Specific Aims

In 2013, the United States Preventive Task Force (USPSTF) recommended use of annual low dose CT scans (LDCT) to screen high-risk individuals for lung cancer. This recommendation was based on evidence that detecting and treating early-stage lung cancer would greatly lower the risk of dying from this disease. Unfortunately, lung cancer screening rates in the United States are very low– just 3.3% in 2010 and 3.9% in 2015 (1). **Not yet known** is how to effectively promote and increase lung cancer screening while supporting patients and physicians in making this high stakes decision. There is a critical need to develop and implement effective strategies to engage high risk patients, those who have a substantial history of smoking, in a coordinated program of lung cancer screening which includes shared-decision making.

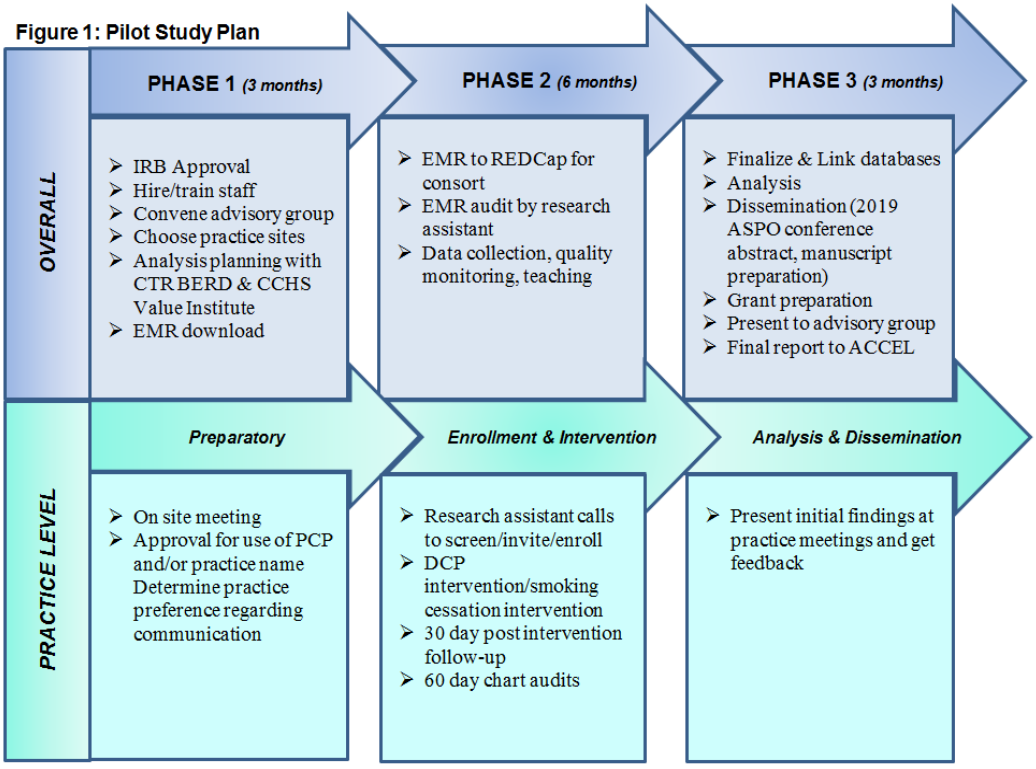
The **long term goal** of this work is to decrease lung cancer mortality through primary care interventions. Such interventions should leverage the patient-physician relationship and support patients to make informed decisions about lung cancer screening that is aligned with current medical evidence and emphasizes patient values and preferences. In 2017, our research team took an initial step to towards achieving this goal by assessing the feasibility of implementing an informed decision making intervention in a single primary care practice among 54 patients who were eligible for lung cancer screening. The intervention centered the Decision Counseling Program ® (DCP)(2) an online software application that focuses on patient education and preference clarification related to lung cancer screening delivered over the phone by a trained nurse educator. DCP results were given to patients and providers. Use of the DCP intervention was feasible, helped primary care patients clarify their preference related to screening, and participants were likely to undergo LDCT screening. We now propose to **modify and expand the intervention**. We will recruit 100 eligible, current smokers from real world primary care practices to participate in a pilot study, outlined in **Figure 1** comparing to usual care by propensity scoring.

Aim 1 Compare low dose CT scan completion in the DCP cohort of current smokers versus usual care, propensity-matched controls at 60 days.

Aim 2 Compare the characteristics of the patients not recruited in the study to the characteristics of those who accepted to enroll

Aim 3 Test the feasibility of intensive smoking cessation as part of the DCP.

Figure 1: Pilot Study Plan

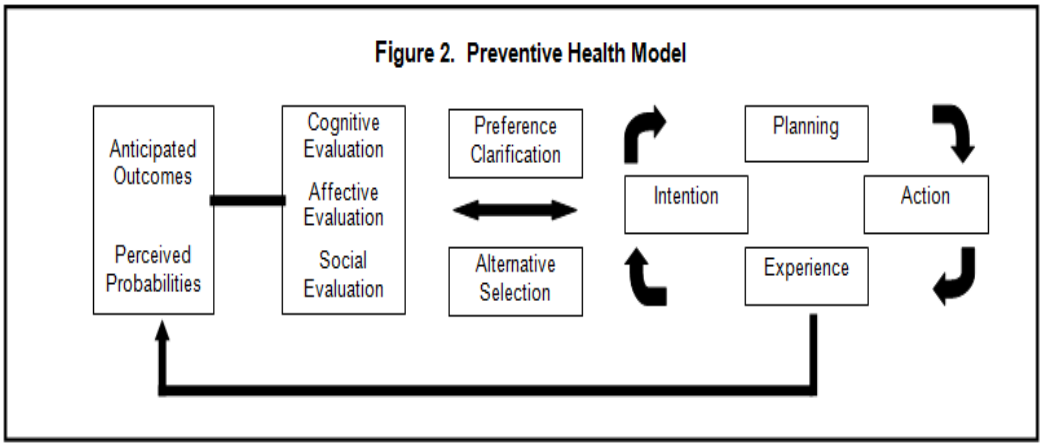


Lung cancer is the leading cancer killer in the United States and effective lung cancer screening could have significant public health impact. This work advances the mission of ACCEL advancing translational science by developing best practices to implement evidence-based prevention in real world clinical practice. This work will advance the implementation of clinical guidelines for lung cancer screening and shared decision making as well advance understanding of health disparities associated with lung cancer screening. Effective implementation of a shared decision making process in primary care would serve as a model for future expansion to other diseases and decisions.

Significance

Lung cancer is the leading cancer killer in the United States. Each year, more people die of lung cancer than of colon, breast, and prostate cancers combined. **Lung cancer screening** or low dose CT scan (LDCT) can find early lung cancer in people at high risk and significantly lower their risk of dying from this disease. The National Lung Screening Trial (NLST) was a randomized trial of low dose CT scan (LDCT) versus chest x-ray in individuals at high risk for lung cancer (3). The NLST demonstrated a 20% reduction in mortality. In 2013, based on the NLST, the United States Preventive Task Force (USPSTF) recommended use of LDCT) to screen for lung cancer in high risk individuals; high risk individuals are defined as people between the ages of 55 and 80 years old, with a 30 pack year history of smoking, who either currently smoke or quit less than 15 years ago (level B recommendation) (4). In response to the USPSTF recommendation, the Center for Medicare and Medicaid Services (CMS) announced that lung cancer screening (LCS) will be included as a covered benefit. However, CMS requires that "a beneficiary must receive a written order for LDCT lung cancer screening during a lung cancer screening counseling and shared decision making visit." This CMS requirement for shared decision making is a first and highlights that lung cancer screening is a high stakes decision. Lung cancer screening is a high stakes decision because the potential mortality benefit for LCS is very high but rests on a single randomized controlled trial. This benefit is counterbalanced by the risks of false positives and incidental findings which may lead to invasive procedures e.g. bronchoscopy and even thoracic surgery. All screening tests are associated with the risk of a false alarms, unnecessary treatment and incidental findings. This CMS requirement for shared decision making is likely to become a common requirement and raises the question of how to best implement shared decision making in real world clinical practice. More importantly, patients prefer shared decision making and the active role it brings to their health care and patients who have share in decision making have better health outcomes and satisfaction with care (5). Our intervention is based on the Preventive Health Model in **Figure 2**. (6, 7).

Figure 2. Preventive Health Model



Innovation

Best practices for implementing high quality informed or shared decision making in primary care are not developed. High quality, shared decision making in medical care should be based on sound clinical evidence, patient education and should include the values, preferences and beliefs of the patient. However, real world clinical practice does not routinely support high quality shared decision making. Most medical care decisions are prompted during a visit with a health care provider and often such visits are brief and focused on acute care (e.g. a "cold") or episodic care (e.g. ongoing management of chronic diabetes). So, patients are usually asked, with little or no preparation, to consider and make high stakes medical decisions such as lung cancer screening. Innovative ways to prepare and support patients and their physicians in complex decision making are needed. Effective implementation of such innovations would be non-disruptive to other ongoing care needs and would leverage the relationship between the patient and their physician. This intervention is **patient-centered** and **proactive** moving outside of the physician-patient visit to reach patients who may be unaware of their own eligibility. Recognizing that physician recommendation is typically one of the strongest predictors of cancer screening, this intervention builds on the patient-physician relationship and allows other team members to practice at the top of their license, a potential for cost-savings. Most importantly, this intervention would prepare the patient to make the most of face to face encounter with their physician and to make the best personal decision. Lung cancer screening represents a teachable moment for a group of heavy smokers. By pairing intense, tailored smoking cessation efforts to lung cancer screening, the benefit of lung cancer screening will be amplified by improving multiple health outcomes associated with smoking cessation.

Approach

Preliminary Studies The DCP ® intervention was implemented in one family medicine practice. Using electronic medical record (EMR) data, we identified a list of over 900 potential enrollees (both current and former smokers age

55-74). There were 297 individuals who were reachable and 54 of these were eligible for LCS according to the USPSTF criteria. We were able to contact a higher proportion of current smokers (47%) than former smokers (30%). Eligibility was higher in current smokers (28%) versus former smokers (11%). Also, of the 54 total eligible, 28 enrolled. Despite these small numbers, we were able to show the DCP participation was associated with LDCT completion at 90 days (p=0.03).

Study Design We propose a 1 year project including a **6 month intervention** period. This study will be a cohort with comparison to usual care in other practices in the same health system using propensity-matching methodology.

Study population/eligibility Inclusion/exclusion criteria will be based on the USPSTF and CMS lung cancer screening guidelines: age 55- 80, with a 30 pack year smoking history, no symptoms consistent with cancer, and no CT scan of the lungs within the last year. Physicians will be given the chance to eliminate participants based on limited life expectancy or prohibitive comorbid conditions. Case finding in our prior work was difficult and recruiting active smokers has a higher yield. Prior work indicated that this pool yielded a higher proportion of truly eligible, reachable individuals. Plus, we want to test the feasibility of a more intense smoking cessation intervention. To address recruitment barriers, we will work with practices and PCPs to promote as a study "conducted with the PCP," including the physician name or practice name when possible on recruitment materials e.g. written letters and email cosigned by their PCP. To address case finding barriers, we will allow patients to easily opt out of future contact via mail, email or phone. We will work with our advisory panel to explore other methods to enhance recruitment and case-finding such as using the secure EMR portal to screen for LCS eligibility and/or updating smoking history. Finally, we have added $50 patient incentives per patient for participation.

Intervention The DCP is an online software application that supports an interactive session that focuses on patient education and preference clarification. Patients will be contacted by phone or other methods to provide information about the study, be invited to participate, consented, and then scheduled for decision counseling. Neither the DCP tool nor this process is directive; the DCP session does not push the patient to screen but, rather, clarifies the patient's current preference (screen or not) and identifies key reasons for that preference. In the session, the decision counselor and patient will review the options, (to screen or not to screen for lung cancer) using publicly available patient education materials (Appendices 1 & 2) (8, 9). Then, the decision counselor will guide the patient through 5 steps: 1) identify factors most likely to influence the decision to screen 2) assign importance (decision weight) to the factors 3) compare the relative weight of the most important factors 4) generate a decision score, and 5) generate a personal summary form which can be made available in the EMR for physician review with the patient. Next steps will be tailored to each practice, and can include referral to PCP for further discussion and/or referral to the Lung Health Screening Program (LHSP). The decision counselor will be trained as a smoking cessation coach and as a "mini-expert" in system and community resources for smoking cessation.

Data Acquisition Following approval by the CCHS Institutional Review board, lists of potentially eligible individuals from participating and non-participating practices will be obtained from EMR data. These lists will be automatically entered into a REDCap® for CONSORT tracking. Lists will be organized according to PCP whom will be given 7 working days to review lists and eliminate any patient they feel would not be appropriate for this study. Remaining potentially eligible patients will receive a letter, cosigned by their personal physician which introduces the study and offers the opportunity to easily opt out of further contact. After an opt-out period of 7 working days, patients will be contacted, screened for eligibility and invited to participate. After formal consent, we will collect demographics, socioeconomic variables and smoking history. Baseline data will be collected regarding knowledge, preference and decisional conflict related to lung cancer screening. Standard patient education materials will be sent to patients. The DCP session will be conducted within 30 days of enrollment. A follow up telephone call will occur within 30 days of DCP completion, and will include items to assess patient perception of the process, knowledge about lung cancer screening and decisional conflict (Appendix 3) related to lung cancer screening (10). At 60 days after the decision counseling session, patient charts/electronic medical record data will be audited for the primary outcome, LDCT scan report. Prior work showed the average time from DCP to LDCT was ≤ 60 days. Intermediate (process) outcomes in EMR include lung cancer screening discussion, referral/order for LDCT, or referral to the CCHS LHSP. Eligible patients in the usual care group (in the non-participating clinics) will be identified electronically as stated above and LDCT screening assessed in a 60 day study period from their most recent office visit. Information available in EMR for all patients including controls and individuals who are "unreachable" comprises gender, age, race, ethnicity, insurance status, marital status, smoking status, comorbidities, such as COPD, Heart disease, diabetes, hypertension and zip code (surrogate for socioeconomic status). Information collected from individuals who are reached but ineligible will include all of the above plus smoking status, pack years, and reason for ineligibility. Information collected from individuals who decline participation will include all of the above plus reason for declining participation.

Statistical analysis

Aim 1 Compare low dose CT scan completion in the DCP cohort of current smokers versus usual care propensity-matched controls at 60 days. *Hypothesis: Participation in the DCP will be associated increased participation in LDCT, compared with both eligible enrollees who do not participate and with eligible patients in usual care practices*. Demographic and clinical variables of the intervention and control groups will be compared using T-Test, Wilcoxon-Rank sum test and chi-squares. We will conduct a 1-to-1 propensity score matching to compare the proportion of patients who screen between the groups. We will use a logistic regression model to build propensity scores to match patients in the intervention and control groups. We will model the probability of being in the intervention group using all the patients level variables extracted from the medical records as listed above. Whether they are in a participating practice or not will not be included in the model as an independent variable. The nearest neighborhood method without replacement will be used for matching. We will set the caliper width according to the standard deviation for the propensity score. Each control will be assigned a probability score and matched with a patient in the intervention group. In a second step, we will compare the characteristics of the patients and chosen controls to verify that they are very similar. We will use a simple chi-square to compare the percentage of patients in the control and intervention groups who complete the LDCT scan within 60 days.

Power calculation based on primary outcome: According to our preliminary study, 45% of those who complete the DCP decided to screen for lung cancer whereas the know rate of screening among patients in usual care is 15%, which makes a difference of 30%. A sample size of 40 patients in each group will achieve 85% power to detect a difference between the group proportions of 30%. The proportion in the intervention group is assumed to be 15% under the null hypothesis and 45% under the alternative hypothesis. To detect a difference of 20%, we will need a sample size of 60 patients in each group to achieve a power of 80%. We expect that 2000 patients will be identified as potentially eligible for the study in the EMR and 1000 will be reachable. Of those 300 (30%) will be confirmed eligible during the phone call and 150 (50%) will accept to participate in the DCP. We will therefore have ample power to detect a difference as small as 20% between our 2 groups.

Aim 2 Compare the characteristics of the patients not recruited in the study to the characteristics of those who accepted to enroll. *Hypothesis: Patients recruited to the study versus those who are not will be different demographically and geographically.* We will use descriptive statistics to examine the characteristics of the patients of the intervention practices who were eligible but could not be reached and of the patients who were reached but refused to be in the study. We will also compare the characteristics of these patients to those of the patients who enrolled in the study. We will use logistic regression models to determine which independent characteristics are associated with agreeing to be in the study.

Aim 3 Test the feasibility of intensive smoking cessation as part of the DCP. *This aim is hypothesis generating*. At 30 days, we will ask patients about participation in smoking cessation, quit attempts and for general comments on their needs and satisfaction with our smoking cessation efforts. We will explore trends associated with these intermediate outcomes related to cessation including engaging in cessation and quit attempts. We will illicit qualitative information from participants about how to make this part of the program useful and patient-centered.

Community Engagement Our team has established relationships with clinical and administrative leadership as would be necessary to conduct this work in a large health system. In addition, we have engaged local community outreach leaders with special knowledge and emphasis on smoking cessation. Dr. Fagan is a frequent speaker for physician educational events locally, regionally and nationally. In the first two months of the project, we will convene an advisory team of patients, physicians and administrative leaders to guide and champion this work. The advisory team will provide expertise on improving lung cancer screening generally and provide specific advice regarding: practice selection, data acquisition and exchange, improving recruitment methods, adding smoking cessation and planning for sustainability beyond the pilot funding period.

Sustainability This work would lay the groundwork for an R01 level randomized controlled trial. The Agency for Healthcare Research and Quality (AHRQ) has issued a Special Emphasis Notice (SEN) to inform the research community that AHRQ intends to support research on models of shared decision making (SDM) that are tailored to the needs of low income and racial and ethnic minority patients (11). The Patient Centered Outcomes Research Institute (PCORI) has a strong focus on comparative effectiveness research which helps patients to make informed or shared decisions (12). The use of non-physician team members to extend care beyond the visit and to provide proactive care is likely to be cost-effective in improving population health and is aligned with the strategic vision of CCHS.