veteran population.
72	5	13.40/53: I'm confused by the number of studies reported in the IPDAS section. The superscript refers to "only for RCTs" (of which there were 12). However, 21 studies are listed: 13 meeting criteria, 8 not.	The foot note indicating that the IPDAS criteria refers only to RCTs was placed in error. It applies to the 21 trials with information available.
73	5	17.12; 31.10: Consider stratifying decision satisfaction results by the screening decision.	Data are not available for this. We have not changed.
74	5	20.26: What is meant by "completed at least one LCS appointment"? Does this refer to having a counseling visit or undergoing LDCT?	An LCS appointment refers to an individual undergoing LCS with LDCT.
75	5	24.45 (27.31): Should be 18.8 percentage point difference—not percent.	Thank you.
76	5	26 (Table 7): Improved participant knowledge is often cited as a benefit of SDM—and was the most consistently positive outcome in the cited literature. I'm curious as to why CoE was not rated for this outcome. Was it due to being considered a less important outcome and/or that the measures were heterogeneous/flawed?	We conducted a rating exercise with our TEP and operational partners to identify the most critical outcomes for GRADE assessment, to include at a minimum 1 harm outcome. Knowledge, while most frequently reported, was not one of the outcomes rated highly by our TEP or OP.
77	5	28.22: Typo. Delete Table 8.	Thank you.
78	5	28.34. Consider describing intervention as ...including incidental findings information.	Thank you we have added the descriptor.
79	5	29. 4: Consider identifying the developer of YouTube video.	Information was not available. We revised Table 9 to read as authors described: "brief educational video about lung cancer screening that was hosted on YouTube"
80	5	29.36: Should read +12 percentage points, not +12%.	Thank you.
81	5	38.45: Clarify in the findings column that the reference group is family physicians	Thank you we have updated.
82	5	48.59. The intervention group for Sharma study is actually a brochure with phone-based in-depth messaging.	Thank you. We have updated.
83	5	51.18-37: What is the heading for the table on the top of page 51? Should it be patient facing preparatory?	This is a continuation of the table on the previous page (Table 18) we have updated the table with the appropriate heading.
84	5	52.3: Other barriers (see list of additional publications) include clinicians lack of awareness about guidelines and trial results and lack of training in SDM.	Thank you. We reviewed the list of provided publications
85	5	56.21: Should the line read, "Few studies provided information whether THEIR INTERVENTION met criteria...."?	Thank you.

Comment #	Reviewer #	Comment	Author Response
86	5	56.21: Clarify whether you mean to say that studies addressed neither adherence with annual exams nor follow up of abnormal exams. Current wording is unclear.	We have updated to clarify.
87	5	58.9: Clarify: adherence with what?	Thank you.
88	5	58.37: As above, current VA was not used in cited reference. Having retired from the VA, I do not have access to the VA guidance site that houses the new decision aid. You might consider providing a link for VA readers.	We have modified this to include the link for the current VA guidance site and tool. Contact with the VA guidance site program manager suggests that an updated link and tool will likely be available soon.
89	5	59.45: Indeed, no other USPSTF grade A or B recommended screenings has led to a CMS requirement for SDM. However, no other USPSTF recommended screening programs target high-risk patients nor involve as potentially high-risk invasive diagnostic procedures or treatments. I'd be cautious about trying to extrapolate strategies from other screening programs to lung cancer. I am also aware that the Medicare advisory board recommended against covering LCS because they were uncertain that it could be implemented as effectively and safely in community practice as it was in NLST. An additional important facilitator for screening programs is that referring clinicians have confidence that their patients will receive high-quality imaging interpretations, diagnostic procedures, and treatment.	Thank you. We agree with several of the reviewers thoughtful and informed your concerns. Nonetheless, the overall assessment of the USPSTF is a "B" recommendation for population of interest. This indicates that that the USPSTF determined that there was at least moderate certainty of moderate net benefit of their screening recommendation given population, intervention and outcomes of interest. Issues regarding applicability and implementation for LCS is not too dissimilar to other cancer screening modalities including mammography for breast cancer and colonoscopy or CT colonography for colorectal cancer.
90	5	61-64: Several references are garbled or incomplete: 4, 6, 9, 14, 6	Thank you, we have updated our citation software so these citation appear complete.
91	6	I appreciated the comprehensive and very clear evidence synthesis provided in this report. My comments are below, with comments regarding content or methods provided first, followed by minor comments related to typographical errors.	Thank you.
92	6	PDF page 11, line 32 (also on PDF page 24, line 5): "The following were ranked the top 6 of clinical importance and CoE ascertained: receipt of lung cancer screening...". Should this be "receipt of lung cancer screening among those who agreed to screening? It feels antithetical to the nature of shared decision-making (SDM) to imply that the goal of SDM is to increase screening uptake; rather it should be to support the patient in coming to a decision that best matches the medical evidence AND their goals and preferences, acknowledging that sometimes that means a high-quality SDM conversation will result in the patient deciding not to get screened.	The outcome of interest was overall receipt of LCS. We agree the other stated concerns. We have also noted that LCS is unique in that despite the USPSTF issuing a "B" recommendation indicating that there is at least moderate certainty of moderate net benefit that SDM is required or indicated prior to LCS despite the overall implication that clinicians should recommend LCS for eligible individuals.
93	6	PDF page 13, Table 1: Row subheader: "Tools for non-clinician (eg, LCS coordinator)" – this example is confusing to me as especially in VA, LCS coordinators ARE typically clinicians such as nurses, NPs, or PAs. Should this instead read "Tools for non-physician (eg, LCS coordinator)" or "Tools for clinicians other than primary care provider (eg, LCS coordinator)"? Similar comment for PDF page 29, line 58.	We have clarified this to use the term "LCS navigator" rather than non-clinician.

Comment #	Reviewer #	Comment	Author Response
94	6	PDF page 39, line 36: Is there something missing here? It states that 57 of 66 in the Mazzone study stating: [followed by a series of what appear to be individual, write-in quotes]. Is there some other category that 57 of 66 participants responded?	Thank you.
95	6	PDF page 70: First sentence of discussion does not make sense, and the first portion of it is not accurate.	We have reviewed the comments and section.
96	6	PDF page 73, line 28: "Future research is needed to enhance implementation by identifying and reducing barriers and encouraging facilitators to both SDM and LCS." Consider citing ATS/VA HSR&D statement on research priorities regarding implementation of shared decision making for LCS (PMID: 35289730).	Thank you. We have added the citation.
97	6	PDF page 73, line 53: "If a main goal of LCS is to have eligible patients receive LCS, reducing barriers to the screening process are needed and may involve reducing barriers inherent with formal shared decision making in eligible individuals." While I appreciate the sentiment being expressed here, it does not seem to be supported by the evidence presented in this review, which largely found that interventions intended to support SDM for LCS tended to result in increased LCS uptake compared with usual care. Thus my read of this evidence synthesis is that formal SDM processes do not appear to serve as a barrier to LCS uptake.	Thank you, we have updated and clarified our statement.
98	6	PDF page 91, Appendix – underway studies: It appears clinicaltrials.gov was the source for identifying underway studies. It may also be useful to check VA's newly funded and ongoing studies webpages or NIH reporter to identify other studies not captured through clinicaltrials.gov.	Thank you for the recommendation, we reviewed these repositories and updated our text and appendix table.
99	6	Appendix Tables describing the included studies are excellent, supplying the key information about each study clearly and concisely.	Thank you.
100	6	Minor/typographical: PDF page 26, line 23: Incomplete sentence starting with "While the cohort by Tanner..."	Thank you.
101	6	PDF page 38, line 51: Typo "SMD" instead of "SDM"	Thank you.
102	6	PDF page 43, line 18, Typo – should read "no difference in receipt"	Thank you.
103	6	PDF page 53, line 32: Typo – should 3/9% be 3.9%?	Thank you.
104	6	PDF page 53, line 38: Suggest avoiding the term "smokers" and replacing with person first language (e.g., people who smoke)	Thank you. We have updated.
105	6	PDF page 55, line 16: Typo: should read "distress/anxiety" or "distress or anxiety"	Thank you.
106	7	This is an excellent, timely, and well-written systematic review of SDM interventions for lung cancer screening. I have the following comments:	Thank you.
107	7	* Period of the search is appropriate given publication of the NLST and subsequent updated recommendations and guidelines	Thank you.

Comment #	Reviewer #	Comment	Author Response
108	7	* Impressive that qualitative studies were included in the review.	Thank you.
109	7	* I assume studies did not report measures of fidelity - ie, how well the intervention was delivered as intended.	Thank you, your assessment is correct.
110	7	* The point about not being able to assess the quality of the tool is important as some may have been promotional/encouraging of screening rather than presenting LCS as a decision.	Thank you.
111	7	* Table 1, does "Person" mean "In person" ?	This was meant to denote that the intervention was delivered by a person.
112	7	* Just an observation that doesn't need to be addressed by the authors - many developers cite IPDAS as guiding development of their tools, but it's often entirely unclear how the applied IPDAS if a development paper was not also published.	Thank you. We agree. No changes.
113	7	* A clarifying point, several of the tools grouped as "for clinician use" (eg, Option Grid) are actually tools used during the clinical encounter where both patients and clinicians use an aid. Consider describing these as "encounter" tools rather than clinician tools. Same point for "non-clinician use".	Yes, we agree it's possible patients were also viewing the tools. However, this wasn't clearly reported in most studies, and some studies included telephone visits. For clarity for the reader, we have added the following information for this section: <i>"Tools described below were used during an in-person or phone encounter with a healthcare professional. These tools are all described as "healthcare professional-facing", though it's possible the patients were also viewing the tools during in-person visits. This was not clearly reported in most studies, therefore we have referred to these as "healthcare professional-facing" tools throughout for consistency."</i>
114	7	The authors should be commended for this is an impressive, comprehensive review of a challenging literature on SDM interventions for LCS.	Thank you.
115	8	Overall, this was a really well-researched review. My largest concerns revolve around the definition of SDM, confusion between decision support interventions and SDM, and a slight lean against SDM. But it is an excellent and thorough review and a resource I will use in the future (when made public). Excellent work and thank you for your contribution to the literature and the fields of MDM and lung cancer screening.	Thank you
116	8	Below i highlight some areas where i have suggestions that i hope are useful.	Thank you.
117	8	On Page 2 (Line 38), the authors define SDM. However, they failed to include a key component—the need for patients to describe their values, goals, and preferences and use that information in their decision-making process with their clinician. Right now, it is focused exclusively on the best available medical/scientific evidence, and that is NOT shared decision-making.	We have added this to the background in both the executive summary and full report as well as the discussion.

Comment #	Reviewer #	Comment	Author Response
118	8	On page 4 where you describe the study design (paragraph starting on line 45) it would be helpful to include citations of each or have a table describing each study with their study design characteristics.	We include study characteristics and design for each study in the appendix tables.
119	8	I am a little concerned about defining educational tools as a SDM tool. Usually they only provide knowledge (medical/scientific) and don't discuss the role of patient preferences/goals/values and the importance of the patient voice. (Page 5, line 5)	We empathize with the reviewer's concerns, however we used as broad a definition as possible regarding what constituted a shared decision tool in order to be as broad as possible. Secondly, authors often did not report if their tool was a decision aid or an educational tool, nor did they provide examples of the tools or the components including whether they discuss the role of patient preferences/goals/values and the importance of the patient voice making it impossible for the team to assess whether the tool met the requirements to be a decision aid.
120	8	In Table 1, citations of the studies would be valuable so people can review themselves or find the articles to inform their work.	While we understand the desire for the citations, it is ESP standard that we do not include citations in the executive summary. This table is a compilation of each of the GRADE tables reported in each section of the Results. In those tables we provide the citations.
121	8	Page 20: The authors describe results, but typically don't include citations (e.g., line 17: Three studies reported on receipt of lung cancer screening, 3 reported on decisional conflict/regret, 2 reported on patient knowledge, 1 reported on quality of communication, and 1 reported on satisfaction with decision. It would be helpful if each of these assertions had a citation accompanying I would also refer to Table 3 in this section (I loved Table 3—well done!). Note on page 34 (e.g., lines 5-20) you do use the convention I suggest. However, there are multiple places where this lack of citations occur (e.g., page 46, line 40 and several other places). I think it is much better for the reader for you to cite everywhere where you make an assertion of a study did this or that.	Thank you, we have addressed and updated with citations.
122	8	Page 24 (Line 34+): The authors write: "Two RCTs <sup>18,29</sup> and 1 pre-post study <sup>32</sup> captured the number of individuals that completed a first LCS appointment, with all 3 finding that exposure to SDM increased uptake of LCS." Was it exposure to SDM to was it exposure to a decision support tool (I don't think the studies compared level of SDM and outcomes—but likely the intervention. Presence of a decision aid does not ensure, unfortunately, SDM.	We agree that presence of a decision aide or decision support tool does not ensure SDM. In discussion with our partners and TEP we considered decision-aides or educational tools being acceptable for SDM. We noted in the "overview of included studies" section the following: <i>Assignment of the intervention to either the decision aid or educational tool category (or whether they met criteria for shared/informed medical decision-making or would meet CMS criteria) was not always feasible, as not all authors provided a copy or access to the tested</i>



Comment #	Reviewer #	Comment	Author Response
			<p><i>intervention. As such, we relied on author report of the tool as a decision aid or educational tool; we refer throughout the text to both as SDM tools. Similarly, we did not assess the accuracy of information provided in any of the SDM tools or concordance with current US-based national LCS recommendations.</i></p> <p>We also added this issue to the limitations section of our report.</p>
123	8	Page 24 (line 51+): Authors reported 94.6% of individuals attending and completing the SMD visit completed an LCS visit. <sup>32</sup> Typo should be SDM. Also, I would not necessarily call a clinical visit a SDM visit—again, just because you get a tool does not mean the visit will result in SDM.	Thank you. Fixed. We recognize that receiving a tool does not necessarily mean the visit will result in SDM. As noted above we used a broad categorization of SDM.
124	8	Page 30 (Line 9+) Refers to the Health Care Decisions scale to measure decisional conflict/regret. Please cite the scale. I had never heard of it so I googled it and could not find it easily—so reference is definitely needed. I was concerned if it really measured decisional conflict/regret, but since I could not find it, I could not assess it. It is highly unusual not to use the decisional conflict scale to measure decisional conflict (though even I admit the scale is flawed)	Added as: DOI <a href="https://doi.org/10.1177/0272989X9601600114">10.1177/0272989X9601600114</a> .
125	8	On page 30, the authors report overall numbers for those who report from a little to very nervous in several places. That is not really useful for a reader—I assume it's any nervousness (for example) vs. none. But feeling a little nervous vs. very nervous is very different.	We agree that greater granularity of “nervousness severity” would be useful. However, authors did not provide this information.
126	8	Page 31-32: Is there a better way to describe knowledge findings—right now it reads as a very long laundry list (and you put the results so nicely in tables). Could you just indicate which there were differences vs. no difference with citations?	We appreciate the concerns. We do have directionality of findings in Table 10. We have elected not to change the text as we are uncertain how to better describe findings (and knowledge was not a “prioritized clinical outcome”
127	8	Page 39, line 8: “Four studies (3 RCTs and one cohort study) evaluated SDM compared with usual care. All found higher LCS with SDM.” The next paragraph does the same thing: “The other two RCTs included (or primarily evaluated) care coordinators or patient navigators in addition to SDM.” Again, did the studies evaluate SDM, or did they evaluate a decision support tool (decision aid or patient education tool)? I think there is a common conflating of SDM and decision tool that should not occur. I am trying to catch all of them (not to nag, but to help you correct them), but a close review by the authors is needed.	Thank you for this note and others. We agree this is an important distinction. However, based on discussions with our Operational Partners and TEP we took a broad approach to included tools that we categorized as SDM. We noted that of 31 eligible and included studies, 21 (68%) used author described “decision aides”. Of these, 13 (62%, or 42% of all eligible studies) were author described decision aid that met IPDAS standards. Little additional information was provided as to how they met those standards, what components were met and whether values and preferences were addressed. We have highlighted this as an evidence gap and future research need.



Comment #	Reviewer #	Comment	Author Response
128	8	Page 56 (line 11+): Thus, prior to LCS, clinicians are encouraged to provide patients with information about risks and benefits including the importance of screening adherence and smoking cessation (ie, SDM). This is most definitely not SDM. First, it only refers to the clinicians telling patients information—nothing about the patient sharing their goals/values. Second, emphasizing the importance of screening is not engaging in shared decision making—it's trying to convince people what to do, not engaging them in a shared decision making.	Thank you. We have changed this to state: Thus, prior to LCS, clinicians are encouraged to provide patients with information about risks and benefits including the importance of screening adherence and smoking cessation as well as eliciting and supporting patient preferences and values in the decision (ie, SDM).
129	8	Page 57 : A repository of published tools that SDM researchers could review and critique would be very helpful in understanding what has been tested in these at-risk populations. Is this what you were thinking? <a href="https://decisionaid.ohri.ca/AZinvent.php">https://decisionaid.ohri.ca/AZinvent.php</a> This might not contain all of the LCS—but probably many.	Thank you. Agree. We have added this to the future research need section.
130	8	Page 57 (line 49): Some studies did not base their interventions on recognized criteria for informed medical decision making. Do you mean informed MDM or SDM? They are very different. You might want to clarify why now describing informed vs. shared if you meant to do so.	Thank you. Changed for consistency to read SDM rather than MDM.
131	8	Page 58 (Line 19+) Mode of delivery/timing A final challenge to synthesizing the evidence is the variation in when study authors choose to administer the tool and the method in which they choose to deliver the intervention. The testing of timing and mode of administration is necessary and does provide useful information. However, the variation in delivery mode and timing changes further complicates synthesizing the evidence. I understand this comment—but you might also highlight that this is a fascinating research question in it's own—when is the best time to present a decision support intervention? Is a patient vs. clinician based tool more effective? Is before or during visit most valuable?	Thank you. Added.
132	8	Page 59 (line 1_) "Given that LCS is recommended and underutilized among eligible individuals, the most important LCS facilitator may not be to define and refine the "best SDM" method. Rather, a critical facilitator is to enhance methods for accurate and efficient identification, communication and referral of LCS eligible individuals for screening, as well as to ensure LCS adherence and follow-up. As a corollary, strategies are needed to avoid unnecessary or even harmful referral of either ineligible individuals or those who are unlikely to adhere or follow-up." I am not sure how you meant this section to be interpreted, but how I did was that you do not believe that this should be a shared decision and that the clinicians should just get people into screening because it is underutilized.	Thank you. This is a challenging area. <i>We note that if a main goal is to have eligible patients receive LCS than reducing barriers to the screening process are needed and may involve reducing barriers inherent with formal SDM in eligible individuals.</i> And we then note that consistent with a USPSTF B recommendation, clinicians should generally recommend LCS in eligible individuals... We stand by this statement though have added <i>This includes improving efficiencies and reducing patient, clinician, health system burden of SDM implementation.</i> The current guideline recommends, and many performance measures assess, LCS for eligible individuals (B recommendation; moderate certainty of net benefit) rather than SDM (typically

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			emphasized for “C” recommendations where assessed net benefit is “small” and likely to vary based on preferences and values. We agree that SDM is important, including for LCS, and that for any screening in asymptomatic individuals a test should only be performed in individuals who are aware of benefits and harms and is consistent with their preferences and values. Beyond the clinical benefits and harms to patients of LCS are the health system burden and costs especially of referring ineligible individuals or those who are unlikely to adhere to initial or subsequent LCS or follow-up of abnormal findings. Thus LCS is one area (though one could argue that similar situations occur for mammography for breast cancer or colonoscopy for colorectal cancer screening) that despite an overall assessment of “moderate certainty of moderate net benefit” that SDM would be particularly valuable.
133	8	You highlight the need to standardize methods and measures—which I strongly agree with. You could reference the SUNDAE recommendations to strengthen your argument: <a href="https://pubmed.ncbi.nlm.nih.gov/29269567/">https://pubmed.ncbi.nlm.nih.gov/29269567/</a>	Thank you, we have added this citation to our statement in the limitations.