

Rationale and Design of the Lung Cancer Screening Implementation Evaluation of Patient-Centered Care Study

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Abstract

Screening for lung cancer using low-dose computed tomography has been demonstrated to reduce lung cancer-related mortality and is being widely implemented. Further research in this area is needed to assess the impact of screening on patient-centered outcomes. Here, we describe the design and rationale for a new study entitled Lung Cancer Screening Implementation: Evaluation of Patient-Centered Care. The protocol is composed of an interconnected series of studies evaluating patients and clinicians who are engaged in lung cancer screening in real-world settings. The primary goal of this study is to evaluate communication processes that are being used in routine care and to identify best practices that can be readily scaled up for implementation in multiple settings. We hypothesize that higher

overall quality of patient-clinician communication processes will be associated with lower levels of distress and decisional conflict as patients decide whether or not to participate in lung cancer screening. This work is a critical step toward identifying modifiable mechanisms that are associated with high quality of care for the millions of patients who will consider lung cancer screening. Given the enormous potential benefits and burdens of lung cancer screening on patients, clinicians, and the healthcare system, it is important to identify and then scale up quality communication practices that positively influence patient-centered care.

Keywords: lung cancer screening; patient-centered outcomes research; patient-clinician communication

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The NLST (National Lung Screening Trial) showed that annual low-dose computed tomography (LDCT) reduced relative lung cancer and overall mortality by 20 and 7%,

respectively, among older people with a history of cigarette smoking (1). On the other hand, the absolute benefits of screening are small, with a number needed

to screen of 320 to prevent one lung cancer death, and there are many potential harms, including a high false-positive rate, mental distress, physical harm, and overdiagnosis

of indolent tumors (2–5). After weighing these benefits and risks, the U.S. Preventive Services Task Force, the American Cancer Society, the American Thoracic Society, and others recommend annual screening for people who meet eligibility criteria (3, 6–9). Concordantly, the Centers for Medicare and Medicaid Services agreed to cover lung cancer screening with several stipulations intended to reduce the frequency and severity of harms (10). Many healthcare systems have now begun implementation of lung cancer screening, but there is still uncertainty about the risks and benefits in real-world settings (11).

The goal of implementation of LDCT screening in routine care settings is to maximize the benefit and mitigate the harms of screening. Because the absolute reduction in mortality due to lung cancer screening is small, a relatively small increase in rates of harms may negate the benefit (12, 13). For this reason, it is important to evaluate all potential risks and benefits of screening, including patient-centered outcomes. Some patient-centered outcomes from screening trials have been described previously (2, 4, 5, 14, 15). For instance, quality of life, distress, and changes in smoking behaviors are not affected by screening itself, but nodule detection, both incidentally and from screening, is associated with increased distress and positive changes in smoking behaviors (2, 5, 16–21). The occurrence and magnitude of the expected risks and benefits in routine care settings have not been reported, and are likely to differ from those reported from trials.

Many lung cancer screening recommendations center on the communication process surrounding a patient's decision to undergo screening with a goal of improving patient-centered outcomes. For instance, the American Thoracic Society, the American College of Chest Physicians, and the Department of Veterans Affairs recommend a shared decision-making approach (11–13, 22). In a landmark decision, the Centers for Medicare and Medicaid Services *mandated* that patients undergo counseling and shared decision-making during the screening visit by a physician or other qualified practitioner to increase patients' understanding of the process (10). This visit must include the use of a decision aid, and patients must receive counseling regarding the benefits and harms of screening and the importance of

adherence while emphasizing the importance of smoking cessation or continued abstinence. Although these requirements seem intuitive, there is limited evidence (23–30) that decision aids for patients in other cancer screening settings improve patient-centered outcomes beyond improving knowledge, and there is limited information available about lung cancer screening in routine care settings.

In addition, lung cancer screening is a process that involves much more than a decision of whether or not to undergo lung cancer screening. Screening involves additional steps, such as identifying eligible patients, reporting results, and coordinating follow-up procedures for positive results, all of which will likely require differential communication practices. There are likely complex interactions at each step of screening and subsequent patient-centered outcomes (5, 19). Thus, it is important to study many aspects of communication at multiple time points during the screening process.

The purpose of this report is to describe our study, Lung Cancer Screening Implementation: Evaluation of Patient-Centered Care. Given the knowns and unknowns associated with real-world lung cancer screening, a prospective, longitudinal, mixed-methods study may be particularly informative and useful (31). We hypothesize that higher overall quality of patient–clinician communication processes will be associated with lower levels of distress and decisional conflict, which are important patient-centered outcomes. Institutional Review Board approval has been granted at all study sites (3482, Portland Veterans Affairs [VA], Portland, OR; 4645-B, Minneapolis VA, Minneapolis, MN; and Pro00073394, Duke University, Durham, NC).

Overview

We will evaluate patient-centered outcomes and important care delivery processes for patients who are considering and undergoing lung cancer screening during routine care. We use a validated theoretical model of patient-centered communication (PCC; Figure 1) (32). This model informs the study design through its emphasis on communication as a process rather than a one-time interaction. Furthermore, it

emphasizes that high-quality communication is composed of multiple domains, each of which may influence outcomes differently. Using a mixed-methods design will allow us to triangulate our findings and identify facilitators and barriers that will guide dissemination and implementation efforts. Communication studies (19, 33–38) often focus on a single domain of communication, such as information exchange or shared decision-making. By evaluating communication through multiple domains, we hope to facilitate implementation of “best practices” that reflect the nuances of the real world.

The specific aims are as follows:

- Aim 1: among patients engaged in lung cancer screening, evaluate the association of patient–clinician communication processes with patient-centered outcomes, such as distress.
- Aim 2a: among patients engaged in lung cancer screening, use qualitative methods to explore how PCC influences health outcomes.
- Aim 2b: among clinicians involved with lung cancer screening processes, use qualitative methods to explore the barriers and facilitators to implementation of PCC processes.

Methods

We are conducting a nested mixed-methods, repeated-measures (32), longitudinal study of patients and clinicians who are engaged in lung cancer screening (Table 1). We will enroll subjects from three sites: VA Portland Health Care System (Portland, OR), VA Minneapolis Health Care System (Minneapolis, MN), and Duke University (Durham, NC). We strategically chose these sites to include patients with demographic diversity across racial, ethnic, and urban/rural domains.

Each study site uses screening processes designed to accommodate their populations (*see* Appendix A in the online supplement). Both the Minneapolis and Portland sites use electronic clinical reminders to identify potentially eligible patients (based on U.S. Preventive Services Task Force criteria) during a routine care visit. The primary care provider (PCP) briefly reviews the eligibility criteria and refers interested

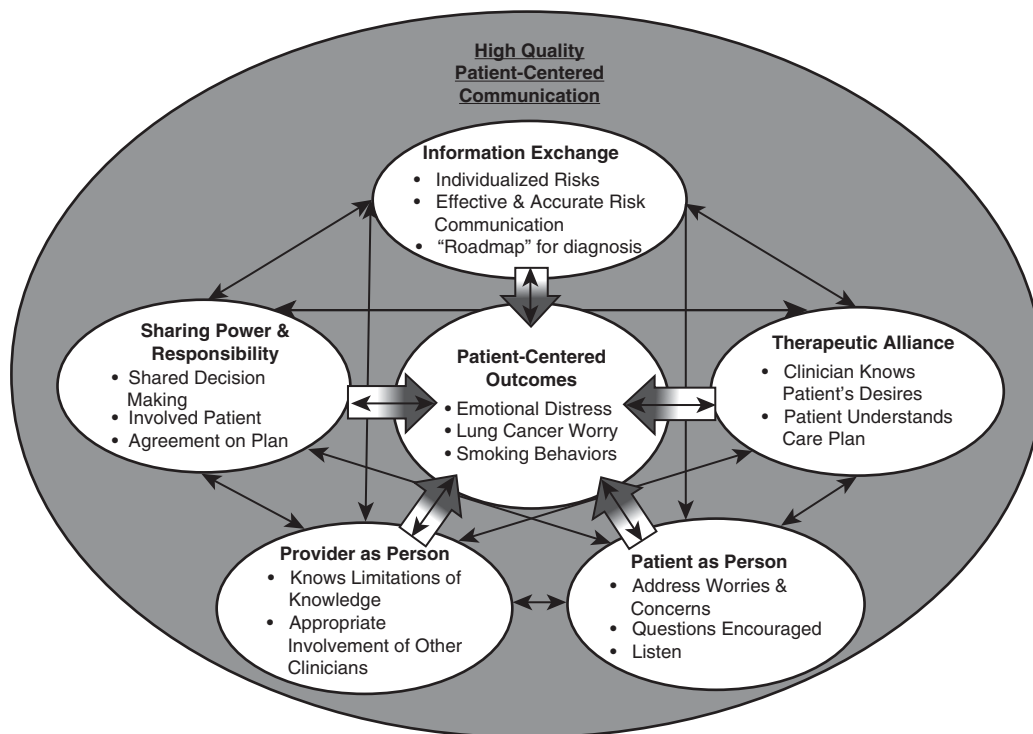


Figure 1. Patient-centered communication and lung cancer screening.

patients to a lung cancer screening coordinator (nurse or a public health professional). The coordinator then completes the shared decision-making visit and arranges the LDCT.

At Duke University Medical Center, shared decision-making for lung cancer screening can occur in one of three ways: (1) during a routine visit, the PCP performs shared decision-making and then refers directly for LDCT; (2) a patient who is actively smoking is first referred by their PCP to a clinician who is a Certified Tobacco Treatment Specialist who counsels the patient about smoking cessation, performs lung cancer screening shared decision-making, and then refers directly for LDCT; or (3) a patient self-refers or is referred to a clinic-based screening site, where an advanced practice nurse conducts shared decision-making about lung cancer screening, and offers smoking cessation interventions (if applicable) within the same visit. All sites use a decision aid (Appendix B) provided to the patient at the visit or mailed beforehand. Both the Portland VA and Minneapolis VA are using the decision aid developed by the VA Lung Cancer Screening Demonstration Project (10)

(<http://www.prevention.va.gov/docs/lungcancerscreeninghandout.pdf>), whereas Duke University is using a site-specific decision aid (39). In Minneapolis and Portland, it can take up to 4 weeks for patients to be notified about the LDCT results from the coordinator by phone and/or letter. At Duke, the results are reviewed and discussed immediately after the LDCT study. Baseline interviews and surveys are expected to last about 1 hour, whereas follow-up visits are projected to take half an hour or less.

Eligibility

Participants in Aims 1 and 2a will be outpatients who are eligible for CT screening based on age, smoking history, and comorbid diseases. The criteria for study eligibility are almost identical to clinical screening criteria (Table 2). No exclusions will be made based on race/ethnicity, although enrollees will be English speakers.

Aim 1 Project: Recruitment

Our recruitment strategies vary between sites (Appendix A). We anticipate the need to recruit 10% of all patients potentially eligible for screening. We will recruit up to

600 patients and follow them from the time of the screening decision to 1-year follow-up LDCT (Figure 2) for Aim 1 among the three sites.

Aim 1 Project: Patient Surveys

At the initial study visit, we will collect data on the primary outcome (emotional distress) and secondary outcomes (quality of life, utility, decisional conflict, and smoking behaviors), along with demographic, health history, and other electronic medical record data (Table 3). We will use several validated instruments of PCC to measure communication practices. At the follow-up visits (Figure 2), we will collect data on our primary and secondary outcomes (Table 3), and measure anxiety, satisfaction with the clinician, LDCT findings, new medical diagnoses, and information regarding communication tools. All visits will be conducted either over the phone or in person in paper format.

The coordinating site will oversee training and provide baseline survey guides to each study site. Research staff will practice surveys before administering surveys to patients. The lead coordinator will review the first 10 surveys from each site to ensure consistency.

Table 1. Summary of Aim 1 and 2 elements

	Aim 1	Aim 2
Hypothesis/rationale	Higher overall quality of patient–clinician communication processes will be associated with lower levels of distress and decisional conflict as patients decide whether or not to participate in lung cancer screening.	Qualitative methods will be used to better understand mechanisms and domains of communication that influence patient-centered outcomes, develop novel hypotheses, and contextualize quantitative findings. Understanding facilitators and barriers to high-quality, patient-centered communication processes will improve future implementation efforts.
Primary exposure	Overall quality of communication	
Primary outcome	Emotional distress	
Secondary exposures	Decisional conflict Smoking behavior Quality of life Utility	
Measurements	Surveys (about 1 h for baseline, 30 min for follow-up surveys)	Qualitative Interviews (about 1 h for baseline, 30 min for follow-up interviews)
Recruitment goals	600 subjects (200/site)	33 subjects (11/site)

The primary outcome is distress, measured with the Impact of Event Scale (IES) (40). The IES will be used to generate continuous and categorical (clinically significant elevated distress vs. less stress [40]) measures. There is no agreed-upon minimally important difference for the IES, but it has been used as an outcome measure in many trials (41) and previous lung cancer screening studies (5).

Secondary outcomes will include decisional conflict, smoking behavior,

quality of life, and utility. The Decisional Conflict Scale is a validated 16-item scale with 5 subscales that evolved from decisional conflict theory (42), and has been used in over 100 evaluations of decision support tools and decision aids. Self-reported smoking status will be assessed at baseline and follow-up.

Future cost–utility analyses will be conducted to evaluate whether allocation of limited health care resources toward lung cancer screening is a good investment.

Utility values of health states associated with lung cancer screening will be needed to derive quality-adjusted life-years, required for cost–utility analyses. This study provides an opportunity to collect these utility values for future research. The European Quality of Life–Five Dimensions Index (EQ-5D) will be used to elicit the utility value of her/his current health state at baseline and during each follow-up visit (43). The EQ-5D assesses health status for five domains: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each of these domains has five descriptions of increasing morbidity (none, slight, moderate, severe, and extreme or unable). For each domain, the patient chooses the morbidity description that best represents her/his current condition, or they may choose “don’t know.” The responses are then input into an algorithm to calculate an overall utility value (44).

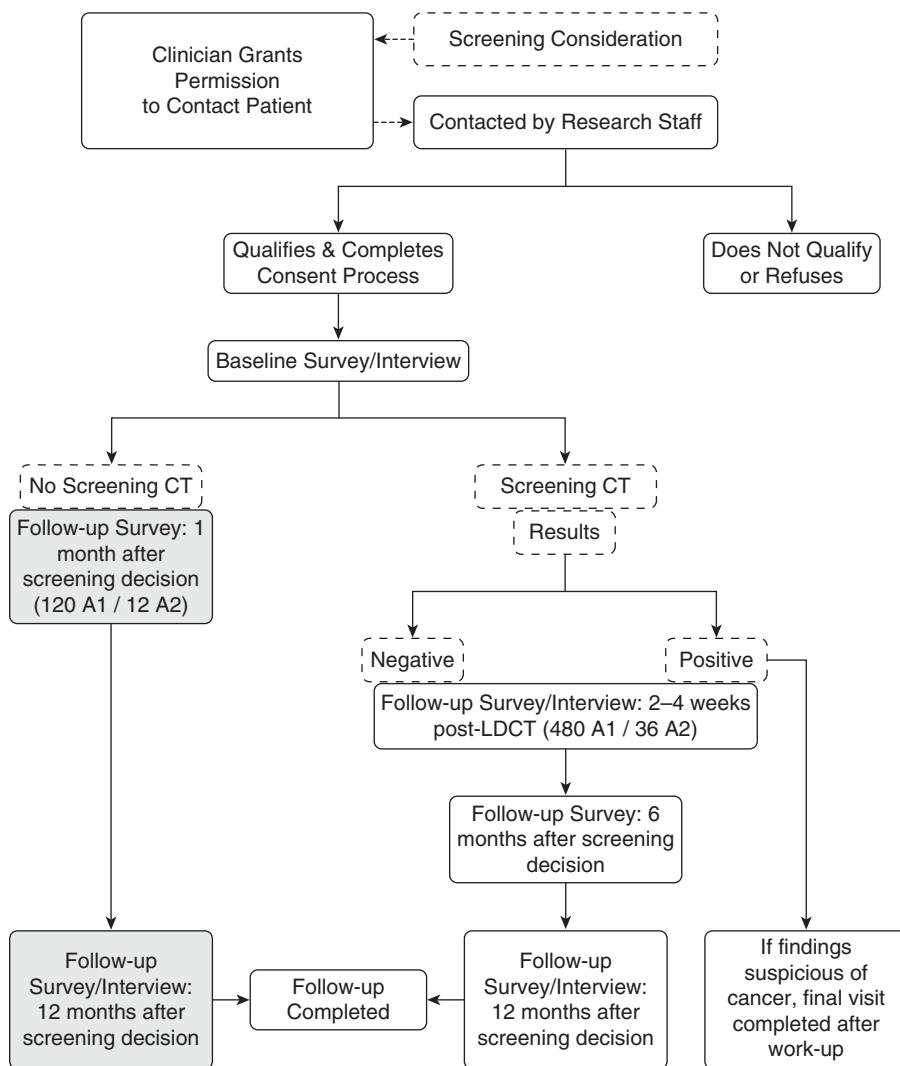
Because the EQ-5D is a generic tool designed to evaluate a wide range of health states, it may not be sensitive enough to detect changes in utility values associated with lung cancer screening. Therefore, we will also use the time trade-off (45, 46) approach to assess utility values. This method compares the trade-off of either living in a less-than-ideal health condition for a longer period of time *or* in an ideal condition for a shorter period of time. With the time trade-off, we will ask each patient to think about the quality of life of her/his current health, specifically taking into consideration her/his physical, psychological, and social functions, as well as any symptoms they may be experiencing. Participants consider the hypothetical of living for 30 years in their current health condition or a shorter period of time in the most perfect health they can imagine. We start with bids of 29 and 28 years in perfect health and continue to titrate bids down by 2 years until they are no longer willing to accept the tradeoff. The previously accepted trade-off bid is considered their indifference point. For example, if the shortest length of time they are willing to trade-off for perfect health is 24 years, then their utility value for their current health state is 0.8 (24/30) (47).

The primary exposure variable is the participant-reported overall quality of communication with the clinician. We will use the instrument developed by Little and colleagues (48) to measure overall communication quality and four of the

Table 2. Eligibility

Eligibility	Clinical- or Research-Specific Requirement
Inclusion	
Age 55–74 yr	Clinical
Active or former smoker (≤15 yr since quitting and ≥30 pack-years)	
Offered lung cancer screening by provider	
Exclusion	
Unexplained weight loss or hemoptysis	Clinical
History of lung cancer	
Chest CT, ≤12 mo	
Active cancer treatments	
Pregnancy	
Dementia (SLUMS, <17/30)	Research
Non-English speaker	
Reside in skilled nursing facility	
Severe mental illness	
Severe hearing impairment	

Definition of abbreviations: CT = computed tomography; SLUMS = Saint Louis University Mental Status Exam.



A1: Aim 1 expected enrollment
 A2: Aim 2a expected enrollment
 Dashed box: Clinical encounter
 Solid box: Research encounter
 Shaded solid line box: Survey schedule for decliners
 Clear solid line box: Survey schedule for accepters

Figure 2. Study flow diagram. Dash line box represents clinical encounter. Solid line box represents research encounter. Shaded solid line box represents survey schedule for decliners. Open solid line box represents survey schedule for accepters. A1 = Aim 1 expected enrollment; A2 = Aim 2a expected enrollment; CT = computed tomography; LDCT = low-dose computed tomography.

PCC domains (not clinician as a person). This instrument is based on the PCC model, and was recommended after an analysis of multiple communication instruments (49). The instrument includes exploring the disease and illness experience, understanding the whole person, finding common ground, health promotion, and enhancing the patient-clinician relationship. For the primary analysis, we will use the

summary score for general communication, measured continuously to identify quality of communication among clinicians (50).

Shared decision-making is a key component of effective communication and a core domain of the PCC model. We use the Control Preferences Scale (51), a five-point scale of the patient's role in decision-making. It is a valid and reliable measure of decision-making preference (51). We use the Control

Preferences Scale to measure the preferred and actual role in decision-making.

Information regarding the CT finding(s) will also be collected based on electronic medical record review. At the final study visit, information regarding any follow-up procedures will be collected from the electronic medical record as well. We will ask specific questions about decision aids at each site (Appendix B), including if the participant recalls receiving one and if it was useful in making the decision to get screened.

Aim 1 Project: Analysis Plan

The primary analysis will examine the longitudinal association over the course of the study between overall communication quality and at least mild distress, as measured by the IES. We will perform multivariable, multilevel hierarchical, logistic regression. We anticipate using generalized estimating equations (which will account for site-level variability), but may change the hierarchical model based on findings from our qualitative studies. We will also include time-dependent covariates of changes in overall communication quality. *A priori*, we will adjust for age, sex, race/ethnicity, smoking status, lung cancer risk perception, and baseline anxiety trait symptoms. Importantly, this analysis will examine mental health and a marker of the patient-perceived risk for an eventual diagnosis of lung cancer. Finally, we will evaluate the association of overall communication quality with distress for effect modification by Lung CT Screening Reporting and Data System (52) categories on the LDCT and the decision whether or not to undergo screening.

After completing the primary analysis, we will then evaluate each PCC domain with distress. We hypothesize that subjects who report higher-quality communication from multiple domains will have less distress than those who report high quality in fewer domains. We will include summary measures of each domain and then perform likelihood ratio tests to determine if the inclusion of individual domains is associated with distress.

Next, we will perform similar analyses of the secondary outcomes of quality of life, utility, decisional conflict, and smoking behaviors. We will also analyze the association between the decision to undergo screening with these outcomes. We will calculate descriptive statistics of the utility values at each time point, as well as use generalized linear mixed modeling to account for multiple sites, repeated

Table 3. Exposure and outcome measurements

Characteristic/State	Instrument/Source	Validation	Description
Primary outcome Emotional distress	IES (40)	Yes	22-item scale to measure symptoms of emotional distress
Secondary outcomes Decisional conflict	O'Connor Instrument (42)	Yes	16-item scale with 5 subscales evolved from decisional conflict theory
Lung cancer worry	Lerman Worry Instrument (56)	Yes	Adapted Lerman's instrument to measure lung cancer worry. Questions categorize frequency and impact on mood and ability
Smoking behaviors	Smoking questions	Yes	Self-reported smoking status assessed at baseline and follow-up
Utility	Patient experience (57)	Yes	0–10 scale to rate overall patient experience at baseline
Primary exposure Patient–provider communication	PCC (48)	Yes	1–7 range to rate patient–provider communication during the lung cancer screening discussion
Additional data items Patient–provider communication	PACE (58)	No	Asks patient perspectives on communication with providers around lung cancer screening
	CAHPS (59)	Yes	Measures quality of care with lung cancer screening providers
Quality of communication	Little and colleagues (48)	Yes	Based on the theoretic model of PCC to measure overall communication quality
Lung cancer risk perception	Lee and colleagues (60)	No	11-point Likert scale to measure subject's perceived estimate they might develop lung cancer
Lung cancer risk perception	Perceived Susceptibility Scale (61)	Yes	5-point Likert scale to measure patient's perception of how likely they are to get lung cancer in the future
Shared decision-making	Control Preference Scale (62)	Yes	Asks patient about preferences for making decisions with their provider around lung cancer screening
	CollaboRate (63)	Yes	9-point Likert scale to rate how much effort was made to help patient understand lung cancer screening
Decision-making	Choice predisposition (64)	Yes	Asks patient to rate how strongly they feel about their lung cancer screening decision
	Decision self-efficacy (65)	Yes	Measures how confident a patient feels in making decisions around lung cancer screening
	Stage of decision-making (66)	N/A	Asks patient to choose stage of decision-making regarding lung cancer screening
	Preparation for decision-making (67)	Yes	Evaluates communication with provider regarding lung cancer screening
	Decision Regret (68)	Yes	5-point Likert scale to measure how much a patient agrees or disagrees about their screening decision
Mental health	STAI (69)	Yes	Measures present feelings
Numeracy	Berlin Numeracy Test (70)	Yes	Range of possible scores to measure numeracy skills
Literacy	Single-Item Literacy Screener (71)	Yes	5-point Likert scale to measure how often a patient needs help reading instructions from a healthcare provider
Screening knowledge and attitudes	Knowledge and attitudes (72)	Yes	Measures current knowledge and attitudes of lung cancer screening
Quality of life	European Quality of Life-5 Dimensions Index (43)	Yes	Measures present health
Utility	Time trade-off, Burström and colleagues (45, 46)	Yes	Patient is asked how many years in perfect health they would consider over present health
Values	Sheridan and colleagues (73)	Yes	Measures the value a patient places on risks and benefits of lung cancer screening
Medical utilization	Medical maximizer, Scherer and colleagues (74)	Yes	Questions measure general preferences related to wanting more or less health care to predict utilization
Experience of CT scan	Discomfort of CT scan and waiting for results (75)	No	Measures discomfort experienced during and after the CT scan
Other data items Demographics	Health history/other	Electronic medical record and other	
Sex	Communication	Screening decision	
Race/ethnicity	Lung disease (severity)	CT findings	
Marital status	Comorbid conditions	Medications	

(Continued)

Table 3. (Continued)

Characteristic/State	Instrument/Source	Validation	Description
Socioeconomic status	Previous and family history of cancer	Diagnoses	
Smoking	Length of relationship with clinician	Other screening/prevention behaviors	
Occupation (asbestos)	Satisfaction with clinician/communication	Clinician characteristics	
Highest education		Screening program characteristics	
Clinician characteristics			
Indirect costs			

Definition of abbreviations: CAHPS = Consumer Assessment of Health Plans Study; CT = computed tomography; IES = Impact of Event Scale; N/A = not applicable; PACE = patient assessment of cancer communication; PCC = patient-centered communication; STAI = State Trait Anxiety Inventory Short Form.

measurement, and missing values, if needed. The utility values will be used to estimate area under the curve to derive quality-adjusted life-years (53). As described previously here, we will first evaluate overall communication quality and then each PCC domain with the secondary outcomes. These analyses will be analyzed using a Bonferroni correction for multiple testing.

Finally, we will use our qualitative findings from the Aim 2 project to inform the analysis of communication domains with patient-centered outcomes in the Aim 1 project. We will query patients and clinicians regarding their views on how communication processes, tools, and providers' behaviors best fit with the PCC domains. We can then incorporate this knowledge about how sites differ in the PCC domains into the quantitative analyses. If we find differential associations between site and patient-centered outcomes, we can use the qualitative results to better explain potential causal mechanisms.

Aim 2a Project: Recruitment

Recruitment eligibility for Aim 2a will be similar to Aim 1. To obtain a broad range of participants with demographic and experiential diversity, we anticipate recruiting 33 subjects (11 per site) for Aim 2a. We will use purposive sampling that strives for maximum variation in patient characteristics and response to the evaluative process. We plan to interview 24 patients who opt for screening and 9 who do not. Given our hypothesis that patients with nodules may be at risk of distress, we plan to oversample three extra patients known to have positive results and ask them to recall their experiences before the LDCT. These patients will be recruited in Year 2, after the initial cohort has been enrolled. If the rate of positive LDCT findings is higher than estimated, we

may alter our recruitment strategy. Although it will be rare for patients to be diagnosed with lung cancer, we will purposively oversample the group with nodules with a very high risk of lung cancer. It is beyond the scope of this study to include many patients with lung cancer, but we hope to qualitatively interview at least six. If we do not reach saturation, we will continue recruitment.

Aim 2a Project: Patient Interviews

Patients will be interviewed two to three times (Figure 2). They will describe their experiences with lung cancer screening, focusing on communication processes and PCC domains (Appendix C [Interview Guide], Table E4). For patients who decline screening, we will explore their rationale. For patients who accept screening, the second interview will explore the follow-up processes of care, focusing on how these processes align with the PCC domains.

Finally, we will review the preliminary quantitative findings with the patients at their last qualitative visit to guide future implementation efforts and research directions. We will review the qualitative results from the clinicians with the patients at their final visit. We will also discuss future research ideas and questions with the patients so that our next projects will benefit from increased stakeholder involvement.

Aim 2b Project: Recruitment

Approximately 24 clinicians (eight per site) will be asked to participate in one 1-hour interview. There are many disciplines/specialties of the clinicians who care for patients considering screening. We will use purposive sampling to maximize the diversity of responses. Coding and analysis will be ongoing and, should themes reach early saturation, fewer subjects will be recruited (54).

Aim 2b Project: Clinician Interviews

Clinicians will be interviewed once regarding the communication process and perceptions of how patients are influenced by communication (Appendix C [Interview Guide], Table E4). We will also review the facilitators and barriers to communication processes. Because the clinician interviews begin after the patient study has begun, we will discuss patients' responses to obtain clinicians' theories regarding mechanisms and processes that might explain the findings, as well as to probe their perspectives on how to improve outcomes that are important to patients.

Aim 2 Project: Analyses Plan

All interviews will be digitally recorded and transcribed, and we will use ATLAS.ti (available at <http://atlasti.com/>) for organization and analysis. We will use the inductive approach for analysis, which allows for distillation of raw data to elucidate and interpret concepts and themes (55).

A qualitative analyst will first read each completed transcript closely to become familiar with the content. Next, the analyst will review two transcripts to develop a preliminary codebook, although some preliminary codes will have been identified previously as key concepts based on the interview guide. The principal investigator will review the same two transcripts and review the coding and codebook with the initial coder. The initial coder will then independently code an additional three transcripts and discuss with the principal investigator. As a group, we will meet to discuss and refine the codebook, and review and recode transcripts, as needed, until all are coded. If other themes arise from the data, we will add them to the coding scheme and recode any transcripts coded previously.

Finally, we will review the data again to identify further codes, create new memos, and reconcile discrepancies. Throughout this process, we will evaluate any overlapping coding or uncoded text to verify appropriateness.

Discussion

Lung cancer screening has begun, and will soon affect millions of people. Our study leverages ongoing implementation efforts in three geographically diverse sites to evaluate the process of communication as one of the few modifiable influences on patient-centered outcomes (5, 31).

This study will likely be one of the first to longitudinally evaluate patient-centered outcomes among patients in multiple settings undergoing lung cancer screening during routine care. The utilization of a validated theoretic model of PCC that will employ longitudinal, mixed-methods analyses of communication processes increases the potential to make improvements to the process (32).

For instance, if we find that higher-quality information exchange is associated with improved knowledge, but not decreased distress or decisional conflict, clinicians may want to more strongly emphasize additional communication strategies, such as understanding patients' values and preferences. Alternatively, if shared decision-making is associated with substantial burdens to clinicians and patients, but not improved outcomes, professional organizations and payers may want to *suggest* using a decision aid rather than *requiring* one. We hope this focus on validated and innovative methodologies with established partnerships will lead to interventions that can be quickly and efficiently scaled up for widespread implementation of lung cancer screening. ■

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