DGIM Project Summary

Name of Project: Lung Cancer Screening: A Multilevel Intervention (Aim 2)

Investigator(s). (Include phone numbers and email address, indicate PI and primary contact):

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Research question(s): The goal of Aim 2 of the study is to conduct a randomized control trial (RCT) to evaluate the Lung Cancer Assessment of Risk and Education (LungCARE) intervention. We will determine whether the intervention is accepted by patients and physicians. We will also establish whether patients who receive LungCARE are more likely to discuss lung cancer screening with their physicians.

AIM 2. Implement and evaluate the impact of LungCARE among primary care patients who are at high-risk for lung cancer.

> **2.a.** Conduct a randomized control trial (RCT) at the University of California, San Francisco (UCSF) General Internal Medicine (GIM) clinics and the Women's Health Primary Care (WHPC) Clinic to evaluate the LungCARE intervention among 120 patients and 50 primary care physicians (PCPs).
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> **2.b.** Evaluate feasibility and acceptability of the intervention and study procedures among patients and PCPs.
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> **2.c.** Assess primary outcomes including discussion of lung cancer screening, perception of lung cancer risk, and knowledge of lung cancer screening.

Brief Background/Significance:

Currently, most cases of lung cancer are discovered at advanced stages, only after symptoms appear. Treatment options for both small cell and non-small cell lung cancer are based on stage of diagnosis. Although treatments have improved slightly over the last several decades, survival remains low, highlighting the importance of early detection. In December 2013 the USPSTF issued a draft recommendation that high-risk patients be screened for lung cancer annually with low dose computed tomography (LDCT) scans. The task force determined that a reasonable balance of benefits and harms could be reached by screening people who are 55 to 80 years old, either current smokers or quit within the past fifteen years, and have a 30-pack year or greater history of smoking. In February 2015, the Centers for Medicare and Medicaid Services provided final support to cover the costs for LDCT. There are several lung cancer risk assessment tools and educational materials currently available, but they are limited and have not been tested or adapted for use with low literacy or racial/ethnic minority populations, particularly in a clinical setting. Our project will develop a clinic-based intervention to promote discussion of lung cancer risk and screening among high-risk patients and their PCPs.

Inclusion/exclusion criteria:

Inclusion:

- Patient Component: Eligibility criteria will be 1) age 55-80, 2) smoked at least 30 pack-years in lifetime, 3) if former smoker, quit smoking within the last 15 years, 4) English speaker, 5) no prior history of lung cancer, 6) did not have a lung cancer screening test within the last year, and 7) PCP does not object to patient's participation. In addition, patient must have a scheduled visit at the GIM or WHPC clinics.

- Physician Component: Eligibility criteria will be 1) practices in the GIM or WHPC clinics at UCSF and 2) dedicates at least 20% of his/her time to direct patient care in a primary care, continuity setting.

Exclusion:

- Patient Component: Exclusion criteria will be 1) speaking a language other than English, 2) has a history of lung cancer, 3) had a lung cancer screening test within the last year, or 4) PCP objects to patient's participation.

Method of contact/recruitment (be specific):

Aim 2:

PCP Randomization:

- Physicians will be identified using a list of internal medicine physicians providing clinical care in the GIM and WHPC clinics, including faculty, fellows, and residents.

- We will create two sets of physician groups with matching physician characteristics (faculty, fellow, resident), years in practice, gender, and panel profiles (racial/ethnic and age distribution). Physicians will then be randomly assigned to either the intervention or comparison group.

Patient Recruitment and Enrollment Procedures:

- Using the electronic health record (EHR), we will identify current and former smokers. The DGIM staff will create a list of potentially eligible patients.

- Physicians will be sent an email explaining the study, along with a list of potentially eligible patients in their practice. We will ask them to inform us if they object to any patient's participation in the study.

- On a biweekly basis, we will obtain a list of potentially eligible patients who have appointments at the GIM and WHPC clinics.

- Prior to the PCP visits, we will mail all eligible patients appointment reminder letters that also introduce the study.

- One week before the PCP visit, a research assistant (RA) will call all patients to provide additional study information, screen them, offer them the opportunity to participate in the study, and inform them of the $10 incentive for participation. After confirming study eligibility, the RA will conduct a 20-minute baseline and risk assessment survey with those who wish to participate.

- Patients will then be randomized according to their physician condition.

- All patients will be scheduled to meet with the RA at the clinic 20 minutes prior to their PCP visit. Patients in the comparison group will sign a HIPAA form and proceed to their regular appointment.

- Patients in the intervention group will sign a HIPAA form, watch the LungCARE video, answer a few assessment questions, and receive a patient report. Their corresponding physicians will receive a physician report that summarizes patient responses.

- One week after the PCP visit, the RA will call all patients to complete a short follow-up survey.

- Two months later, the RA will conduct an EHR review for all participants who have agreed to have their EHR reviewed. We will also randomly select 12 intervention patients to participate in an in-depth interview to assess the intervention.

Physician Component:

- One month after clinic visit, all intervention PCPs will complete a web-based survey. They will receive hard copies of the survey if preferred.

- Two months after the clinic visit, we will randomly select six intervention PCPs to participate in an in-depth interview to assess the intervention.

Benefits/burden for participants (clearly identify potential for harm):

There are no physical risks to the participants in this study. However, there is some risk that the participants will feel discomfort or anxiety resulting from discussing lung cancer screening.

Any benefits or burden to DGIM practitioners?

- Benefit: Patients may be able to understand better the lung cancer screening process.

- Burden: None.

Timeline for recruitment (projected start and stop dates)

Starting January 1, 2019 and ending January 1, 2021.

Funding source: Tobacco-Related Disease Research Program

Potential for DGIM collaborators? (We encourage DGIM resident and fellow involvement in particular): All investigators are faculty at DGIM.

Do you agree to notify us when recruitment is completed? Yes

Date form completed: 11/14/2018