University of Pennsylvania School of Medicine
Hospital of the University of Pennsylvania

Caroline Rosen, Clinical Research Coordinator
Department of Radiology

Community Support Program for Lung Cancer Screening

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Study Protocol and Statistical Analysis Plan

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Caroline Rosen
Clinical Research Coordinator
Department of Radiology | Interventional Radiology
3620 Hamilton Walk
Anatomy Chemistry B-25
Philadelphia, PA 19104
caroline.rosen@pennmedicine.upenn.edu

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Abstract

Lung cancer screening (LCS) using low-dose CT (LDCT) for high-risk individuals is a critical public health tool for reducing lung cancer mortality. Despite the recent expansion of the inclusion criteria to be more equitable, uptake and adherence remains low and is lowest among low-income and racial/ethnic minority populations and in individuals with a negative baseline screening study (Lung-RADS 1&2). Community-based programs promoting cancer screening uptake have demonstrated increased screening engagement compared to clinic-based programs in reaching disadvantaged individuals but suffer from lack of robust funding and limited data demonstrating impact on a population level. Community-based participatory research (CBPR) utilizes a partnership approach, bringing together researchers and community stakeholders as equal partners throughout the research process to contribute expertise and share in decision making. CBPR has demonstrated the ability to reduce cancer health disparities and reduce mistrust between academia and surrounding communities through reciprocal learning.

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.

We will target individuals in our healthcare system residing in Philadelphia with a negative baseline screening CT and an upcoming or missed follow-up screening CT. Participants will be divided into receiving clinic + community support vs routine clinic only (control) based on residential location. The intervention group, consisting of individuals residing in West Philadelphia, will receive the option of enrolling in the CSP for obtaining their recommended LDCT. Community members designated as CSP representatives will receive basic training about LCS, transportation vouchers and information regarding other support services. They will also provide feedback to inform an interactive approach to reevaluating the intervention throughout the course of the study. Primary analysis will measure the 12-month follow-up LDCT adherence rate difference between clinic + CSP group vs clinic only group and its association with CSP enrollment. Additional analyses will measure differences in follow-up LDCT utilization before vs after intervention and extent of enrollment in the CSP in the intervention group. Planning and evaluation of our program will be performed using the widely utilized RE-AIM framework with emphasis on measuring reach, effectiveness, and sustainability of our approach.

Hypothesis: A community support program to facilitate lung cancer screening appointments will improve adherence to yearly follow-up screening compared to routine care alone.

Detailed Research Plan

Significance and Rationale:

Lung cancer remains the leading cause of cancer deaths in the United States, accounting for 25% of all cancer deaths[1]. 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 screening[2,3]. 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 uptake[4–7]. For example, eligible black patients were 2.8 times less likely to receive LDCT[4] and were also less likely to complete follow-up after an initial baseline screening[8]. 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 stages[9], and have reduced survival compared to white patients[9,10]. Furthermore, current cigarette smoking—one of the strongest risk factors—is highest among vulnerable patient populations and lower socioeconomic status[11,12]. 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 communities[13–15]. It has also been shown to improve health literacy in underserved populations[16,17] which is an independent predictor of adherence to screening programs across multiple cancer types[18]. Interventions applying principles of CBPR have taken the form of decision aids[19,20], patient navigators and 'citizen scientist'[21–25], and mobile clinics[26] 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 challenge[27]. *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 an intervention, RE-AIM provides a framework for planning and measuring impact of health promotion and disease prevention initiatives with focus on sustainability[28–30] . 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.*

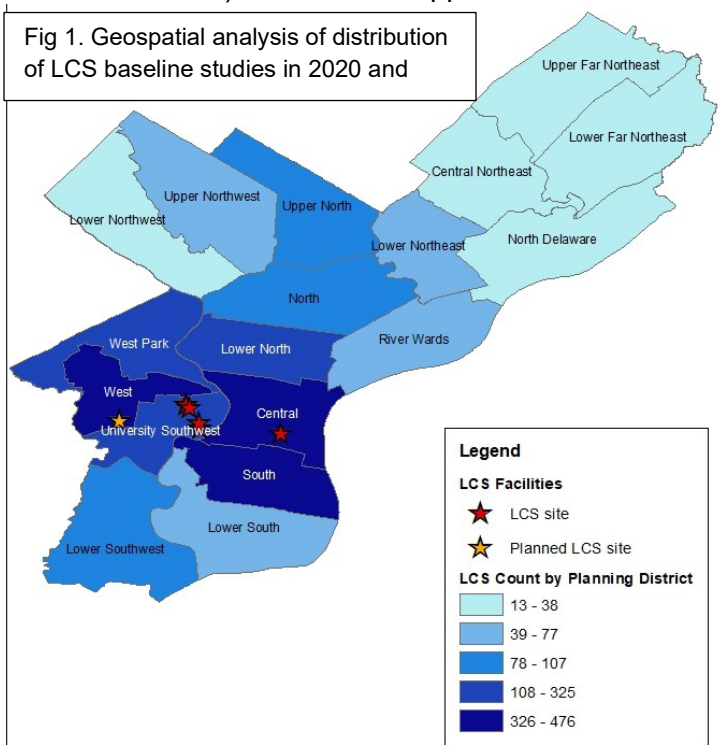
Specific Aims and Objectives:

1. Develop a community support program for lung cancer screening adherence
2. Measure the impact of the community support program in improving adherence to lung cancer screening follow-up

Innovation: This study leverages novel neighborhood-level data to design and evaluate a community-based intervention using a robust implementation science framework, RE-AIM. This design allows for measuring impact on a population level thereby overcoming a common limitation of community-based interventions[27]. Our utilization of CBPR builds on a strong collaborative community partnership with an extensive track record of successful community-based events. Led by members of the study team, our department has collaborated with the Community of Compassion CDC community center in West Philadelphia over the past two academic years to offer 3 events to the surrounding community (see letter of committment). This would support a seamless incorporation of CBPR, an approach that is strikingly absent from the radiology literature despite evidence of its effectiveness in reducing disparities in cancer health outcomes.

Preliminary Data: Using data from our NCI-funded Population-based Research to Optimize the Screening Process (PROSPR) Center, which assesses LCS outcomes in five diverse healthcare systems[31], we observed low adherence rates to LCS recommendations (55% across five systems; 36% overall at Penn Medicine)[32]. Adherence is significantly lower in Black patients at Penn Medicine and varies by baseline Lung-RADS score (21%-70% in Black patients; 32%-88% in White patients). Additionally, adherence is lower among patients living in impoverished neighborhoods (44% vs 63% in high-income neighborhoods). Geospatial analysis for neighborhood-level data of the 349 and 1,328 Philadelphia residents who received LCS in 2020 and 2021 respectively was applied to support our intervention at the planning district level (Figure 1). West and Southwest districts contained 28% and 19% of all patients respectively. For residents who received a LDCT in 2020 with a Lung-RADS 1 or 2 recommendation, which accounted for 90% of all studies, adherence to a 12-month follow-up study in 2021 was 24%. Data collection from 2022 is still in progress so estimates from 2020 and 2021 were utilized.

Fig 1. Geospatial analysis of distribution of LCS baseline studies in 2020 and



A questionnaire developed by Dr. Dako in 2017 was administered to patients visiting Temple University Hospital Radiology Department as part of an effort to understand modifiable patient barriers to LCS in North Philadelphia[33]. It was completed by 124 predominantly African American patients with health insurance. The average score was 33% on items accessing knowledge about LCS. Perceived cost and inability to get out of work were the top two reported reasons for lack of adherence to appointments. These preliminary data, supported by review of the literature, informed our initial approach to reducing barriers to LCS adherence.

The Philadelphia Lung Cancer Learning Community (PLC2) is a collaborative agreement involving a multidisciplinary team across Jefferson Health, Penn Medicine, and Temple Health that aims to decrease lung cancer morbidity and mortality across the greater

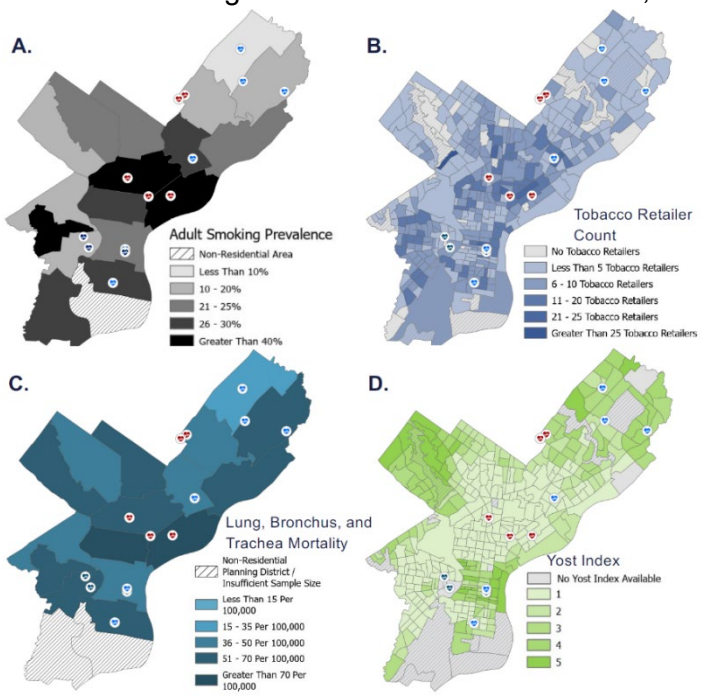


Fig 2. Philadelphia Neighborhood Characteristics. Neighborhood-level data were mapped for each Planning District or Census Tract in the city of Philadelphia.

Philadelphia region by developing and implementing effective ways to increase LCS and tobacco treatment, particularly in populations at greatest risk. The PLC2 has systematically characterized LCS using a city-wide, multi-institutional approach and applied geospatial analyses for neighborhood-level data[34] (Figure 2). This allows for comprehensive strategies that integrate population health approaches and the ability to measure impact on a population health level. Our data sharing and collaboration agreement would support scaling our intervention to a multi-institutional and city-wide level for external validation and increased population impact.

Experimental Design and Methods:

Specific Aim 1. Develop a community support program for lung cancer screening adherence

A consortium of representatives chosen by an established community center with a track record of providing social services to their surrounding communities and Penn Medicine multidisciplinary team will be formed and will work to develop rules of operation and decision making for the community support program (CSP). Penn Medicine team members include researchers in radiology, implementation science and CBPR and a patient navigator (PN). CSP representatives will be individuals chosen by our partner community center that have demonstrated commitment and prior experience in providing social support to their surrounding communities. The consortium members will meet over the course of 2 weeks at the commencement of the study to agree on goals, timeline, organizational structure, and standardized processes. Using the collaborative principles of CBPR, representatives from academia and the community will engage in reciprocal learning sessions to create CSP material that is socially and culturally sensitive to the needs of the community. Initial community support will be developed based on preliminary data and evidence that two of the main barriers to utilization of lung cancer screening are transportation cost/availability and limited education about lung cancer screening[35,36]. We therefore propose providing transportation assistance and education augmentation. In addition, resources will be allocated to provide additional support throughout the study period based on feedback from CSP representatives.

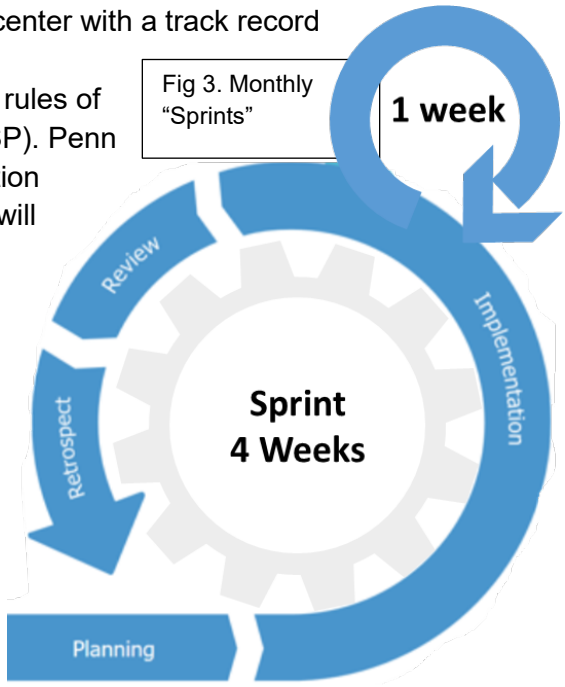


Fig 3. Monthly "Sprints"

Education: CSP representatives will be trained about the basics of lung cancer screening needed to provide support for patients with an upcoming LDCT appointment. Patient-facing LCS material, adapted from ACR and Penn Medicine websites[37], will be created to ensure a fifth-grade readability level and sensitivity to local context in collaboration with a PN 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[38] and the Centers for Medicare and Medicaid Services (CMS) health literacy resource toolkit for making written material clear and effective[42]. Readability will be assessed with a commercial web-based suite of tools (readable.com) using a mean score from multiple validated indices [39,40,41]. 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.

Transportation: 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. Transportation vouchers will be created at an upper limit of $30, which is expected to result in 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.

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 planning[43] (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 (Table 1). 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.

Table 1. Demonstrating the RE-AIM planning and evaluation metrics

RE-AIM components	Question answered	Metric	Future Planning
Reach	How many patients that were offered entry into the community support program engaged with the representative Reasons for non-participation in program.	Number of patients who chose community support / total number of patients who were offered it; demographic and geographic differences of patients reached vs. not reached	Identify potential reasons for patients not choosing community support Identify other possible forms of community support.
Effectiveness	Did addition of community support option lead to increased adherence to follow-up recommendation?	% Of patients who obtained yearly follow-up LDCT in intervention vs control groups % Of patients in intervention group who obtained yearly follow-up LDCT after intervention vs during a similar prior time frame	Identify and compare characteristics of adherent vs non-adherent patients Capture any unintended consequences of community support for LCS Capture additional barriers to LCS adherence
Maintenance (Sustainability)	If the lung cancer screening community support program is effective, how can it be sustained?	Measure actual cost of community support program	Explore options for additional funding including through grants and institutional support Explore institutional return on investment for increased lung cancer screening utilization through community support program

Specific Aim 2. Measure the impact of the community support program in improving adherence to lung cancer screening follow-up.

A prospective study would be designed to measure the impact of the CSP on a population level by utilizing aggregated neighborhood level data. The database contains information of patients who received baseline LCS with individual level residential address geocoded to determine neighborhood level characteristics (see preliminary data). The West Philadelphia planning district will be chosen as the intervention group because it is within the catchment area of Penn Medicine, has the highest number of LCS patients and is one of the districts noted to have consistent high rates of smoking prevalence and lung cancer mortality. In addition, we have strong community partnerships in the region. The control group would be individuals residing in the adjacent Southwest Philadelphia planning district which has a similar Yost score - a composite index of socioeconomic status[41]. Patients will be stratified into those with upcoming or missed appointments with primary analysis focused on patients with upcoming appointments. Informed consent will be provided prior to patient inclusion in the CSP. All activities will be approved by our Institutional Review Board prior to study commencement

We will identify patients residing in West Philadelphia who underwent lung cancer screening in 2020-2022 with a Lung-RADS 1 or 2 result and have an upcoming or missed appointment in our healthcare system downtown hospitals. We will analyze the EHR and RIS data to identify dates of LDCT upcoming appointments over 6 consecutive months with plans for 6 monthly cycles of intervention (Figure 3). A trained radiology PN will contact patients two weeks prior to their upcoming appointment, provide descriptions of the CSP and offer participation. Patients who agree to participate in the CSP would be contacted by a community representative

1 week and 1 day prior to their appointment to offer support based on their identified needs and the available resources. The CSP representatives will be provided transportation vouchers, educational material and resources for other social support and liaise with the radiology PN to report information from patient encounters including additional needs and patient plans to attend appointments. Patients with missed follow-up appointments who still receive care at Penn Medicine will be contacted by the radiology PN for inclusion in the CSP program. The CSP representative will offer appointment support and collaborate with the radiology PN to offer a rescheduled LDCT appointment to this group of study participants.

Recruitment and Sample: The eligibility criteria for study inclusion are 1) obtained LDCT in 2020-2022 with a Lung-RADS 1 or 2 result 2) upcoming or missed follow-up LDCT 3) residence in the city of Philadelphia. Preliminary data revealed that 1,328 individuals residing in Philadelphia received a LDCT in 2021, 90% of which are Lung-RADS 1 or 2. Assuming the same number of patients receive LCS in 2022 and follow-up LDCT scans are evenly distributed throughout the year, we anticipate that 598 individuals will have an **upcoming LDCT study** in the first 6 months of 2023 of which *167 (28%) in West and 114(19%) in Southwest* planning district will be included in our primary analysis. For secondary analysis, patients residing in West Philadelphia (28%) with **missed appointments** (66%) following a Lung-RADS 1 or 2 recommendation on LDCT(90%) in 2020 and 2021 will be included, resulting in an *additional 278 patients*.

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. Mcnemar's 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 for project deliverables and timeline.

Table 2. Deliverables and Timeline (assuming start date of 11/1/2022)

Deliverable	Target Completion
IRB Approval	11/30/2022
Identification of CSP Representatives	11/15/2022
Establishment of Consortium	11/30/2022
Development of Support Material: Education, Transportation etc	12/31/2022
Initiation of the CSP	01/01/2023
Completion of the CSP	06/30/2023
Data and Feedback Analysis	07/31/2023
Manuscript and Presentation Preparation	09/30/2023
Develop Structure for Future City-wide CSP	10/31/2023

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