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

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PREFACE

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

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

ACKNOWLEDGMENTS

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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
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Technical Expert Panel

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

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Disclosures

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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.

Executive Summary

KEY FINDINGS

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

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

BACKGROUND

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

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

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

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

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

CURRENT REVIEW

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

Key Questions

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: i. age, race/ethnicity, comorbidities, current smoking status, socioeconomic status/education, residency, geographic region, rural/urban ii. primary care, smoking cessation, prevention clinics, public forums
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?

METHODS

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

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

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

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

RESULTS

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

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

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

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

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

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

CONCLUSIONS

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

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

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

ES Table. Certainty of Evidence Ratings

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

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

GRADE Working Group grades of evidence:
High certainty: We are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: We are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: Our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: We have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations:

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

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

c. Rated up 1 level for magnitude of effect.

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

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

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

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

h. Rated down 2 level for indirectness (study population included participants not eligible for LCS).

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

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