IRB Protocol Application #24-0648 (855800), PI: Farouk Dako (dakof)

Title: Community Support Program for Lung Cancer Screening Abstract

Initial Approval Date	08/02/2024
Expiration Date	
Protocol Overall Status	Approved
Current Status	Approved
Protocol's Review Type	Expedited

Protocol Description

Is there a standalone protocol that outlines the following: background, purpose, objectives, design, selection criteria, research procedures, recruitment methods, informed consent plan, analysis plan, monitoring plan, risks, benefits, and a privacy & confidentiality plan?	Lung cancer remains the leading cause of cancer deaths in the United States, accounting for 25% of all cancer deaths1. Despite the established impact of lung cancer screening (LCS) with low-dose CT (LDCT) and coverage by major health insurances, less than 5% of all eligible individuals receive recommended screening2,3. Furthermore, there are significant disparities in the uptake of recommended LCS in the US on the basis of sociodemographic factors, with individuals who are black, low-income, underinsured, with low education levels, and residing in underserved urban or rural communities having lower rates of LDCT screening uptake47. For example, eligible black patients were 2.8 times less likely to receive LDCT4 and were also less likely to complete follow-up after an initial baseline screening8. This is not inconsequential given the pre-existing disparities in incidence, stage of detection and mortality from lung cancer. For example, black patients are more likely to present at a younger age, at more advanced stages9, and have reduced survival compared to white patients9,10. Furthermore, current cigarette smokingone of the strongest risk

Background:

Describe succinctly and clearly the past findings which justify the plan for this project. A summary of the relevant literature in the area of interest and reports of previous studies should be included.

factorsis highest among vulnerable patient populations and lower socioeconomic status11,12. These trends in screening uptake risk even further exacerbation of disparities in lung cancer outcomes over time.

This study aims to address disparities in lung cancer screening (LCS) adherence using principles of community based participatory research (CBPR) to implement a community support program (CSP) for LCS. By bringing researchers and community stakeholders together as equal partners in decision-making and knowledge sharing, CBPR has demonstrated an ability to reduce health disparities and reduce mistrust between academic and surrounding communities1315. It has also been shown to improve health literacy in underserved populations16,17 which is an independent predictor of adherence to screening programs across multiple cancer types18. Interventions applying principles of CBPR have taken the form of decision aids19,20, patient navigators (Penn Employee) and citizen scientist2125, and mobile clinics26 and have shown positive impact in cancer screening uptake and patient satisfaction among underserved populations, including in LCS. Although there is extensive evidence of the efficacy of community-based cancer prevention programs in improving knowledge and screening uptake, demonstration of their impact in reducing health disparities on a population level remains a challenge27. Our study design overcomes this challenge by utilizing novel population-level data that includes geospatial analysis of neighborhood-level data of patients residing in Philadelphia who have received a LDCT for LCS, allowing for a targeted population-level intervention and robust impact evaluation.

The proposed intervention will be guided by the RE-AIM (Reach Effectiveness Adoption Implementation Maintenance) framework, a robust implementation strategy, widely applied to interventions at the community and population-health levels. With the principal concepts of pragmatic engagement of various stakeholders and iterative reevaluation across multiple domains throughout all stages of

Please detail the study purpose and aims	an intervention, RE-AIM provides a framework for planning and measuring impact of health promotion and disease prevention initiatives with focus on sustainability2830 . Utilization of a robust planning and evaluation framework is critical to ensuring external validity and sustainability of community-based interventions. Our study aims to leverage an existing strong community partnership, novel population-level data, and robust research and evaluation frameworks to implement a scalable intervention to reduce disparities in LCS adherence. See attached grant submission for list of references. The overall objective of this project is to demonstrate the impact of a community support program (CSP) on improve adherence to LCS follow-up guidelines in an urban environment. This project aims to collaborate with community partners to develop an infrastructure and iterative process to provide social support to community members that facilitates obtaining their follow-up LDCT for LCS. It utilizes novel population level data that includes geospatial analysis of neighborhood-level data of patients residing in Philadelphia who have received a LDCT for LCS. This allows for targeted community level interventions and the ability to evaluate impact on a population level.

Describe in detail your design and methodology. Use nontechnical language.	This is a prospective, two arm community support program. First, we will identify Community Support Program (CSP)Representative. We will do so by posting a job advertisement at a local church: The Church of Christian Compassion. We will interview candidates as we would anyone applying for a job within the Penn system. Once hired, the CSP representative will be trained about the basics of lung cancer screening needed to provide support for patients with an upcoming LDCT appointment. The CSP will be selected by our community partners but do not need any medical background. Highest level of education needed is a high school diploma. Patient-facing LCS material, adapted from ACR and Penn Medicine websites, will be created to ensure a fifth-grade readability level and sensitivity to local context in collaboration with a Patient Navigator (Penn Employee) experienced in patient education and the CSP representatives. To adapt resources for fifth-grade readability, we will utilize an interactive process guided by resources from LUNGevity and the Centers for Medicare and Medicaid Services (CMS) health literacy resource toolkit for making written material clear and effective42. Readability will be assessed with a commercial web-based suite of tools (readable.com) using a mean score from multiple validated indices Patient LCS education material would include information on lung cancer, cost and payment options, risks and benefits of screening, radiation exposure, treatment options and smoking cessation. We will also have the patient navigator (employee of Penn)who has access to PennChart and other Penn Medicine systems who will help with the appointment schedules.
Will the research involve obtaining, using, studying, or analyzing of pre-existing data, documents, records or specimens? (I.e., does this protocol involve retrospective record/specimen review?)	No

The Patient Navigator (PN--Penn Employee) will review upcoming and ordered LDCT lung screening appointments through PennChart.The PN will keep a log divided into two groups: 1. Community Support Program (CSP) and 2. Control Group.

1. Community Support Program Group
Patients living within the local radius (see attached map) will be contacted and asked if they are willing to be included in this research study.

The PN will contact patients via MyPennMedicine (if available), e-mail, text, and/or phone call to ask if they are interested in enrolling in the Community Support Program (CSP). We do not plan to send PHI over these telecommunication mechanisms. Please see attached screening form for details.

Describe what participants will be asked to do and, if applicable, what information or specimens will be collected from them.	The PN will contact patients to ask if they are interested in being apart of the Community Support Program (CSP). If the patient agrees, a CSP Representative will reach out to the patient via telephone, text messaging and/or email. The CSP Representative and Patient Navigator will communicate with the patient directly, assist with Scheduling, travel and the appointment. The PN will log the date of the appointment, zip code of the patient and the adherence (or lack of) of the appointment completion. If the patient denies participation, the Patient Navigator will log the patient declined and not pursue any further contact. We will utilize the Uber or Lyft transportation vouchers to provide rides to participants from their home location in West Philadelphia to and from the Penn Medicine downtown hospital locations on the day of their LCS study at no out of pocket cost for most patients. The mean distance from the patient's residential address to the closest Penn Medicine hospital location is 2 miles and an approximate round trip ride costs $22. Participants will also be given the option of a CSP representative arranging their transportation if they do not have access to Uber or Lyft transportation software. Based on projections from our preliminary data, allocation would be made to provide transportation support to 450 patients throughout the study period. 2. Control Group The control group are Penn Medicine patients who are scheduled (or recently missed) a LDCT appointment and not residing in West Philadelphia (under the zip codes listed above). We will monitor their adherence to their appointments through Penn Chart and missed appointment status reports. We will not be in contact with these patients. The Patient Navigator will keep a log of the control group as well. This log will include a subject identifier, gender, zip code, date of LDCT scan and the adherence (or lack of) of the scheduled appointment.

Consortium
The CSP program will be set up to have month-long intervention periods that end with a review process and planning for the next intervention period, utilizing the agile principle of sprint planning43 (Figure 3). This process will allow for iterative changes that incorporate feedback from CSP representatives and foster an equitable research partnership. The radiology PN and CSP representatives will meet weekly to discuss day-to-day activities and hurdles and maintain an open line of communication for daily interactions. Time-sensitive issues will trigger consortium meetings separate from the scheduled monthly review meetings. The initial and monthly consortium meetings will be guided by the RE-AIM framework with emphasis on improving the reach, effectiveness, and maintenance of our interventions. The meeting following the 6-month intervention period will be focused on future planning. The Mixed Methods Research Lab (MMRL), under the guidance of co-investigator Dr. Rendle, will provide technical support to facilitate and evaluate the equitable inclusion of the various stakeholder perspectives into the study design and interactive changes.
See attached grant for more details.

Provide a sequential list of all study procedures/ components, including any follow-up. Include the estimated time commitment on the part of participants. Specify the area(s)/location(s) where the research will be conducted and discuss how this is adequate to ensure the protection of participants.

Describe the plan to analyze the data. Describe the sampling plan, rationale for the proposed sample size, and planned data analysis (quantitative or qualitative as applicable). For quantitative data analysis, include the statistical power of any planned statistical tests.

Evaluation: Evaluation will be guided by the RE-AIM framework with focus on Reach, Effectiveness and Maintenance of our program (Table 1). Primary outcomes of the study include: 1) difference in obtaining the recommended follow-up LDCT screening study in patients with upcoming appointments between the intervention and control group 2) association between participation in the CSP and adherence to follow-up LDCT. An intention-to-treat approach will be used for our primary analysis to measure the effectiveness of the CSP and will be done 2 weeks after completion of the 6-month intervention period. Chi-squared test will be used to measure a difference in adherence to follow-up LDCT between groups. A logistic regression model will be used to determine the association between adherence and utilization of CSP while controlling for demographic, geographic and socioeconomic variables. Secondary outcomes include: 1) difference in follow-up LDCT utilization in the intervention group compared to a similar period prior to implementation of CSP 2) reach of the CSP (what percentage of participants who were offered it engaged with the CSP representative). Evaluation of reach of the CSP would include descriptive analysis to evaluate differences in characteristics between participants who utilized the CSP and those who did not. Secondary analysis will include patients with upcoming and previously missed appointments following a negative screening study from 2020-2022. Mcnemars test will be used to measure a difference in follow-up LDCT utilization after the intervention compared to a similar period pre-intervention. Power Considerations: All sample size and power calculations were conducted using PASS 2022 (NCSS, version 22.0.2), assuming a 5% type I error rate and using two-sided hypothesis tests. With a proposed sample size of 281 patients (167 in West and 114 in Southwest Philadelphia), we will have 80% power to detect an effect size W = 0.17 or larger using one degree of freedom to determine the difference in the proportion of adherence to follow-up LDCT between groups. See Table 2 in the attached grant application.

Please detail how the study has adequate resources to protect participants.

1. Describe research staff and justify that the staff are adequate in number and qualifications to conduct the research.
2. Describe how you will ensure that all staff assisting with the research are adequately informed about the protocol and their research related duties (through training, meetings, etc.)
3. If Penn personnel will be conducting research activities at extramural locations, please identify any additional resources that will be utilized or procedures that will be implemented to ensure human subjects protections.

All staff on this project will undergo training on departmental processes, CITI, CGP and HIPAA.

Staff are familiar with clinical research, community support programs and lung screening.

The CSP Representative will also complete CITI and HIPAA training.