CLINICAL STUDY PROTOCOL

Understanding Shared Decision-Making in Lung Cancer Screening (DECIDE)

Protocol Version

10.31.2022

version 2

Please note the data for this study has already been collected at my prior institution and the only activity occurring at present is data analysis.

Study Personnel

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Protocol Development support (if applicable): Name, Title

Name and information of sponsor: National Cancer Institute, Grant #R01CA222090

Research Locations (all non-HMH locations):

Kaiser Permanente Washington Health Research Institute

1800 Minor Avenue

Abbreviations

Abbreviation	Explanation
SDM	Shared Decision Making
LCS	Lung Cancer Screening
LDCT	Low-dose computed tomography
KPWA	Kaiser Permanente Washington

Revision History

Revision #	Version Date	Summary of Changes	Consent Change?

Summary

Please note the data for this study has already been collected at my prior institution and the only activity occurring at present is data analysis.

Study Title	Understanding Shared Decision-Making in Lung Cancer Screening (DECIDE Study)
Study Design	Cross-sectional, survey
Primary Objective	1) Decision quality, 2) Lung cancer screening completion, and 3) Advances in stage of adoption for smoking cessation among individuals who currently smoke
Secondary Objective(s)	n/a
Research Intervention(s)	n/a
Study Population	Adults aged 55-80 years who currently smoke or quit within the past 15 years with a 30 pack-year tobacco smoking history
Sample Size	552
Study Duration for individual participants	6 months

1 – Introduction

Our long-term goal is to develop the next generation of decision support tools, including alternative communication strategies, for clinicians and patients to use for lung cancer screening decisions.

This project specifically seeks to identify the components of patient-clinician discussions about lung cancer screening that contribute to high quality decisions and subsequent important behavioral outcomes (screening completion among patients who decide to screen; stage-of-readiness advancement for smoking cessation among current smokers).

Our central hypothesis was that patients who perceive lung cancer screening discussions with their clinician as shared/mutual will have positive decisional and behavioral outcomes. The behavioral outcomes we are evaluating are consistent

with recent findings linking lung cancer screening with improved smoking cessation rates.

We are examining clinician and patient factors simultaneously by collecting patient and clinician survey data and integrating it with patient EHR data.

2 – Background

2.1. Background/literature review (make sure you provide references)

a. Scientific Background

Provide the scientific or scholarly background for, rationale for, and significance of the research based on the existing literature and how will it add to existing knowledge. A short list of references or bibliography must be included as part of this document, uploaded separately, or provide the relevant page number(s) of the grant where references or bibliography can be found.

Lung cancer kills more people in the U.S. than any other cancer, primarily because most people are diagnosed at an advanced stage where treatment options are limited, and mortality is high. Lung cancer screening is a complex issue because there are associated risks and potential harms including false-positive results, over-diagnosis, and incidental findings that can lead to a cascade of follow-up tests and treatments. The decision to screen for lung cancer is not straightforward and is the epitome of a preference-sensitive cancer screening decision best made in the context of SDM. Multiple professional organizations advocate for SDM in lung cancer screening,[1,2] and in an unprecedented move, Medicare mandated SDM documentation for screening reimbursement. SDM has been studied in other types of cancer screening but has focused primarily on screening *behavior* as opposed to the decision-making process.

SDM is viewed as the pinnacle of patient-centered care and resonates with the ethical imperative of respect for patient autonomy and engagement.[3] Epstein and Street's summary of the evidence on patient-centered communication posits clinical encounters between a patient and clinician should be based upon collaboration and deliberation.[4] Research advancing the science of SDM has been thwarted primarily because the process of SDM has become somewhat synonymous with patient decision aids. The prevailing belief that information exchange via patient decision aids would enhance the patient-clinician collaborative process has resulted in studies that narrowly focused on the effects of decision aids rather than understanding the causal mechanisms between SDM and patient decisional and behavioral outcomes.[5] This project focuses on the critical components of SDM and factors associated with positive patient decisional and behavioral outcomes essential to advancing the state of the science in lung cancer screening decisions.

1. Wender R, Fontham ET, Barrera Jr, E, et al. American Cancer Society lung cancer screening guidelines. CA Cancer J Clin. 2013;63(2):107-117. PMCID: PMC3632634

2. Bach PB, Mirkin JN, Oliver TK, et al. Benefits and harms of CT screening for lung cancer: a systematic review. JAMA 2012;307(22):2418–2429. PMCID: PMC3709596

3. Crossing the quality chasm: A new health system for the 21st century. Institute of Medicine (US) Committee on Quality of Health Care in America. Washington (DC): National Academy Press (US); 2001. PMID:25057539

4. Epstein RM, Street RL. Patient-Centered Communication in Cancer Care: Promoting Healing and Reducing Suffering. NIH Publication No. 07-6225. Bethesda, MD: National Cancer Institute. 2007, Retrieved from: https://healthcaredelivery.cancer.gov/pcc/pcc_monograph.pdf

5. Shay LA, Elston Lafata J. Where is the evidence? A systematic review of shared decision making and patient outcomes. *Med Decis Making*. 2015;35(1):114-131. PMCID: PMC4270851

3 – Rationale, Objectives and Hypothesis

3.1. Study Rationale/Problem Statement/Research question or Study significance

This project specifically seeks to identify the components of patient-clinician discussions about lung cancer screening that contribute to high quality decisions and subsequent important behavioral outcomes (screening completion among patients who decide to screen; stage-of-readiness advancement for smoking cessation among current smokers)

3.2. Hypothesis (if applicable)

Our central hypothesis was that patients who perceive lung cancer screening discussions with their clinician as shared/mutual will have positive decisional and behavioral outcomes. The behavioral outcomes we are evaluating are consistent with recent findings linking lung cancer screening with improved smoking cessation rates.

3.3. Primary Objective

Aim 1. Use survey and EHR data to identify clinician factors that predict: a) patient-perceived lung cancer screening decision quality; b) screening completion among patients deciding to screen; and c) stage of readiness for smoking cessation among current smokers. *Hypothesis 1: Increased clinician knowledge, positive attitude toward lung cancer screening, positive attitude toward shared decision making (SDM), decreased clinician perceived barriers, and high lung cancer screening referral propensity predict higher decision quality, screening completion, and advances in stage of readiness for cessation.*

Aim 2. Use survey and EHR data to identify patient factors that predict: a) patient-perceived lung cancer screening decision quality; b) screening completion among patients deciding to screen; and c) stage of readiness for smoking cessation among current smokers. *Hypothesis 2: Patient-perceived stigma and medical mistrust predict decreased decision quality, screening completion, and advances in stage of readiness for cessation.*

3.4. Primary Outcome Variable(s)

a) patient-perceived lung cancer screening decision quality; b) screening completion among patients deciding to screen; and c) stage of readiness for smoking cessation among current smokers

4 - Study Design

Please note the data for this study has already been collected at my prior institution and the only activity occurring at present is data analysis. The following is offered for context:

4.1 General Design

DECIDE is a descriptive, observational study that includes two populations:

1. KPWA primary care providers (PCP - MDs, DOs, PAs and ARNPs), who have documented, in EPIC, at least one lung cancer screening SDM conversation with an eligible KPWA patient.
2. KPWA patients who have recently engaged in a documented LCS SDM conversation with a KPWA PCP.

Both populations were invited to participate in a survey (two different surveys for the two different populations), regarding their opinions about and experiences with the LCS SDM process. Prospective LCS-related clinical data about the patient participants were collected for 12 subsequent months after they completed the study survey to determine whether they screen, the outcome of their screening and any use of smoking cessation services.

Data from the surveys and electronic medical records will be used to determine where improvements can be made in the SDM for LCS space and to help work toward the goal of developing revised or new tools for this process.

4.1.1 Study Duration (if applicable)

Total study duration = 5 years (2018-2023). Participants were enrolled in the study and had one follow-up time point in the study at 6 months post shared decision making discussion with their primary care clinician.

4.1.2 Number of Study Sites 1

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4.2 Study Population

This was a descriptive, observational study that included two populations:

1. KPWA primary care providers (PCP - MDs, DOs, PAs and ARNPs), who have documented, in EPIC, at least one lung cancer screening SDM conversation with an eligible KPWA patient.
2. KPWA patients who have recently engaged in a documented LCS SDM conversation with a KPWA PCP.

4.2.2. Eligibility Criteria

a. Inclusion criteria

Provider Inclusion Criteria:

- KPWA primary care provider (Family Practice or Internal Medicine)
- MD, DO, ARNP or PA
- Has documented at least one SDM for LCS in a patient EMR since KP (GH) program rollout in January 2015.

Patient Inclusion Criteria

- KP-enrolled
- Meet LCS eligibility criteria (age 55-80, 30+ pack years cigarette smoking, current smoker or quit in past 15 years)
- Had EMR-documented LCS SDM conversation with a KPWA PCP in the past month

b. Exclusion criteria

- Anyone who is on KPWHRI's Do Not Contact list
- Patients who engaged an interpreter during the visit at which the LCS for SDM conversation took place

4.2.3. Vulnerable populations (if applicable). Vulnerable populations include children, prisoners, cognitively impaired individuals, economically or educationally disadvantaged individuals, employees, students. When vulnerable populations are included, indicate what safeguards are in place to minimize coercion or undue influence to participate.

n/a

4.2.4. Withdrawal criteria (as applicable)

n/a

4.3. Study procedures

n/a (data collection completed at prior institution; currently analyzing de-identified data only)

4.3.a. Subject Identification

n/a (data collection completed at prior institution; currently analyzing de-identified data only)

4.3.b. Data for Identification

n/a (data collection completed at prior institution; currently analyzing de-identified data only)

4.3.c. Screening and Recruitment Process

n/a (data collection completed at prior institution; currently analyzing de-identified data only)

4.3.1. Study discontinuation (if applicable) n/a

4.3.2. Concomitant medication (if applicable) n/a

4.4. Risks and Benefits

n/a (data collection completed at prior institution; currently analyzing de-identified data only)

5 – Methods

Sample Size Justification and Power Analysis. We enrolled 125 primary care providers and 553 patients. Power calculations were performed via simulation studies with a two-sided significance level set to 0.05. These power simulations accounted for the anticipated subsamples for the patient behavioral outcomes (for example, stage of readiness for smoking cessation and the fact that only current smokers will contribute data for this outcome). Based on this sample size, we are appropriately powered for fully testing the associations in Aims 1 and 2 with at least 80% power. Specifically, for the continuous outcomes, we are appropriately powered for testing the effect of an unbalanced binary variable with prevalence 25% or 75% and an adjusted standardized coefficient of at least 0.2, based on a linear mixed-effects model. Additionally, we are sufficiently powered in terms of the binary outcomes of the aims, for testing the effect of an unbalanced binary independent variable with a prevalence of 25% or 75% and an (adjusted) odds ratio (OR) at least 2.5, using a mixed-effects logistic model. The tests for the continuous independent variables are expected to be more powerful for a given effect size in both continuous and binary outcomes.

Quantitative Data Analysis and Interpretation. Our analyses were being defined *a priori* to address the study aims. We are using descriptive statistics such as means, standard deviations, and frequency distributions to examine data quality, identify patterns of missing and out-of-range values, and evaluate the assumptions of statistical tests. Remediation of normal distribution assumption violations will be accomplished using methods such as Box-Cox family transformations, or other methods as appropriate. Assessment of internal consistency reliability of all scales will be carried out using the Cronbach's alpha coefficient. Continuous outcomes (Aims 1 and 2) will be analyzed based on linear mixed effects models, with a random intercept according to the clinician, to account for the association between patients within the same clinician. Secondary analyses of item level components, consisting of Likert scale data, will be analyzed using Generalized Estimating Equations, which allow for the use of distributions in the Exponential Family other than the Normal Distribution. This will allow for the testing and use of the appropriate probability distribution to be used, while also accounting for the association between patients within the same clinician. Model selection for analyses focused on correlates of decision quality and screening completion will be based on Akaike's Information Criterion (AIC), instead of the usual statistical significance level (to avoid type I error inflation); this approach has been shown to lead to optimized models. We will only consider the statistical significance of each independent variable in the final models if the corresponding overall model test is significant at an alpha=0.05.

Patient-Provider Data Analyses. We are conducting a planned secondary analysis for physicians who have patients who respond to the survey (an estimated 40% of the total number of patients). We will perform a multilevel analysis using a model that contains

variables from providers and patients nested within those providers. This comparison may be on a 1:1 or 1:many level, depending on how many SDM patients of a given enrolled provider also enroll in the study. These multi-level models will be used to test physician level and patient level variables for their potential significant association with the outcomes. For continuous outcomes a linear link and normal error distribution will be used, and for binary outcomes a logit link and binomial error distribution will be used. The results will be interpreted in terms of the model's coefficients which represent average effects over the sample; therefore, analyses involving linking of patients and providers will protect the providers and patients from being identified.

Data Quality Control. Much of the data collected has been as part of previously validated instruments, yielding high quality data.

5.1. Screening

n/a (data collection completed at prior institution; currently analyzing de-identified data only)

5.2. Recruitment, enrollment and retention (including screen failures as applicable)

n/a (data collection completed at prior institution; currently analyzing de-identified data only)

5.3. Study intervention (including schedule of events and study visits)

n/a

5.4. Assignment / randomization (if applicable)

n/a

5.5. Section of instruments (to include for all studies with a social behavioral intervention) - *data has already been collected at prior institution; currently analyzing de-identified data only*

Table 2. Measures (Clinician Survey and Patient Survey) and Sources of Data			
Construct (*Variables*)	**Source**	**Instrument**	**∝**
Clinician-Level (survey component takes approximately 15 minutes to complete)			
Personal Characteristics *(demographics, clinician type, specialty, time since graduation, time in system)*	Survey	Investigator-Developed Survey	
Attitudes *(lung cancer screening, SDM, toward referring patients for screening)*	Survey	Investigator-Developed Survey	
Barriers *(lung cancer screening, SDM)*	Survey	Investigator-Developed Survey	
Knowledge	Survey	Investigator-Developed Survey	
Subjective Norms	EHR	Assessed with LCS referral propensity of clinicians in same clinic	
Lung Cancer Screening Referral Propensity	EHR	{Total # LCS-eligible patients referred for LCS in past 12 mo} ***divided by*** {Total # LCS-eligible patients seen by clinician past 12 mo}	
HEDIS Scores; **Clinician Smoking Cessation Referral Rate**; **Length of Clinician-Patient Relationship**; **Visit Characteristics** *(type, length of visit)*; **Clinic Size**; **Clinician Panel Characteristics** *(% screening-eligible patient population)*	EHR		
Documented SDM Discussion *(high/low)*	EHR		
Patient-Level (informed by our prior work, this survey takes approximately 30 minutes to completed)[50,55]			
Demographics (*education, income*); **Health Status Characteristics** (*health status, family hx lung cancer*); **Cost**	Survey	Investigator-Developed Demographic Survey	
Cognitive Variable (*Knowledge*)	Survey	9-item Likert Knowledge: Lung Cancer & Screening Scale	
Cognitive Variable (*Literacy*)	Survey	3-item Likert Health Literacy Screening Questionnaire [81]	
Cognitive Variable (*Numeracy*)	Survey	8-item Likert Subjective Numeracy Scale [82]	
Psychological Variable (*Stigma*)	Survey	5-item Cataldo Lung Cancer Stigma Scale-Smoking Subscale [78]	0.89
Psychological Variable (*Mistrust*)	Survey	5-item Patient Trust in Medical Profession Scale [80]	0.84
Health Belief (*Perceived Risk*)	Survey	3-item Perceived Risk of Lung Cancer Scale [55]	0.88
Health Belief (*Perceived Benefits*)	Survey	6-item Perceived Benefits of Lung Cancer Screening Scale [55]	0.76
Health Belief (*Perceived Barriers*)	Survey	17-item Perceived Barriers to Lung Cancer Screening Scale [55]	0.87
Health Belief (*Self-efficacy*)	Survey	9-item Self-Efficacy for Lung Cancer Screening Scale [55]	0.92
Control Preference (*for decision-making*)	Survey	Control Preference Scale (clinician, shared, patient) [83]	
Patient Perspective of SDM	Survey	9-item SDM-Q-9 [77]	0.94
Use of a Patient Decision Aid	Survey	Dichotomous [Y/N]	
Decision Quality: Screening	Survey	16-item Decision Conflict Scale: Lung Cancer Screening [74-75]	0.81
Decision Quality: Smoking Cessation	Survey	16-item Decision Conflict Scale: Smoking Cessation [74-75]	0.81
Screening Completion (among those who decide to screen)	EHR		
Smoking Cessation (stage of readiness among current smokers)	Survey	1-item Contemplation Ladder [76]	0.82

5.6. Data management (data collection, source and storage)

The study data is stored on secure KPWHRI servers behind a firewall. The SRP and the study programmer will have access to the identifiers/linking files. The identifiers/linking files will be destroyed no more than five years after the completion of study funding (8/23) – August 31, 2028. Since we plan to characterize the eligible study populations of providers and patients before obtaining consent from those who choose to participant, we will assign different study IDs for the analysis we plan to do of the eligible participants as a whole from the IDs we assign to consented participants. Only the study programmer will have access to a linking file between the two.

We will use KPRHWI's Secure File Transfer site to transfer limited data sets to our collaborating partners at Hackensack Meridian Health and Indiana University. We will

also put a DUA in place with these partners to ensure that transferred data, which we expected to be a limited data set, have requisite privacy protections.

5.7. Follow-up and end-of study (if applicable) n/a

6 - Trial Administration

n/a (data collection completed at prior institution; currently analyzing de-identified data only)

7- Resources Available

7.1. Describe the resources available to conduct the research:

The research has been conducted – all data has been collected. At this point, the study team is analyzing the data for dissemination.