Institutional Review Board
Intervention/Interaction Detailed Protocol

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Project Title: A Systematic Approach to designing an Implementation strategy to increase Lung cancer screening and Smoking cessation treatment among Federally Qualified community Health Center patients who smoke (SAILS-FQHC)

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1. Background and Significance

Tobacco use is the leading preventable cause of death in the US and a major driver of health disparities. Smoking prevalence is disproportionately high among people with low levels of income and educational achievement, those receiving Medicaid, experiencing homelessness, living with HIV, and people in the LGBT+ community. There are also disparities in tobacco use by race and ethnicity. American Indians and Alaska Natives have high smoking rates, as do other racial and ethnic subgroups such as Puerto Ricans, Cuban-, Vietnamese, and Korean-Americans.(2, 3) African-Americans also suffer disproportionately from tobacco. Although African-Americans have lower smoking prevalence than white Americans, they face higher rates of lung cancer mortality. Tobacco use in groups at risk for health disparities is costly, with an estimated 15% of Medicaid expenditures attributable to tobacco.(4) Plus, this expenditure is poised to grow based on data in California showing the proportion of current smokers who receive Medicaid is growing.(5)

To address this costly driver of health disparities, we have evidence-based treatment options. Both behavioral and pharmacologic treatments are cost-effective and widely available, yet less than 30% of US smokers use an evidence-based treatment when they try to quit. Federally-qualified community health centers (FQHCs) are major providers or care for populations disproportionately affected by tobacco. They also have access to resources that place them in a position to impact tobacco-related illness. In terms of resources, 45% of FQHC patients are MassHealth recipients who are eligible for cessation benefits that include minimal-cost access to FDA-approved pharmacotherapies. Many FQHCs have an available but underused tool to proactively refer smokers to the Quitline using an eReferral feature, currently in Epic OCHIN, and available for mapping in other EHRs.

Also among our tools for reducing the harms of tobacco is lung cancer screening (LCS). In 2015, the US Preventative Services Task Force recommended, and Medicare currently covers, annual lung cancer screening (LCS) among adults aged 55 to 80 years who have a 30 pack-year smoking history and currently smoke or have quit within the past 15 years. In March 2021, the USPSTF expanded their recommendations to individuals 50-80 years with a 20 pack-year smoking history;(6) Medicare coverage for these younger individuals with a shorter pack-year history is expected to start in 2023. The expanded screening criteria is inclusive of more women and African-Americans. Prior to this expanded eligibility, only 2-5% of eligible Americans had

undergone screening. Previously reported barriers to LCS in FQHCs include ability to assess eligibility, costs, lack of support from leadership, and specialty care access. These barriers need to be re-examined in the setting of expanded eligibility criteria.

Optimizing the use of these resources and increasing the delivery of evidence-based interventions in community health centers will produce large public health impacts by reducing lung cancer mortality and other tobacco-related illness and promoting health equity. Implementation science offers important tools to do this.

2. Specific Aims and Objectives

We will combine a review of existing qualitative and quantitative data on barriers to lung cancer screening and smoking cessation in underserved populations, a quantitative analysis of predictors of lung cancer screening and smoking cessation treatment use among Massachusetts FQHCs, and a stakeholder advisory board to synthesize these data and select an implementation strategies that reflects the critical determinants and the strengths and resource constraints of the FQHC context. We have the following aims:

Aim 1) To design an implementation strategy that targets critical components in the delivery of SCT or LCS services for patients who smoke. Deidentified Massachusetts FQHC EHR data will be analyzed to identify risk factors for underuse of SCT and LCS among patients who smoke. This will be integrated with the growing body of literature on barriers and facilitators to LCS or SCT among populations served by FQHCs using a stakeholder engaged approach to identify the critical components of implementation in the FQHC context. Using a collaborative design process, FQHC stakeholders and investigators will select implementation strategies that target the critical barriers to the delivery of LCS and SCT implementation for adults who smoke, matching the strategy to local resources such as IT solutions including Quitline eReferrals, smoking registries, registries of LCS eligible patients, and task shifting approaches to engage navigators or CHWs in SCT and LCS.

Aim 2) To assess the acceptability, appropriateness and feasibility of the implementation strategy. In a pilot test of the strategy with two FQHCs, we will measure implementation process outcomes of acceptability, feasibility, and appropriateness of the strategy will be assessed through surveys, workflow tracking data, and qualitative interviews with FQHC staff and other healthcare providers from two FQHCs. We will also measure reach and effectiveness by measuring rates of LCS orders, LCS completion, smoking cessation treatment prescriptions and quitline e-referrals in our two pilot FQHCs, compared to two matched non-intervention FQHCs.

3. General Description of Study Design

Aim 1) To design an implementation strategy that targets critical components in the delivery of SCT or LCS services for patients who smoke. To identify the critical components of LCS and SCT implementation, we will combine quantitative data measuring risk factors for underuse of these interventions in Massachusetts CHCs and existing literature on barriers to implementation of these interventions in a collaborative, stakeholder-engaged approach. We will leverage the Azara DRVS system (a data reporting and visualization system that maps onto EHR structured data and is used by most Massachusetts FQHCs for quality improvement and data reporting purposes) to measure LCS and SCT use patterns including lung cancer screening orders, LCS completion, prescription of smoking cessation pharmacotherapies, and quitline e-referral utilization. We will examine predictors of underuse of these interventions among LCS eligible

adults patients who smoke. Predictors will include measurement of critical factors that could drive inequities such as language assistance needs or geographic accessibility of specialty services. This data is stored in the Implementation Science Center for Cancer Control Equity Data Ecosystem housed at DF/HCC (HSPH IRB Repository Protocol #IRB20-0988). The Data Ecosystem includes deidentified patient level data, community health center organizational data, and area-level public health data.

Review literature on barriers to SCT and LCS: Combined with this analysis of EHR data, our team will also review existing literature on the multi-level barriers to implementation of LCS and SCT among underserved populations. We will work with the Treadwell library to develop search criteria for each intervention. Articles retrieved using these searches will be reviewed to compile a list of barriers and facilitators to implementation of LCS and SCT. To optimize the delivery of SCT for patients referred for LCS, we will compare barriers and facilitators for implementing LCS and barriers and facilitators to implementing SCT in order to identify overlapping critical factors that represent efficient, high-impact targets in an implementation strategy.

Stakeholder advisory group: We will convene a stakeholder advisory group to review the risk factors for underuse of these interventions, the list of barriers and facilitators to implementation from the existing literature, and a menu of implementation strategies that leverage local resources. The members of the stakeholder advisory group will help inform what implementation strategies best fit the CHC setting and they will include CHC providers, quality improvement specialists, community engagement staff, and specialty providers. This group will be invited to advise on interpretation of risk factors identified with analysis of CHC EHR data, the relevance of barriers and facilitators identified in the literature in their contexts, and the potential feasibility of implementation strategies on the menu of discrete strategies. This menu will include provider audit and feedback, technical assistance with the DRVS tool to generate registries/identify eligible patients, redefining clinician roles/task-shifting, identification of a clinical champion, academic detailing, advisory/stakeholder workgroups through our stakeholder advisory board, and leveraging the DRVS population health tool to support and monitor quality improvement in delivery of LCS and SCT.(7) The product of this collaborative process will be a menu of these discrete strategies that are matched with the critical factors in implementation for each intervention in the local FQHC context, paired with an overall external facilitation strategy.

The group will be asked to participate in four meetings prior to launching the pilot study to inform the pilot approach and one meeting after the pilot study to advise on the development of a toolkit for community practitioners to support use of this implementation approach with external facilitation plus the menu of specific implementation strategy options.

Aim 2) To assess the acceptability, appropriateness and feasibility of the implementation strategy To ensure that we can evaluate the acceptability, appropriateness, and feasibility of the implementation strategy at FQHCs serving groups at risk for inequity, we will select two pilot FQHCs that serve these populations. In this aim we will measure implementation process outcomes of feasibility, acceptability, and appropriateness of the implementation strategy. We will also use the data ecosystem to measure service outcomes

Figure 1. Brief measures using 5-point scale(1) (Completely agree – completely disagree)

Acceptability of Intervention Measure (AIM)

1) [Implementation strategy] meets my approval.
2) [Implementation Strategy] is appealing to me.
3) I like [Implementation Strategy].
4) I welcome [Implementation Strategy].

Intervention Appropriateness Measure (IAM)

1) [Implementation Strategy] seems fitting.
2) [Implementation Strategy] seems suitable.
3) [Implementation Strategy] seems applicable.
4) [Implementation Strategy] seems like a good match.

Feasibility of Intervention Measure (FIM)

1) [Implementation Strategy] seems implementable.
2) [Implementation Strategy] seems possible.
3) [Implementation Strategy] seems doable.
4) [Implementation Strategy] seems easy to use.

of lung cancer screening CT orders, LCS completion, quitline referrals, and prescription of smoking cessation medications.

Process outcomes: We will use a mixed methods approach to assessment of feasibility, acceptability and appropriateness of the strategy (overall strategy plus specific strategies selected from the menu of options) will be measured using Weiner's brief instruments by email survey among implementing staff.(1) The email survey will be sent prior to conducting a group interview (virtual or in-person, depending on infection control policies) to explore these measures.

4. Subject Selection

Aim 1) To design an implementation strategy that targets critical components in the delivery of SCT or LCS services for patients who smoke. For the aim 1 analysis of predictors of LCS and SCT in FQHCs, we will examine LCS eligible adults aged 50-80 who are listed as current smokers in the EHR of partner FQHCs and who have had a primary care visit in the past 2 years. These patients will be selected from the ISCCCE data ecosystem using deidentified data.

Aim 2) To assess the acceptability, appropriateness and feasibility of the implementation strategy.
For the Aim 2 activities, two pilot FQHCs will be intervention sites in which we identify implementation barriers and work with the FQHCs to select a menu of implementation strategies. Two sites will be control sites, matched by size and patient population characteristics. De-identified patient data in the ISCCCE data ecosystem will be used to evaluate the impact of the implementation strategy in terms of lung cancer screening and smoking cessation treatment rates in the intervention sites compared to two matched control sites.

The second subject sample in aim 2 are the FQHC implementation team staff in the intervention FQHCs.

5. Subject Enrollment

We are seeking a waiver of consent for enrollment of the de-identified patient sample in the data ecosystem. The data ecosystem methods and processes have been reviewed by the Harvard IRB as a data coordinating center. Data use agreements are in place between partner FQHCs and the data coordinating center to share data that is stored in a de-identified database in REDCap.

FQHC staff on the implementation teams will be emailed a link to a brief redcap survey that includes language about implied consent prior to initiating the survey. Group interview participants will be read study information at the start of the group discussion that explains that their participation is voluntary, that the discussion will be recorded and transcribed and that their data will be kept confidential. Participants will be invited to ask questions prior to starting the discussion and recording.

6. Study Procedures

Aim 1

In Aim 1 we will convene a stakeholder advisory group (CHC providers, quality improvement specialists, community engagement staff, and specialty providers) to review the results of the literature review and quantitative analysis of deidentified data in order to select a set of implementation strategies from a menu of strategies to implement in Aim 2.

Quantitative analysis will include: patient level: age, sex, primary payer, race, ethnicity, language, zip code (first 3 digits), housing status, educational level, employment status, food insecurity, transportation needs, smoking status, receipt of smoking cessation counseling, Charlson comorbidity score (CVD, CKD, stroke, cancer, dementia, cirrhosis, diabetes, CHF, hypertension, or PVD), obesity, number of visits, history of chest CT, covid history, smoking cessation medications; organizational level: implementation climate, leadership, institutional resources; and community level: poverty, area deprivation, distance from the health center to primary low dose CT facility, and area smoking prevalence.

The implementation strategies are developed in Aim 1. These include provider training led by internal staff on screening for tobacco use and documentation of pack years, establishing communications between CHCs and radiology providers, systematic referral of patients eligible for lung screening to health center's patient navigation services, and implementation of Azara DRVS alerts notifying the care team when a patient has a care gap in tobacco use status or lung screening.

Aim 2

The two intervention FQHCs will be asked to identify an implementation team consisting of CHC staff members to meet with the study investigators to implement the strategies selected in Aim 1.

The qualitative group interviews will be conducted by the PI and the CRC. Participants will be the implementing teams at pilot FQHCs, which we expect to include a total of 15 participants overall. The discussion guide will be developed using the Consolidated Framework for Implementation Research Interview Guide Tool. This framework is selected to align with ISCCCE's overall conceptual model. In these discussions, in addition to exploring the acceptability, appropriateness and feasibility of the strategies, the discussion will cover other barriers to implementation that were encountered in the inner setting or outer setting, barriers or facilitators inherent to the intervention, the impact of the implementing team make-up, and barriers and facilitators to the implementation process. We will further explore solutions for overcoming those barriers that the group tried or is planning, any inequities in delivery of services that the group identified, and any recommended modifications to improve the feasibility, acceptability, appropriateness of the implementation strategy or the equity of LCS and SCT services delivered. The qualitative group interviews and the survey will take approximately 60-90 minutes with the potential of it being shorter depending on how much participants share.

Discussion will be audio-recorded and transcribed for analysis. Analysis will use Nvivo 12 and a framework approach that incorporates elements of the Consolidated Framework for Implementation Research. Transcripts will be double-coded by a team of two research staff and investigators. The coding framework will cover intervention characteristics, inner setting, outer setting, impact of individual team members, and the implementation process as well as emergent themes, emphasizing equity in implementation.

Study info will be sent to participants prior to the email survey or the scheduled group interview.

Qualitative results will be combined with the brief email survey data plus ISCCCE data ecosystem resources including organizational characteristics of the participating CHCs and outer context, area-level measures of the communities served by the pilot CHCs that is stored in

the ISCCCE Data Ecosystem. Qualitative themes will be presented in a joint display with quantitative measures of acceptability, feasibility and appropriateness to gain further insight into how the implementation strategies were or were not feasible in the pilot CHC context.

Service outcomes: We will measure reach and effectiveness of the strategy by measuring closure of tobacco use status care gaps, closure of lung screening care gaps, lung screening no-shows, and smoking cessation prescriptions in the two pilot sites and two matched non-intervention FQHCs who participate in the data ecosystem. These outcomes will be measured in the pilot sites in the six months before implementation and the six months during the implementation.

7. Risks and Discomforts

Risks of this project include risks of breach of confidentiality and psychological distress. Individuals may find it stressful to answer questions about their work in the resource limited setting of the FQHCs. The risks associated with these discussions are minimal, especially when compared to the potential to benefit quality of care for FQHC patients.

The information collected about barriers and facilitators to lung cancer screening and smoking cessation treatment delivery and information about the feasibility, acceptability and appropriateness of the implementation strategy are not expected to place the participant at risk of liability, financial standing, employability, insurability or reputation.

To minimize the risk of breach of confidentiality all data will be kept in password protected, institutional shared file areas. Data sharing between institutions will include only deidentified data. Individuals may find it stressful to answer questions about their work in the resource limited setting of the FQHCs. The risks associated with these discussions are minimal, especially when compared to the potential to benefit quality of care for FQHC patients. These risks will be described by the research staff moderating group discussions and will be clearly outlined in the study information script prior to starting the group discussion.

8. Benefits

Participants may derive satisfaction from knowing study results may contribute toward improving lung cancer screening services or smoking cessation treatment delivery for individuals in their community.

9. Statistical Analysis

Aim 1

We will measure the prevalence of lung cancer screening among age-eligible patients documented as current smokers in EHRs. Similarly, we will measure the prevalence of smoking cessation medication prescriptions (varenicline, nicotine replacement therapy, and bupropion), quitline referrals, or other cessation counseling. We will measure the predictors of underscreening and undertreatment including: 1) socio-demographics of sex, gender identity, race, ethnicity, language, and insurance status, 2) social determinants of health including housing instability and transportation needs, 3) comorbid mental and behavioral health diagnoses, and 4) area-level measures including area-level deprivation, smoking prevalence and distance to low-dose CT facility. Predictors of LCS and predictors of SCT will be assessed

using multilevel logistical models to understand the variation in screening attributable to the patient-, clinic-, and area-level. Understanding the contribution of these levels of influence will be important for determining critical implementation factors at each level.

Aim 2

This pilot study will be underpowered to measure a statistically significant difference pre- and post-implementation. It aims to provide data on the estimated effect size and to identify predictors of equitable reach and effectiveness. The change in LCS and SCT reach and effectiveness will be stratified by key risk factors identified in aim 1 and will include race, ethnicity, language, insurance status, social determinants of housing and transportation needs, and community-level socioeconomic measures and distance to low-dose CT facilities. This exploratory difference in differences analysis will be hypothesis generating to inform a larger scale trial of this systematic approach to selecting implementation strategies.

10. Monitoring and Quality Assurance

Data quality and enrollment will be discussed in weekly steering committee meetings. The PI will work with a clinical research coordinator and the Data Ecosystem team to monitor data protocol adherence. We do not anticipate adverse events from this research, however, any unanticipated problems or adverse events will be reported to the IRB within 5 working days of when the unanticipated problem is discovered.

11. Privacy and Confidentiality

- ☒ Study procedures will be conducted in a private setting
- ☒ Only data and/or specimens necessary for the conduct of the study will be collected
- ☒ Data collected (paper and/or electronic) will be maintained in a secure location with appropriate protections such as password protection, encryption, physical security measures (locked files/areas)
- ☒ Specimens collected will be maintained in a secure location with appropriate protections (e.g. locked storage spaces, laboratory areas)
- ☒ Data and specimens will only be shared with individuals who are members of the IRB-approved research team or approved for sharing as described in this IRB protocol
- ☒ Data and/or specimens requiring transportation from one location or electronic space to another will be transported only in a secure manner (e.g. encrypted files, password protection, using chain-of-custody procedures, etc.)
- ☒ All electronic communication with participants will comply with Mass General Brigham secure communication policies
- ☒ Identifiers will be coded or removed as soon as feasible and access to files linking identifiers with coded data or specimens will be limited to the minimal necessary members of the research team required to conduct the research
- ☒ All staff are trained on and will follow the Mass General Brigham policies and procedures for maintaining appropriate confidentiality of research data and specimens
- ☒ The PI will ensure that all staff implement and follow any Research Information Service Office (RISO) requirements for this research
- ☐ Additional privacy and/or confidentiality protections

12. References

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