Evidence Synthesis Program

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

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# AUTHORS

Author roles, affiliations, and contributions (using the CRediT taxonomy) are listed below.

| Author | Role and Affiliation | Report Contribution |
|---|---|---|
| Adrienne Landsteiner, PhD, MPH | Project Lead<br>Senior Scientist, Minneapolis Evidence Synthesis Program (ESP) Center<br>Minneapolis, MN | Conceptualization, Methodology, Investigation, Formal analysis, Visualization, Writing – original draft, Writing – review & editing, Supervision, Project administration |
| Nick Zerzan, MPH | Research Associate, Minneapolis ESP Center<br>Minneapolis, MN | Conceptualization, Methodology, Investigation, Formal analysis, Visualization, Writing – original draft, Writing – review & editing, Project administration |
| Kristen Ullman, MPH | Program Manager, Minneapolis ESP Center<br>Minneapolis, MN | Conceptualization, Methodology, Investigation, Formal analysis, Writing – original draft, Writing – review & editing |
| Maylen Anthony, MPH | Research Associate, Minneapolis ESP Center<br>Minneapolis, MN | Conceptualization, Methodology, Investigation, Formal analysis, Visualization, Writing – original draft, Writing – review & editing |
| Amy Claussen, MLIS | Medical Librarian, University of Minnesota Evidence-based Practice Center, Minneapolis, MN | Conceptualization, Methodology, Writing – review & editing |
| Robertson Bayer, MD, PhD | Staff Physician, Minneapolis VA Health Care System, Assistant Professor of Medicine, University of Minnesota Twin Cities<br>Minneapolis, MN | Conceptualization, Methodology, Writing – review & editing |
| Tam Do, MSN, RN, PHN | Nurse, Minneapolis VA Health Care System<br>Minneapolis, MN | Conceptualization, Methodology, Writing – review & editing |
| Allison Gustavson, PT, DPT, PhD | Core Investigator, Center for Care Delivery and Outcomes Research, Minneapolis VA Health Care System<br>Assistant Professor, University of Minnesota Twin Cities, Minneapolis, MN | Conceptualization, Methodology, Investigation, Formal analysis, Writing – review & editing |
| Anne Melzer, MD, MS | Staff Physician, Minneapolis VA Health Care System<br>Associate Professor of Medicine, University of Minnesota Twin Cities<br>Minneapolis, MN | Conceptualization, Methodology, Writing – review & editing |
| Timothy Wilt, MD, MPH | Co-Director, Minneapolis ESP Center<br>Staff Physician, Core Investigator, Center for Care Delivery and Outcomes Research, Minneapolis VA Health Care System<br>Professor of Medicine and Public Health, University of Minnesota Twin Cities<br>Minneapolis, MN | Conceptualization, Methodology, Writing – review & editing, Supervision, Funding acquisition |

# 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.

**Christopher Slatore, MD**
*Chief Consultant*
National Center for Lung Cancer Screening

### *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:

**Angela Fagerlin, PhD**
Associate Vice President for Faculty, Health Sciences
Professor and Chair, University of Utah Intermountain Healthcare Department of Population Health Sciences
Jon M. Huntsman Presidential Endowed Chair
Research Scientist, Salt Lake City VA Informatics Decision-Enhancement and Analytic Sciences

**Scott Pawlikowski, MD**
*Director, Improvement and Innovation*
VACO Office of Primary Care

**Robert Volk, PhD**
*Professor, Department of Health Services*
Research, Division of OVP, Cancer Prevention and Population Sciences, The University of Texas MD Anderson Cancer Center

**Renda Wiener, MD, MPH**
*Deputy Chief Consultant, National Center for Lung Cancer Screening*
*Associate Director, Center for Healthcare Organization & Implementation Research (CHOIR)*
VA Boston Healthcare System

**Disclosures**

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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.

# *Main Report*

Evidence Synthesis Program

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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.[1] 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.[1] 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.[2]

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.[3] Older adults in the US (including Veterans) also face higher risk of death from competing causes compared with trial participants.[3]

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.[4] The new recommendations are also intended to reduce racial/ethnic disparities in LCS mortality and access to screening.

As noted by others,[3] 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.[5] 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.[5]

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.[6,7] 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."[8] 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.[9]

The Veterans Health Administration (VHA) serves approximately 9 million Veterans,[10] 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.[11] 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.[11] 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). 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:

| | |
|---|---|
| **Key Question 1** | What communication strategies, tools, and/or approaches used for shared decision making (SDM) in lung cancer screening are reported in the literature? |
| **Key Question 2a** | What is the effectiveness and comparative effectiveness of communication strategies, tools, and/or approaches used to enhance SDM for lung cancer screening? |
| **Key Question 2b** | Does effectiveness vary by patient (i) or clinical setting (ii) characteristics:<br>i. age, race/ethnicity, comorbidities, current smoking status, socioeconomic status/education, residency, geographic region, rural/urban<br>ii. primary care, smoking cessation, prevention clinics, public forums |
| **Key Question 3** | What are the harms of the communication strategies, tools, and/or approaches used to enhance SDM for lung cancer screening? |
| **Key Question 4** | 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** |
| **Population** | Adults (≥ 18 years of age) in the US | Individuals considering lung cancer screening modalities other than LDCT (such as chest radiography)<br>Populations at increased risk for lung cancer unrelated to smoking exposure/history (*eg*, non-Hodgkin's lymphoma) |
| **Intervention** | Shared decision-making tools/aids | Non-lung cancer screening decision making tools/communication strategies/approaches |
| **Comparator** | Any | |
| **Outcomes** | KQ1: Types of SDM stratified by patient decision aid or educational tool, tool format, and tool environment<br>KQ2:<br>• Patient experience (*eg*, quality of communication, satisfaction with decision, decisional conflict/regret, concordance of decision with patient's values and preferences, distress/anxiety) | |

| | Eligibility Criteria | |
|---|---|---|
| | **Inclusion Criteria** | **Exclusion Criteria** |
| | • Participation in the screening program<br>• Receipt of lung cancer screening<br>• Receipt of additional tests/procedures for identified findings<br>• Adherence to subsequent screening<br>• Knowledge of screening benefit and harms<br>• Participant need for additional information<br>• Smoking behaviors<br>• Resource allocations/usage (*eg*, primary clinician time, additional clinical staff time, staff, patient time, medical media support, IT support)<br>• Cost (*eg*, cost or cost effectiveness)<br><br>KQ2b: (KQ2 outcomes stratified by the following effect modifiers)<br>• Rural/urban<br>• Regional<br>• Ethnicity<br>• Health literacy<br>• Lung cancer risk<br>• Competing comorbidities<br>• Serious mental illness<br><br>KQ3: Any harm reported by study authors<br><br>KQ4:<br>• 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)<br>• Facilitators (staff education, support from leadership, allocated time, ease of delivery, *etc*) | |
| **Timing** | 2010 (post guidance for use of shared decision making for lung cancer screening) | < 2010 |
| **Setting** | US Clinics, including community outreach | Hospice |
| **Study Design** | KQs 1–3: RCT, observational with comparator or quasi-experimental<br>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,[12] JBI Cohort RoB tool,[13] JBI Quasi-Experimental RoB tool,[14] or the CASP Qualitative Checklist.[15] 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).[16] 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.[16]

## 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.[17] 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

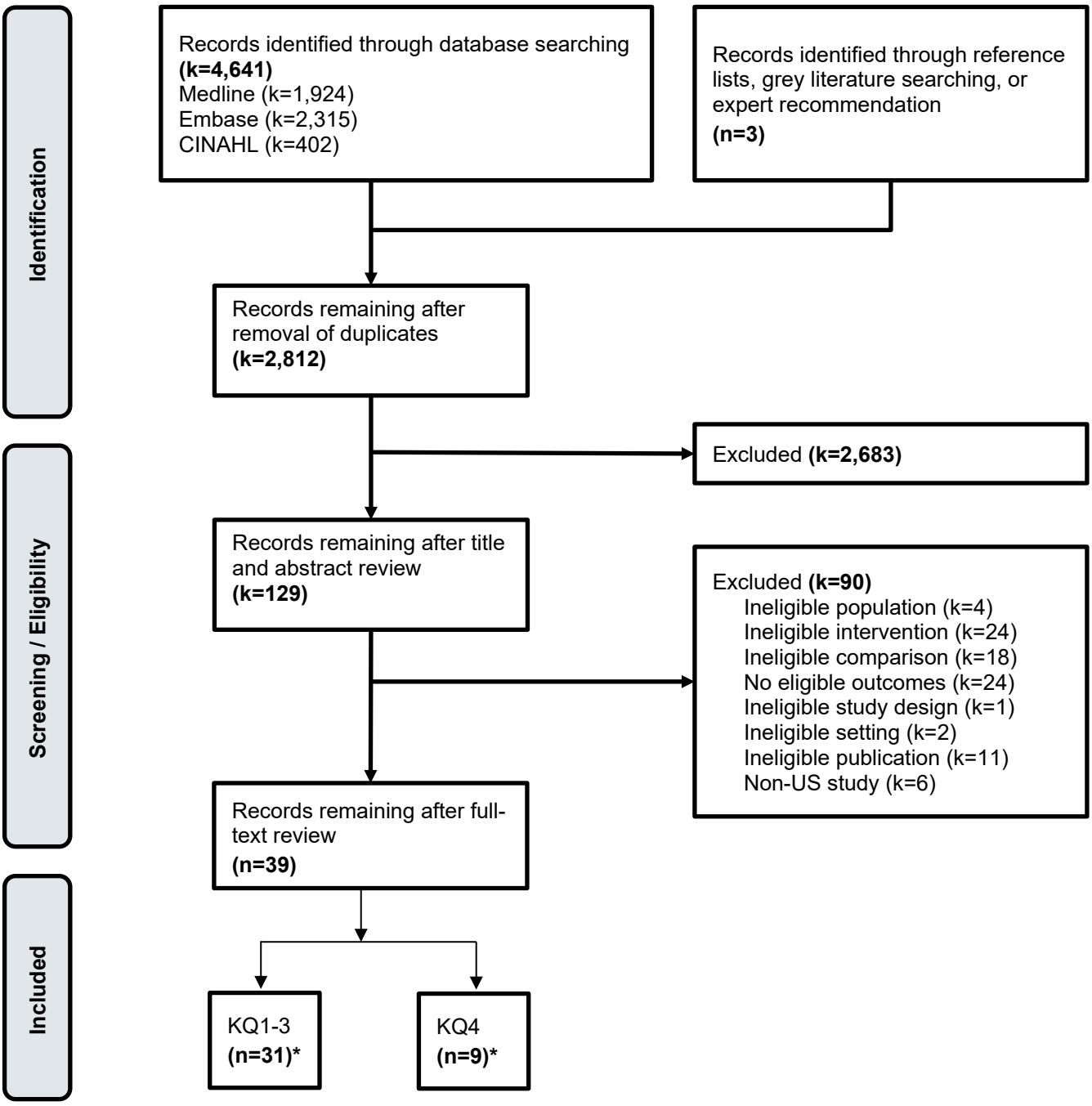
content experts, operational partners, and TEP to determine which of the included outcomes were most important. Among the included outcomes, the following were ranked the top 6 and CoE ascertained: receipt of LCS, distress/anxiety, adherence to subsequent screening, concordance of decision with patient's 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.[18]

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 ≤ 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[19,20] and 2 qualitative studies assessing barriers and facilitators were in Veteran populations.[21,22] Of the quantitative studies, 1 was an RCT that compared the LCSDec tool to an attention control intervention.[19] 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.[20] 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.[23]

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.[6,24] 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) 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 |
|---|---|
| *Brochures and Printed Materials* | |
| 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*<br>Han, 2019* |
| *Videos* | |
| "Lung Cancer Screening: Is It Right for Me?"<br>(6- and 9.5-minute versions) | Volk, 2014*<br>Volk, 2020*<br>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* |
| *Websites or Electronic Viewing/Interaction* | |
| www.shouldiscreen.com<br>5-15 minutes as electronic or print versions; available in English, Spanish, Chinese | Webster, 2023*<br>Lau, 2015*<br>Lau, 2021*<br>Crothers, 2016*<br>Mazzone, 2017*<br>Tanner, 2019*<br>Sferra, 2021* |
| Decision Counselling Program (online software application) | Bittner Fagan, 2023*<br>Bittner Fagan, 2020*<br>DiCarlo, 2022* |
| Option Grids | DiCarlo, 2022*<br>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* |
| *Other Miscellaneous* | |
| 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*<br>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."[18,20,25-31] 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.[18,28] One RCT and 1 cohort study utilized shouldiscreen.com in various ways. The RCT compared shouldiscreen.com to Option Grids,[31] 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.[20] One controlled clinical trial evaluated an integrated clinician-facing electronic medical record (EMR) template, comparing data before and after implementation.[29]

Most studies were rated moderate/some concerns RoB,[20,28,29,31] and only 1 was rated as low RoB.[18] Three studies reported on receipt of LCS,[17,19,26] 3 reported on decisional conflict/regret,[19,25,28] 2 reported on patient knowledge,[25,28] 1 reported on quality of communication,[28] and 1 reported on satisfaction with decision.[19] 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.[29]

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).[20] 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.[18]

#### *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).[31] 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).[20] 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.[28]

*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).[31]

*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 ± 2.8) versus telephone (24.6 ± 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.[20]

*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).[31] The second pre-post study rated moderate RoB only provided knowledge scores collected immediately post intervention.[28]

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

| Author, Year<br>Sample Size<br>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 |
| *RCT* | | | | | | | | | | |
| **Sferra, 2021**[31]<br>*N* = 237<br>SDM discussion utilizing Option Grids vs shouldiscreen.com | - | - | - | ↓ | - | ↔ | - | - | - | ↔ |
| *Controlled Clinical Trial* | | | | | | | | | | |
| **Kukhareva, 2023**[29]<br>*N* = 2116<br>EHR prompts and integrated SDM tool (pre-post implementation of tool) | - | ↑ | - | - | - | - | - | - | - | - |
| *Cohort* | | | | | | | | | | |
| **Tanner, 2019**[20]<br>*N* = 137<br>In-person vs telephone SDM visit with printed materials, PLCOm2012 calculator, and shouldiscreen.com | - | ↔ | - | ↔ | - | - | - | ↔ | - | - |
| *Pre-Post* | | | | | | | | | | |
| **Han, 2019**[18]<br>*N* = 60<br>Option Grid 1-page FAQ and PLCOm2012 calculator | - | ↔ | - | - | - | - | - | - | - | - |
| **Ito Fukunaga, 2022**[28]<br>*N* =23<br>Option Grid 1-page FAQ | - | - | - | ↓ | - | - | - | - | - | NA* |

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

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

*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,[25,26] care coordinators,[27] and patient navigators.[30] SDM tools varied across studies: 3 studies used the Decision Counseling Program in some capacity,[25-27], 1 used Option Grid,[27] and another used a patient navigation program to introduce SDM to participants.[30] Two studies were RCTs,[27,30] 1 was a cohort study,[26] and 1 was a pre-post design.[25]

All studies were rated moderate or some concerns RoB. All 4 studies reported receipt of LCS,[25-27,30] 1 study reported decisional conflict/regret,[25] and 1 study reported receipt of additional tests/procedures.[30] 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,[27,30] 1 cohort study,[26] and 1 pre-post study assessed the number of individuals that completed at least 1 LCS appointment.[25] 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, $p = 0.12$).[27] 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 ($p < 0.001$)[30] 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 ($p = 0.0003$).[26]

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.[25]

#### *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.[25]

*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.[30]

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

| Author, Year<br>Sample Size<br>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 |
| *RCT* | | | | | | | | | | |
| **DiCarlo, 2022**[27]<br>*N* = 2376<br>Reviewed mailed material including printed Option Grid decision aid with care coordinator, with or without additional review of Decision Counseling Program vs usual care | - | ↑ | - | - | - | - | - | - | - | - |
| **DiCarlo, 2022**[27]<br>*N* = 628<br>Reviewed mailed material including printed Option Grid decision aid with care coordinator, with vs without additional review of Decision Counseling Program | - | ↔ | - | - | - | - | - | - | - | - |
| **Percac-Lima, 2018**[30]<br>*N* = 1200<br>Patient navigator program plus SDM vs usual care | - | ↑ | - | - | - | - | ↔ | - | - | - |
| *Cohort* | | | | | | | | | | |
| **Bittner Fagan, 2023**[26]<br>*N* = 80<br>Phone call guiding patient through Decision Counseling Program, followed by visit with PCP or LCS program | - | ↑ | - | - | - | - | - | - | - | - |
| *Pre-Post* | | | | | | | | | | |
| **Bittner Fagan, 2020**[25]<br>*N* = 28<br>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<br>Follow-Up | Total № of Participants (Studies) | Findings | Certainty | Importance |
|---|---|---|---|---|---|
| **Receipt of Lung Cancer Screening** | % receiving screening<br>280 days – 1 year | *N* = 3,547<br>(2 RCTs)[27,30] | 127/999 (12.7%) SDM tools plus care coordination vs 100/2548 (3.9%) usual care | ⊕⊕◯◯<br>Low[a,b] | **SDM tools combined with care coordination may result in increased receipt of lung cancer screening compared with usual care.** |
| **Decisional Conflict or Regret** | Decisional Conflict Scale<br>30 days | *N* = 28<br>(1 pre-post)[25] | Mean difference = -0.57 | ⊕◯◯◯<br>Very low[a,c] | **The evidence is very uncertain on the effect of SDM tools on decisional conflict/regret.** |

*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.[19,32-35]

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[19,35] and the remaining 3 were a pre-post design.[32-34]

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[19,35] and 1 pre-post study[33] 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.[35]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).[19] 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.[33]

##### *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).[19] 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.[36] 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[19] and 1 pre-post study[32] 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.[32]

*Quality of Communication*

Two pre-post studies[32,33] 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[32] 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[33] 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.[19,33-35] Each study created its own tool to assess knowledge and assessed knowledge at varying time points, from immediately[34] to 3 months[19] 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,[35] 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<br>Sample Size<br>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 |
| *RCT* | | | | | | | | | | |
| **Walsh, 2023**[35]<br>*N* = 66<br>LungCare delivered on tablet in waiting room prior to visit | - | ↑ | - | - | - | - | - | - | - | ↑ |
| **Schapira, 2023**[19]<br>*N* = 140<br>Web-based Lung Cancer Screening Decision Tool (LCSDecTool) used independently before clinic visit versus attention control | - | ↑ | - | ↔ | ↔ | - | - | - | - | ↑ |
| *Pre-Post* | | | | | | | | | | |
| **Flores, 2021**[32]<br>*N* = 15<br>Two 30-minute educational sessions led by a radiologist and mental health clinician | - | - | - | - | ↓ | 93% (satisfied with tool) | - | - | - | - |
| **Sakoda, 2020**[34]<br>*N* = 680<br>Group education class led by a specialist prior to a clinic visit | - | - | - | - | - | - | - | - | - | ↑ |
| **Mazzone, 2017**[33]<br>*N* = 423<br>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

↔ no difference between arms after receiving intervention

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

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

| Outcome | Measurement Tool<br>Follow-up | Total № of Participants (Studies) | Findings | Certainty | Importance |
|---|---|---|---|---|---|
| **Receipt of Lung Cancer Screening** | % receiving screening<br>2 months | *N* = 66<br>(1 RCT)[35] | 32% LungCare vs 13% usual care | ⊕◯◯◯<br>Very low[a,b] | **The evidence is very uncertain on the effect of LungCare on receipt of lung cancer screening compared with usual care.** |
| **Receipt of Lung Cancer Screening** | % receiving screening<br>6 months | *N* = 140<br>(1 RCT)[19] | 18 percentage point difference between LungCare and usual care | ⊕⊕◯◯<br>Low[b] | **LCSDecTool may result in increased lung cancer screening compared with usual care (attention control).** |
| **Quality of Communication** | Author-developed<br>Same day –1 month | *N* = 438<br>(2 pre-post)[32,33] | 93% and 86.4% described SDM tool positively | ⊕◯◯◯<br>Very low[a,c] | **The evidence is very uncertain on the effect of SDM tools on quality of communication.** |
| **Decisional Conflict/Regret** | Decisional Conflict Scale<br>3 months | *N* = 140<br>(1 RCT)[19] | 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), *p* = 0.33 | ⊕⊕◯◯<br>Low[b] | **LCSDecTool may result in little to no difference in distress/anxiety compared with usual care (attention control).** |
| **Distress/Anxiety** | State Trait Anxiety Index<br>3 months | *N* = 140<br>(1 RCT)[19] | No statistically significant difference between LungCare and usual care | ⊕⊕◯◯<br>Low[b] | **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.[23,37-39,40-42,43-47,48-50]

Authors utilized diverse tools. Four studies[23,37-39] utilized a version of shouldiscreen.com, 3 studies[40-42] used a decision aid video called "Lung Cancer Screening: Is It Right For Me?", 5 studies[43-47] used a variety of video and/or web based media, and the remaining 3 studies[48-50] used printed materials (Table 9). Seven studies were RCTs[37,41,45,46,48-50] and 9 were pre-post studies.[23,38-40,42-44,47] 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 |
|---|---|---|
| *RCT* | | |
| **Carter-Harris, 2020** | 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 |
| **Clark, 2022** | A 4.5-minute video decision aid including incidental findings information | Same video, without incidental findings information (4-min) |
| **Fraenkel, 2016** | Education on screening via 3 different formats: Numbers | Numbers plus icons;<br>numbers plus slides |
| **Robichaux, 2023** | Mailed letter, facemask, LCS brochure; second mailing including Native American traditional medicine and story book about traditional tobacco | Mailed letter, facemask, LCS brochure |
| **Sharma, 2018** | 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 |
| **Volk, 2020** | 9.5-minute narrated video "Lung Cancer Screening: Is It Right for Me?" | 2-page brochure from a lung cancer advocacy group |
| **Webster 2023** | Provided with shouldiscreen.com website when contacting Quitline | Provided with shouldiscreen.com printed materials when contacting Quitline |
| *Pre-Post* | | |
| **Crothers, 2016** | Review of shouldiscreen.com and printed pamphlet during focus groups | NA |
| **Hoffman, 2018** | "Lung Cancer Screening: Is It Right for Me?" viewed online | NA |
| **Lau, 2015** | Initial development of shouldiscreen.com | NA |
| **Lau, 2021** | Provided with shouldiscreen.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.[37,41,48,49] 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.[41] "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).[37,48,49] In their pre-post study, Reuland, 2018 reported that 10 out of 50 (20%) participants received LCS after viewing the SAILS Decision Aid.[47]

*Concordance of Decision*

Two pre-post studies reported on concordance, participants' LCS preference, and eligibility.[38,39] 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).[39] 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).[38]

*Decisional Conflict/Regret*

Two RCTs[37,41] and 4 pre-post studies[38-40,44] 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.[37-41,44] 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).[38,39] 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).[40,41] 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.[41] 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.[44] 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.[51] 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).[37]

*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."[37] 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[37,41,46] and 1 pre-post study[42] 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."[37] 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[46] 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."[42] Volk, 2014 also reported 78.8% of participants stated that they would be more interested in screening after viewing.[42] 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.[41]

*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.[47]

*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.[37] Authors reported that in the web version of shouldiscreen.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 shouldiscreen.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[37] and 2 pre-post studies[40,44] reported participants' need for additional information. In the RCT by Webster, 2023 comparing web and print versions of shouldiscreen.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.[37] 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).[40] 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).[44] The difference of 35.3 between time points was significant ($p < 0.0001$).

*Knowledge*

5 RCTs[37,41,45,46,50] and 7 pre-post studies[23,38-40,42,43,47] reported knowledge of screening benefits and harms as an outcome. Two studies utilized the 12-item LCS measure.[40,43] 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?"[40] 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]; $p = 0.00$).[43] Two studies utilized the Ottawa Decision Support Framework, or a measure derived from it, to measure change in knowledge after viewing shouldiscreen.com.[38,39] Both studies found statistically significant ($p < 0.001$) improvements in knowledge. While Lau, 2015[39] only reported the mean (SD) scores pre-intervention (7.5 [1.9]) and post-intervention (10.9 [2.2.]), Lau, 2021[38] reported a 1.4-point improvement after viewing the video compared with before viewing. Volk, 2020 utilized a questionnaire developed by Lowenstein et al[52] to measure the percentage of questions answered correctly at 6 months following use of a decision aid or standard education.[41] 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.[46] 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.[23,42,45,47,50] 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]; $p = 0.2$).[45] 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.[47] Fraenkel, 2015 compared the presentation of information on LCS in 3 different formats: numbers only, numbers + icon array, and numbers + slides on LCS scans.[50] 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?"[42] 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.[23] 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<br>Sample Size<br>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 |
| *RCT* | | | | | | | | | | |
| **Carter-Haris, 2020**[46]<br>*N* = 60<br>LungTalk vs generic info sheet on lung cancer screening from the ACS | - | - | - | - | - | 73% very satisfied (intervention), 28% very satisfied (comparator) | - | - | - | ↑ |
| **Clark, 2022**[45]<br>*N* = 348<br>Video decision aid with incidental findings segment vs video decision aid w/o incidental findings segment | - | - | - | - | - | - | - | - | - | ↑ |
| **Fraenkel, 2015**[50]<br>*N* = 253<br>Education interface on screening via numbers only vs numbers + icons, or numbers + slides | - | - | - | - | - | - | - | - | - | ↑ |
| **Robichaux, 2023**[48]<br>*N* = 469<br>Mailed letter, face mask, LCS brochure, & story about Native American traditional medicine vs LCS brochure alone | - | ↔ | - | - | - | - | - | - | - | - |
| **Sharma, 2018**[49]<br>*N* = 1000<br>LCS brochure with tear-off feature, in-depth messaging from quit line staff vs LCS brochure alone | - | ↔ | - | - | - | - | - | - | - | - |
| **Volk, 2020**[41]<br>*N* = 516<br>"Lung Cancer Screening: Is It Right for Me?" video vs standard educational material | - | ↔ | - | ↔ | - | 87.2% (sufficient info) | - | - | - | ↑ |

| Author, Year<br>Sample Size<br>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 |
| **Webster, 2023**[37]<br>*N* = 298<br>Shouldiscreen.com print vs web | - | ↔ | - | ↔ | ↔ | No differences (preparedness or clarity) | - | ↔ | ↔ | ↔ |
| *Pre-Post* | | | | | | | | | | |
| **Crothers, 2016**[23]<br>*N* = 45<br>Shouldiscreen.com, printed pamphlet | - | - | - | - | - | - | - | - | - | ↑ |
| **Hoffman, 2018**[40]<br>*N* = 30<br>"Lung Cancer Screening: Is It Right for Me?" video | - | - | - | ↓ | - | - | - | - | ↑ | ↑ |
| **Lau, 2015**[39]<br>*N* = 60<br>Initial development of shouldiscreen.com | - | - | ↑ | ↓ | - | - | - | - | - | ↑ |
| **Lau, 2021**[38]<br>*N* = 74<br>Shouldiscreen.com | - | - | ↑ | ↓ | - | - | - | - | - | ↑ |
| **Reuland, 2018**[47]<br>*N* = 50<br>6-min SAILS decision aid video | - | 10 participants | - | - | - | - | 1 participant | - | - | ↑ |
| **Strong, 2020**[43]<br>Educational YouTube video on LCS | - | - | - | - | - | - | - | - | - | ↑ |
| **Studts, 2020**[44]<br>Online educational narrative coupled with decisional regret exercise | - | - | - | ↓ | - | - | - | - | ↓ | - |
| **Volk, 2014**[42]<br>"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<br>Follow-up | № of Participants (Studies) | Findings | Certainty | Importance |
|---|---|---|---|---|---|
| **Receipt of Lung Cancer Screening** | % receiving screening<br>6 months | 516<br>(1 RCT)[41] | 57/259 (22%) SDM vs 68/257 (26.5%) LCS brochure | ⊕⊕⊕⊕<br>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<br>6 months | *N* = 298<br>(1 RCT)[37] | 11.0% shouldiscreen.com web vs 11.2% shouldiscreen.com print | ⊕◯◯◯<br>Very low[a,b] | **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<br>4-6 months | 1469<br>(2 RCTs) [48,49] | 41/734 (5.6%) LCS brochure + additional materials vs 40/735 (10.9%) LCS brochure alone | ⊕◯◯◯<br>Very low[c,d] | **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.** |
| **Concordance of Decision** | Ottawa Decision Support Framework<br>0 days | *N* = 60<br>(1 pre-post)[39] | 23.7% concordant pre-intervention vs 59.3% concordant post-intervention | ⊕◯◯◯<br>Very low[e] | **The evidence is very uncertain on the effect of SDM tools on concordance of decision.** |
| | Question from Decisional Conflict Scale<br>6 months | *N* = 74<br>(1 pre-post)[38] | 21% concordant pre-intervention vs 33% concordant post-intervention | ⊕◯◯◯<br>Very low[f,g] | **The evidence is very uncertain on the effect of SDM tools on concordance of decision.** |
| **Decisional Conflict/Regret** | Decisional Conflict Scale (Informed and Values Clarity subscales)<br>1 week | *N* = 516<br>(1 RCT)[41] | Mean difference -14.1 | ⊕⊕⊕⊕<br>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<br>4 months | *N* = 298<br>(1 RCT)[37] | 2.9 shouldiscreen.com web vs 2.7 shouldiscreen.com print | ⊕◯◯◯<br>Very low[a,h] | **The evidence is very uncertain on the effect of shouldiscreen.com web compared with shouldiscreen.com print on decisional conflict and regret.** |
| **Distress/Anxiety** | Author-developed<br>4 months | *N* = 298<br>(1 RCT)[37] | 52.2% shouldiscreen.com web vs 54.4% shouldiscreen.com print were distressed/anxious | ⊕⊕◯◯<br>Low[a] | **Shouldiscreen.com web may cause little to no difference compared with shouldiscreen.com print on distress/anxiety.** |

| Outcome | Measurement Tool<br>Follow-up | № of Participants (Studies) | Findings | Certainty | Importance |
|---|---|---|---|---|---|
| **Quality of Communication** | Author-developed<br>1 week | *N* = 60<br>(1 RCT)[46] | 73% SDM tool very satisfied vs 28% usual care, no difference in preparedness | ⊕⊕◯◯<br>Low[f,i] | **LungTalk may result in little to no difference in quality of communication compared with non-tailored LCS information sheet.** |
| | Author-developed<br>4 months | *N* = 298<br>(1 RCT)[37] | 25.6% shouldiscreen.com web vs 33.3% shouldiscreen.com print were confused by the material | ⊕◯◯◯<br>Very low[a,j] | **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 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.[53,54]

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).[53]

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.[54]

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

| Outcome | Measurement Tool Follow-up | Total № of Participants (Studies) | Findings | Certainty | Importance |
|---|---|---|---|---|---|
| **Adherence** | Participants with complete lung cancer screening claim within 15 months of SDM claim | *N* = 7193 (1 observational) [53] | OR = 1.25, 95% CI [1.01, 1.54] | ⊕◯◯◯ Very low[a] | **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.** |
| **Receipt of Lung Cancer Screening** | Participants with complete lung cancer screening claim within 3 months of SDM claim | *N* = 19,221 (1 observational) [54] | 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[a] | **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[27,30,35] and 1 cohort study[26]) 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).[35]

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).[27] 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.[30] 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).[26] 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 № of Participants (Studies) | Findings | Certainty | Importance |
|---|---|---|---|---|---|
| **Receipt of Lung Cancer Screening** | % receiving screening 280 days – 1 year | *N* = 3,547 (2 RCTs)[27,30] | 127/999 (12.7%) SDM tools vs 100/2548 (3.9%) usual care | ⊕⊕◯◯ Low[a,b] | **SDM tools may result in increased receipt of lung cancer screening compared with usual care.** |
| | % receiving screening 2 months | *N* = 66 (1 RCT)[35] | 32% LungCare vs 13% control | ⊕◯◯◯ Very low[a,c] | **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)[26] | 45.3% telephone DCP with counselor plus mailed educational material plus SDM discussion with PCP or LCS program vs 0% usual care | ⊕◯◯◯ Very low[a,d] | **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,[30,35] 1 trial assessed both efficacy and comparative effectiveness,[27] and 9 trials assessed comparative effectiveness (Table 14).[19,31,37,41,45,46,48-50] One RCT included an intervention that involved a conversation with a physician and the utilization of a decision aid.[31] Two RCTs included interventions that non-physician health care workers used to help guide SDM discussions.[27,30] Two RCTs included patient-facing tools or materials that were used prior to or during an SDM visit.[19,35] The remaining 7 RCTs included interventions that were patient-facing tools or materials that were meant to generate an SDM visit.[37,41,45,46,48-50] 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<br>Sample Size<br>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 |
| *Effectiveness* | | | | | | | | | | |
| **DiCarlo, 2022**[27]<br>*N* = 2376<br>Reviewed mailed material including printed Option Grid ™ decision aid with care coordinator, with or without additional review of Decision Counseling Program vs usual care | - | ↑* | - | - | - | - | - | - | - | - |
| **Walsh, 2023**[35]<br>*N* = 66<br>LungCare delivered on tablet in waiting room prior to visit vs usual care | - | ↑ | - | - | - | - | - | - | - | ↑ |
| **Percac-Lima, 2018**[30]<br>*N* = 1200<br>Navigators contacted patients about SDM vs usual care | - | ↑ | - | - | - | - | ↔ | - | - | - |
| *Comparative Effectiveness – Mode of Delivery* | | | | | | | | | | |
| **Robichaux, 2023**[48]<br>*N* = 469<br>Mailed letter, face mask, LCS brochure, & story about Native American traditional medicine vs LCS brochure alone | - | ↔ | - | - | - | - | - | - | - | - |
| **Webster, 2023**[37]<br>*N* = 298<br>Shouldiscreen.com print vs web | - | ↔ | - | ↔ | ↔ | No differences (prepared-ness or clarity) | - | ↔ | ↔ | ↔ |
| **Sharma, 2018**[49]<br>*N* = 1000<br>LCS brochure with tear-off feature, in-depth messaging from quit line staff vs LCS brochure alone | - | ↔ | - | - | - | - | - | - | - | - |

| Author, Year<br>Sample Size<br>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 |
| *Comparative Effectiveness – Decision aid vs. educational tool* | | | | | | | | | | |
| Schapira, 2023[19]<br>*N* = 140<br>Lung Cancer Screening Decision Tool (LCSDecTool) used independently before clinic visit vs general information on cancer screening + USPSTF lung and other cancer guideline | - | ↑ | - | ↔ | ↔ | - | - | - | - | ↑ |
| **Carter-Haris, 2020**[46]<br>*N* = 60<br>LungTalk vs generic information sheet without LCS developed by ACS | - | - | - | - | - | 73% very satisfied (intervention), 28% very satisfied (comparator) | - | - | - | ↑ |
| **Clark, 2022**[45]<br>*N* = 348<br>Video decision aid about incidental findings vs video aid w/o incidental findings | - | - | - | - | - | - | - | - | - | ↑ |
| **Fraenkel, 2015**[50]<br>*N* = 253<br>Education on screening via numbers vs. numbers + icons vs numbers + slides | - | - | - | - | - | - | - | - | - | ↑ |
| **Volk, 2020**[41]<br>*N* = 516<br>"Lung Cancer Screening: Is It Right for Me?" video vs standard educational material | - | ↔ | - | ↔ | - | 87.2% (sufficient info) | - | - | - | ↑ |
| **DiCarlo, 2022**[27]<br>*N* = 628<br>Reviewed mailed material including printed Option Grid decision aid with care coordinator, with versus without | - | ↔* | - | - | - | - | - | - | - | - |

| Author, Year<br>Sample Size<br>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 | | | | | | | | | | |
| *Comparative Effectiveness – Decision aid vs Decision Aid* | | | | | | | | | | |
| **Sferra, 2021**[31]<br>*N* = 237<br>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).[27,30,35] Interventions included a video administered on a touch tablet titled LungCare plus care coordination,[35] outreach with mailed educational information with or without a telephone administered tool called Decision Counseling,[27] and a patient navigation program with education materials.[30] 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[30] and another trial reported LCS knowledge.[35] All 3 RCTs reported that those in the intervention arm had a significantly higher uptake of LCS than those in the control arm.[27,30,35] The single trial that measured knowledge found that those in the intervention arm had significantly higher knowledge scores than the usual care arm.[35]

One trial[30] 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<br>Risk of Bias<br>Follow-Up | Intervention | Comparator | Mode of Delivery; Patient or Provider Facing | Tool Domains |
|---|---|---|---|---|
| **Walsh, 2023[35]**<br>Some concerns<br>2 months | LungCare Video provided to patient on tablet in waiting room | Usual care | Web-video;<br>Patient-facing | Eligibility for lung cancer screening; what screening is; individual risk for lung cancer screening; where to get screening; time commitment; harms |
| **DiCarlo, 2022[27]**<br>Some concerns<br>280 days | Outreach with mailed educational information plus telephone Decision Counseling Program | Usual care | Person and print;<br>Patient and Provider facing | Eligibility for lung cancer screening; what screening is; harms |
| **Percac-Lima, 2018[30]**<br>Some concerns<br>1 year | A patient navigation program that included SDM | Usual care | Person and print;<br>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 |
|---|---|---|---|---|---|
| *LCS Navigator Facing* | | | | | |
| **Receipt of Lung Cancer Screening** | % receiving screening *280 days – 1 year* | *N* = 3,547 (2 RCTs)[27,30] | 127/999 (12.7%) SDM tools plus care coordination vs 100/2548 (3.9%) usual care | ⊕⊕◯◯ Low[a,b] | **SDM tools combined with care coordination may result in increased receipt of LCS compared with usual care.** |
| *Patient Facing During or Prior To Visit* | | | | | |
| **Receipt of Lung Cancer Screening** | % receiving screening *2 months* | *N* = 66 (1 RCT)[35] | 32% LungCare vs 13% usual care | ⊕◯◯◯ Very low[a,c] | **The evidence is very uncertain on the effect of LungCare on receipt of lung cancer screening 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. 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[19,27,31,37,41,45,46,48-50]; 8 of the interventions were patient facing[19,37,41,45,46,48-50] and 2 were meant to be viewed by both the patient and health care provider.[27,31] 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.[37,48,49] The remaining 7 trials compared the decision aid to an educational tool/material/activity.[19,27,31,41,45,46,50] 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.[48] Webster, 2023 investigated differences in uptake and understanding when shouldiscreen.com was provided in an online or print format.[37] 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.[49] 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[37] 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.[19,27,41,45,46,50] Another RCT, by Sferra, 2021,[31] compared 2 different decision aids, Option Grid and shouldiscreen.com. Five of the 6 trials measured knowledge.[19,41,45,46,50] 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[31] 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.[19,27,41] 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. [27,41] 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.[19]

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

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.[41,46] The third trial reported no significant difference in assessment of the quality of the decision aid when comparing shouldiscreen.com to Option Grids.[31]

## Table 17. Comparative Effectiveness RCTs Study Characteristics

| Author, Year<br>Risk of Bias<br>Follow-Up | Intervention | Comparator | Mode of Delivery<br>Patient or Provider Facing | Tool Domains |
|---|---|---|---|---|
| **Robichaux, 2023**[48]<br>Low<br>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<br>Patient facing | Eligibility for LCS, what screening is, individual risk for LC, and where to get screening |
| **Webster, 2023**[37]<br>High<br>4 months | Shouldiscreen.com | Print version of shouldiscreen.com | Web<br>Patient facing | Eligibility for LCS, what screening is, individual risk for LC, cost, where to get screening, time commitment, harms, and other risk factors |
| **Schapira, 2023**[19]<br>Low<br>9 months | LCSDecTool | 10-page general information on cancer prevention and the USPSTF screening guidelines for breast, colon, cervical, and lung cancer | Web<br>Patient facing | Eligibility for LCS, what screening is, individual risk for LC, cost, where to get screening, time commitment, harms, and other risk factors |
| **DiCarlo, 2022**[27]<br>Some concerns<br>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)<br>Patient facing | Eligibility for LCS, what screening is, and harms |
| **Clark, 2022**[45]<br>Some concerns<br>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<br>Patient facing | What screening is, costs, and harms |
| **Sferra, 2021**[31]<br>Some concerns<br>6 months | Optiongrid.org | Shouldiscreen.com | Web<br>Patient facing | Eligibility for LCS, what screening is, individual risk for LC, cost, where to get screening, time commitment, harms, and other risk factors |
| **Carter-Harris, 2020**[46]<br>Some concerns<br>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<br>Patient facing | What screening is and harms |
| **Volk, 2020**[41]<br>Some concerns<br>6 months | Lung Cancer Screening: Is it Right for Me? | Standard educational material brochure from a lung cancer advocacy group | Web<br>Patient facing | Eligibility for LCS, what screening is, harms, and other risk factors |
| **Sharma, 2018**[49]<br>High<br>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)<br>Patient facing | Eligibility for LCS, what screening is, and costs |

| Author, Year<br>Risk of Bias<br>Follow-Up | Intervention | Comparator | Mode of Delivery<br>Patient or Provider Facing | Tool Domains |
|---|---|---|---|---|
| **Fraenkel, 2015**[50]<br>High<br>0 days | Numbers + a set of slides illustrating LDCT scans of 250 people in random order | Numbers + icon array or numbers only | Print<br><br>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<br>Follow-up | Total № of Participants (Studies) | Findings | Certainty | Importance |
|---|---|---|---|---|---|
| *Clinician Facing* | | | | | |
| **Decisional Conflict or Regret** | Ottawa Decision Regret Scale<br>*6 months* | *N* = 237<br>(1 RCT)[31] | Mean scores 6.0 (Option Grids) vs 10.2 (shouldiscreen.com), *p* = 0.02 | ⊕⊕◯◯<br>Low[a,b] | **Option Grids may result in less decisional conflict or regret compared with shouldiscreen.com.** |
| **Quality of Communication** | CollaboRATE<br>*6 months* | *N* = 237<br>(1 RCT)[31] | Mean scores 97.4% (Option Grids) vs. 98.6% (shouldiscreen.com), *p* = 0.6 | ⊕⊕◯◯<br>Low[a,b] | **There may be little to no difference in quality of communication in SDM using Option Grids compared with shouldiscreen.com.** |
| *Patient Facing During or Prior To Visit* | | | | | |
| **Receipt of Lung Cancer Screening** | % receiving screening<br>*6 months* | *N* = 140<br>(1 RCT)[19] | 18% difference between LungCare and usual care | ⊕⊕◯◯<br>Low[c] | **LCSDecTool may result in increased lung cancer screening compared with usual care.** |
| **Decisional Conflict/Regret** | Decisional Conflict Scale<br>*3 months* | *N* = 140<br>(1 RCT)[19] | 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), *p* = 0.33) | ⊕⊕◯◯<br>Low[c] | **LCSDecTool may result in little to no difference in distress/anxiety compared with usual care.** |
| **Distress/ Anxiety** | Strate Trait Anxiety Index<br>*3 months* | *N* = 140<br>(1 RCT)[19] | No statistically significant difference between LungCare and usual care | ⊕⊕◯◯<br>Low[c] | **LCSDecTool may result in little to no difference in distress/anxiety compared with usual care.** |
| *Patient Facing to Generate a Visit* | | | | | |
| **Receipt of Lung Cancer Screening** | % receiving screening<br>*6 months* | *N* = 516<br>(1 RCT)[41] | 57/259 (22%) SDM tools vs 68/257 (26.5%) usual care | ⊕⊕⊕⊕<br>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.** |
| **Decisional Conflict / Regret** | Decisional Conflict Scale<br>*1 week* | *N* = 516<br>(1 RCT)[41] | Mean difference -14.1 | ⊕⊕⊕⊕<br>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.** |
| **Quality of Communication** | Author-developed<br>*1 week* | *N* = 60<br>(1 RCT)[46] | 73% SDM tool very satisfied vs 28% usual care, no difference in preparedness | ⊕⊕◯◯<br>Low[a,e] | **LungTalk may result in little to no difference in quality of communication compared with nontailored LCS information sheet.** |

| Outcome | Measurement Tool<br>Follow-up | Total № of Participants (Studies) | Findings | Certainty | Importance |
|---|---|---|---|---|---|
| *Patient Facing to Generate a Visit* | | | | | |
| **Receipt of Lung Cancer Screening** | % receiving screening<br>*6 months* | *N* = 298<br>(1 RCT)[37] | 11.0% SDM web vs 11.2% SDM print | ⊕◯◯◯<br>Very low[b,c] | **The evidence is very uncertain on the effect of SDM web compared to SDM print on receipt of lung cancer screening.** |
| **Decisional Conflict / Regret** | Health care Decisions Scale<br>*4 months* | *N* = 298<br>(1 RCT)[37] | 2.9 SDM web vs 2.7 SDM print | ⊕◯◯◯<br>Very low[b,d] | **The evidence is very uncertain on the effect of SDM web compared to SDM print on decisional conflict and regret.** |
| **Distress/ Anxiety** | Author-developed<br>*4 months* | *N* = 298<br>(1 RCT)[37] | 52.2% SDM web vs 54.4% print were distressed/anxious | ⊕⊕◯◯<br>Low[b] | **shouldiscreen.com web may cause little to no difference compared with shouldiscreen.com print on distress/anxiety.** |
| **Quality of Communication** | Author-developed<br>*4 months* | *N* = 298<br>(1 RCT)[37] | 25.6% SDM web vs 33.3% SDM print were confused by the material | ⊕◯◯◯<br>Very low[b,e] | **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.[21,22,55-60] 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.[18] All but 1 study[18] interviewed health care providers, and 4 studies interviewed patients (Table 19).[18,21,22,57]

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[18,21,56-58] identified a specific tool and the remaining 4 assessed SDM as a concept, as multiple tools were in place.[22,55,59,60] 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,[55,56,58,60] 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."[56] The second CFIR domain was innovation recipients, with a number of studies reporting a theme around patients' reticence and lack of engagement with SDM[22,55,57,59,60] and patients' negative response to the SDM.[18,21,59,60] 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."[60] 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.[55,58,61]

Of the included qualitative studies, 5 captured a VA patient population or VA health care providers.[21,22,55,56,60] 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."[55] 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 |
|---|---|---|---|---|---|---|---|
| **Herbst*, 2023**[55] | Low | ✓ | | 15 | 7 | Ethnographic | Any SDM tool used currently in clinic |
| **Lowery*, 2022**[56] | High | ✓ | | 33 | 8 | Inductive thematic content analysis | SDM tool called Decision Precision |
| **Schapira*, 2022**[21] | High | ✓ | ✓ | 42 | 1 | Thematic analysis | SDM tool called LCSDecTool |
| **Martinez, 2022**[57] | Low | ✓ | ✓ | 40 | 1 | Grounded theory approach | LCS-LDCT Smart Set (a pre-programmed Epic tool) |
| **Reese, 2022**[58] | 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 |
| **Abubaker-Sharif, 2022**[59] | High | ✓ | | 16 | 1 | Thematic analysis | Any SDM tool (used Decision Counseling Program as an example) |
| **Melzer*, 2020**[60] | Low | ✓ | | 24 | 3 | Directed content analysis | Any SDM tool used currently in clinic |
| **Han, 2019**[18] | Low | | ✓ | 17 | 1 | Inductive qualitative methods | A lung cancer risk calculator |
| **Wiener*, 2018**[22] | 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<br>CFIR Construct | ☹ Barrier<br>☺ Facilitator | Barrier or Facilitator Description |
|---|---|---|
| ***I. Innovation Domain*** | | |
| Adaptability | ☹☺ | 3 studies reported that **tailoring of the information to the participant** was important,[22,59,60] including developing tools in **other languages.**[59] |
| Complexity | ☹ | 1 study noted the **complexity of SDM**, and the multiple factors needed to know to guide the conversation (patient education, elicitation of personal values, knowing participant risk).[59] |
| Design | ☹ | 2 studies reported the **design of the tool** was a barrier (difficult to navigate and medical terminology difficult for patient to understand,[21] inputting data during visit to calculate risk[56]). |
| | ☺ | 1 study suggested the **use of any tool** prior to a visit would enable SDM.[58] |
| Evidence Base | ☹ | 1 study reported clinicians were **surprised by low specificity of LDCT and frequency of false positives** resulting in unnecessary procedures and major complications.[58] |
| ***II. Outer Setting Domain*** | | |
| External Pressure<br>*Performance Measurement* | ☹☺ | 2 studies reported **organizational priorities or pressure** 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).[56,58] |
| | ☹ | 1 study reported clinicians felt **pressure to demonstrate the value of a dedicated LCS coordinator.**[55] |
| Local Attitudes | ☹ | 2 studies reported clinicians felt **smoking history documentation in the EHR was inaccurate.**[57,58] |
| ***III. Inner Setting Domain*** | | |
| Access to Knowledge and Information | ☹ | 2 studies reported clinicians had **little or no knowledge of health care system initiatives**[55] or lacked knowledge about logistics of an LCS program.[59] |
| Available Resources | ☹ | 4 studies reported that **time constraints** were a significant barrier.[55,56,58,60] |
| | ☺ | 1 study suggested **a decision aid would benefit patients and providers.**[57] |
| Communications | ☹ | 1 study reported **lack of communication** about goals and structure led to confusion about how to implement elements of a lung cancer screening program.[55] |
| Culture | ☹ | 1 study reported clinicians perceived the value of screening as high, therefore **limited information about harms and emphasized benefits** during SDM discussions.[55] |
| | ☹ | 1 study noted the **difficulty in having screening conversations** with patients who are unlikely to be receptive.[59] |
| Relative Priority | ☹ | 3 studies noted that SDM **may not be as high a priority** compared to competing demands such as other preventive screening or patient specific needs.[55,56,58] |
| Structural Characteristics | ☺ | 2 studies reported **integrating the SDM tool into the EHR** would be beneficial, to obtain patient information and facilitate reminders.[55,58] |
| *IT Infrastructure* | ☹ | 1 reported difficulties in integration, especially regarding ordering LDCT.[57] |
| ***IV. Individuals Domain*** | | |
| Capability | ☹ | 3 studies reported on the clinicians' perceived capability to engage in SDM, including conflation of SDM with patient education,[55] difficulties with eligibility criteria,[57] and being unaware of insurance requirements or reimbursements.[58] |
| Innovation Deliverers | ☹ | 1 study reported that **clinicians' personal experiences** led to promotion of screening, regardless of guidelines recommending screening.[55] |

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

*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). 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.[23] 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.[19,20] 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 is doesn't seem like there's much of a decision."[55] 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.[62]

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).[63] 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.[5-7] 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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