

1. Proactive Population Health Strategy to Offer Tobacco Dependence Treatment to Smokers in a Primary Care Practice Network

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2. Abstract

This project will implement and evaluate a novel population health strategy to increase the delivery of tobacco dependence treatment to smokers who receive health care in adult primary care practices affiliated with Massachusetts General Hospital, a member of Partners HealthCare System, Eastern Massachusetts' largest integrated health-care delivery system. Unlike most health-care system-based strategies, which are triggered by a smoker's office visit, this project uses the electronic health record to identify all smokers in the target practices. It proactively reaches out to engage them in tobacco cessation treatment independent of office visits, thereby supplementing but not replacing PCPs' practice-based efforts. Automated telephone calls using interactive voice response (IVR) technology, supplemented by email messages, do the outreach. When a smoker responds, the project compares two strategies to link the smoker to evidence-based tobacco cessation treatments. (1) A Chronic Disease Management model has an internal Tobacco Care Coordinator to help the smoker address tobacco dependence using resources available in the community or health care system. (2) A technology-facilitated health care system-to-community linkage transfers the smoker seamlessly in real time from the IVR call to the Massachusetts Smokers Helpline, a community-based resource. A pragmatic randomized controlled trial will determine whether the population outreach strategy increases the proportion of smokers who receive tobacco cessation treatment over 6 months, compared to usual care, and explore which of the two intervention strategies is more effective. The goal is to build an effective, sustainable, scalable strategy for delivering tobacco cessation treatment that health care systems will adopt.

**A. Proactive Population Health Strategy to Offer Tobacco Dependence Treatment to Smokers
in a Primary Care Practice Network**

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C. Main Section of the proposal

3. Overall Goal & Objectives

Health care systems are key channels for delivering tobacco cessation treatment to the smokers in a population. However, current health care system approaches fail to offer treatment reliably to smokers, in part because they use largely “reactive” strategies. These require busy clinicians with many competing demands on their time to initiate treatment in the course of clinical encounter in the office or hospital. A population-based approach is an alternative that could complement office-based care and offload busy clinicians. The ongoing evolution of the health care system is making this more feasible.¹⁻³ Health care systems have a strong financial incentive from the federal government to adopt electronic health records (EHR) that document patients’ smoking status in a coded field.⁴ This facilitates the creation of a registry of smokers who can be offered tobacco treatment proactively. As health systems transition from fee-for-service care to become accountable care organizations, they have a stronger financial incentive to manage tobacco smoking as a chronic disease.² However, the optimal way to implement a proactive population health strategy for tobacco users is unclear.

Goal of the Project

The goal of the project is to create and test a novel population health strategy to increase the delivery of tobacco dependence treatment to smokers who receive health care in the adult primary care practices affiliated with Massachusetts General Hospital (MGH), a member of Partners Health Care Inc., the largest integrated health care delivery system in eastern MA and an accountable care organization. This innovative project differs from typical healthcare system-based strategies which are triggered by a smoker’s visit to an office practice or hospital. Instead, it uses data from the electronic health record (EHR) to identify the population of smokers enrolled in the target practices. It then reaches out proactively to engage them in tobacco cessation treatment, independent of their office visits or other health service delivery. The program aims to supplement but not replace efforts made by the smokers’ primary care providers during office practice.

This project builds on 3 previous studies that tested population outreach strategies offering treatment to smokers identified by EHR documentation.⁵⁻⁷ Two of them involved the PI, Dr. Rigotti.^{5,7} The other was conducted in a VA setting with a predominantly male population.⁶ The program components varied, but each program increased smokers’ use of tobacco treatment services and tobacco abstinence rates over usual care. They provide proof-of-concept evidence of the value of a proactive population-based approach. The next step is to integrate these concepts into a sustainable model that real-world health care delivery systems and accountable care organizations will implement. That is what the current project aims to do.

To be successful, a population health model for tobacco users must accomplish two tasks. First, it must successfully engage smokers at a time and place independent of typical health care delivery. When a smoker responds, the model must offer attractive and accessible tobacco treatment services and seamlessly link the smoker to those services. To accomplish these tasks, the proposed project will integrate communication technologies and link them to the EHR. In

particular, it will use a novel automated telephone technology, interactive voice response (IVR), to proactively reach, engage, and follow smokers in a cost-effective way. IVR is a telephone technology in which a computer detects a voice and touch tones, and responds to callers with a pre-recorded audio script. We have successfully used IVR technology to deliver tobacco treatment to smokers in inpatient and outpatient settings in our health care system.⁷⁻⁹

Once a smoker responds to the IVR outreach, the project will compare two strategies for providing evidence-based tobacco cessation treatment resources. Both strategies use resources that are currently available in either the community or the health care system. The first strategy uses a Chronic Disease Management (CDM) model. Two previous studies have demonstrated the effectiveness of a care coordination strategy for increasing tobacco cessation treatment use.^{10,11} It should be acceptable to health care systems because they commonly use CDM models to manage other chronic diseases (e.g., diabetes and cardiovascular disease).¹² For our project, the CDM model will connect the smoker with a Tobacco Care Coordinator who partners with the smoker to manage his or her tobacco dependence. After an initial assessment, the Tobacco Coordinator will connect the smoker to appropriate internal (health care system based) and/or external (community based) tobacco cessation resources and monitor progress over time. We have successfully implemented a short-term pilot of this model in our health care system.⁵

The second strategy connects a smoker directly to a community-based tobacco cessation resource, the Massachusetts Smokers Helpline, an evidence-based free community resource that provides both tobacco cessation counseling by telephone and a limited supply of free NRT to eligible smokers.¹³ We will directly transfer a smoker from the IVR outreach call to the MA Helpline in real time, thereby facilitating immediate access to both telephone counseling and free NRT. We have successfully achieved this “warm transfer” capability in an ongoing study of hospitalized smokers.¹⁴ This strategy resembles but improves on prior studies in which proactive referral of smokers from a physician’s office to a state quitline improved rates of tobacco cessation treatment use.¹⁵⁻¹⁷ Those studies featured asynchronous connection of the smoker to the quitline. In contrast, we propose to link the smoker to a quitline in real-time.

Both proposed strategies have been suggested to help health care systems address tobacco dependence. From the health care system perspective, the second model should require fewer resources because it avoids the personnel cost of a Tobacco Coordinator, but the Chronic Disease Management model might be more effective by offering access to a broader range of tobacco cessation treatments and providing continuity of care. To our knowledge, these models have not been directly compared. A comparison of the effectiveness and cost-effectiveness of each model vs. usual care would provide helpful information to health care systems considering adopting a population health system for managing the care of tobacco users.

The proposed program will be evaluated with a pragmatic randomized controlled trial to determine whether the population outreach strategy increases the proportion of smokers who receive tobacco cessation treatment over 6 months, compared to usual care. It will also explore whether the program increases tobacco abstinence rates.

Key Objectives / Specific Aims

The goal of the project is to implement a population-based proactive outreach program to current smokers in a health care system's primary care practices. The program will

- (a) proactively contact smokers independent of their health care visits and
- (b) connect smokers who respond to evidence-based tobacco cessation resources available in the health care system and/or community.

Aim 1: To determine the feasibility and reach of the program

1.a. What proportion of targeted smokers in the primary care practices respond to a proactive outreach program?

1.b. What proportion of smokers in the primary care practices who respond will accept the offer of tobacco treatment made independently of office visits?

Aim 2: To determine whether the program increases the proportion of smokers in a health care system who use tobacco cessation treatment over a 6-month follow-up, compared to those receiving usual clinical care. A pragmatic randomized controlled trial will test:

2.a. Does the proactive offer of tobacco cessation services increase the proportion of smokers who use these services over 6 months, compared to smokers who are offered usual clinical care?

2.b. (Exploratory): Do the two strategies for offering tobacco cessation services differ in the proportion of smokers who use tobacco cessation treatment over 6 months?

2.c. (Exploratory): Do the intervention conditions increase self-reported 7-day tobacco abstinence rates compared to usual care?

Alignment with the funder's and stakeholders' goals

RFP: The project is consistent with the RFP's goal of "improving...the performance of healthcare systems so that all smokers can be helped to quit." It proposes "systems changes that will reach larger numbers of patients." It targets low-income smokers, "a special population...disproportionately burdened by smoking," by targeting patients receiving care from community health centers located in disadvantaged communities. As the RFP encourages, the project is a collaboration within and between institutions: (1) Partners HealthCare Inc., (2) MGH, (3) the Massachusetts Department of Public Health (MDPH) Tobacco Cessation and Prevention Program, which operates the MA Smokers Helpline, (4) the MGH Tobacco Research and Treatment Center, a tobacco research group based in a health care system, and (5) TelAsk Technologies, a provider of health communication services.

Partners HealthCare System: The project aligns with Partners' priority to build Population Health Management capacity as it transitions to becoming an Accountable Care Organization.¹⁸ Current contracts with payers put revenues at risk if breast, cervical, and colorectal cancer screening targets are not met. Partners funded 4 centrally-located Population Health Managers (PHM) in 2014 to work closely with primary care practices to meet these targets. We designed the Tobacco Care Coordinator to resemble PHMs but to extend the model to health behavior change. In the future, the tobacco coordination functions could be integrated into the PHM role to maximize their sustainability. Alternately, the Tobacco Care Coordinator model might

broaden to promote a healthy lifestyle more generally if these goals are part of future Partners risk-sharing contracts.

Massachusetts General Hospital (MGH): The project also aligns well with MGH's new 10-year strategic plan. A core component of the plan is reducing substance abuse in the communities served by MGH practices. Since 2014, MGH Administration has provided new funds to support a Tobacco Coach to offers individual in-person counseling at the 5 MGH community health centers. The project also aligns with Primary Care Administration's goals to transition primary care practices to patient-centered medical homes and to build its Practice-Based Research Network. Dr. Rigotti, the PI, is MGH's long-time local tobacco champion, as well as the tobacco champion for the overall Partners HealthCare System. She leads MGH's Tobacco Research and Treatment Center, a research group that implements and tests strategies to incorporate tobacco cessation treatment into inpatient and outpatient health care settings.

MDPH: The Massachusetts Smokers Helpline, run by MDPH's MA Tobacco Cessation and Prevention Program, created QuitWorks, one of the nation's first proactive fax-referral systems to encourage referrals from health care providers.¹³ MDPH remains committed to this model. It has a strong interest in encouraging a closer link to MGH and Partners HealthCare System because of the large number of providers represented. MDPH is also open to updating the QuitWorks model to incorporate new health communication technologies, including the IVR-to-Helpline link we propose.

4. Technical Approach

a. Current Assessment of Need in Target Area

Target Population: The Massachusetts General Hospital Primary Care Practice-Based Research Network (MGH PC-PBRN) consists of 18 primary care practices, including 5 community health centers, serving a diverse patient population in eastern MA. Over 200 primary care providers, linked by an electronic health record (EHR), cared for 156,887 adult patients during 2011-2013. Patients' mean age was 46 years, 57% were female, 75% were white, 6% were black, and 10% were Hispanic. Among all patients, 112,584 (72%) had smoking status documented in a coded field. Of these, 10,789 (9.6%) were current smokers; for comparison, 15% of MA adults smoke.¹⁹ Practices varied widely in the prevalence of current smoking; the community health centers had the highest smoking prevalence (mean of 18.5%).

MGH Administration is making a major effort to transform the PC-PBRN practices into patient-centered medical homes. This effort, led by Associate Medical Director for Primary Care Dr. Eric Weil, has brought many practice changes that have increased PCPs' clinical and administrative burdens. Consequently, this is an inopportune time to launch a new office-based initiative. However, population-based outreach to provide tobacco treatment separate from office visits was a strategy that PCPs welcomed in our previous pilot study in one practice.⁵ It is also consistent with Partners Health Care's Population Health current priorities,¹⁸ making it an good strategy to improve tobacco treatment delivery in the current environment (*See Dr. Chaguturu's letter*). MGH Primary Care practice administration also strongly supports this effort (*See Dr. Weil's letter*).

Tobacco treatment resources currently available to the target population:

Community-based:

Counseling and pharmacotherapy: MDPH's Tobacco Cessation and Prevention Program funds the Massachusetts Smokers' Helpline, which offers up to 5 multi-session proactive telephone counseling calls, patient education materials, and 4 weeks of free nicotine patch or gum to patients who set a quit date within 30 days. The Helpline served 9,000 callers last year, which is 1.1% of the estimated smoking population of Massachusetts.

Health system-based tobacco treatment services for MGH outpatients:

a. *QuitWorks:* PCPs in all practices can use a QuitWorks form to fax-refer patients to the MA Helpline.²⁰ Upon receipt, Helpline staff proactively contact the smoker to offer standard services and provide feedback by fax to the PCP about the result of the referral. Six months later, all patients who register for telephone counseling are contacted to assess their smoking status. **According to MA Helpline records, only 1.2% (N=134) of smokers were referred to QuitWorks from MGH primary care practices in CY2013**, indicating substantial underuse of this resource by MGH primary care practices.

b. *In-person tobacco cessation counseling services* are available in the 5 community health center practices. In September 2014 these practices received new funding from MGH Administration as part of the MGH-wide effort to improve treatment of substance use disorders in communities served by MGH health centers. Currently, 1.2 FTE tobacco coaches provide individual in-person counseling services at the 5 community health centers.

c. *Pharmacotherapy coverage:* Massachusetts Medicaid covers all FDA-approved smoking cessation medications for two 3-month courses per year with a \$1-\$3/month co-pay. Private insurers generally cover prescription-only FDA approved cessation aids but not OTC nicotine patch, gum or lozenge. This is likely to change with implementation of the ACA.²¹

d. *EHR resources/support:* Partners' EHR includes a coded field for smoking status; 72% of patients in MGH primary care practices had an entry in this field in 2013. Coded fields also exist for problem lists and medication lists, but OTC medications like NRT are not reliably recorded in the medication list. Smoking counseling is not documented in a coded field.

b. Project Design and Methods

Overview

The project is designed to increase the capacity of MGH's Primary Care Practices to connect patients who smoke tobacco with existing evidence-based tobacco treatment services located in the community and the health care system, and to do so without increasing the workload of overburdened practices and clinicians. It will reach out proactively to all documented smokers in the target population to offer them tobacco cessation advice, assessment, and assistance. Specifically, it will implement and compare two innovative models for engaging patients in treatment and compare these to each other and to usual clinical care. If effective, the model has good potential for sustainability. It is sponsored by Partners Health Care System's Population Health Management and it was designed intentionally to mirror other population health initiatives for preventive care delivery that Population Health Management is implementing for this large integrated health care delivery system.

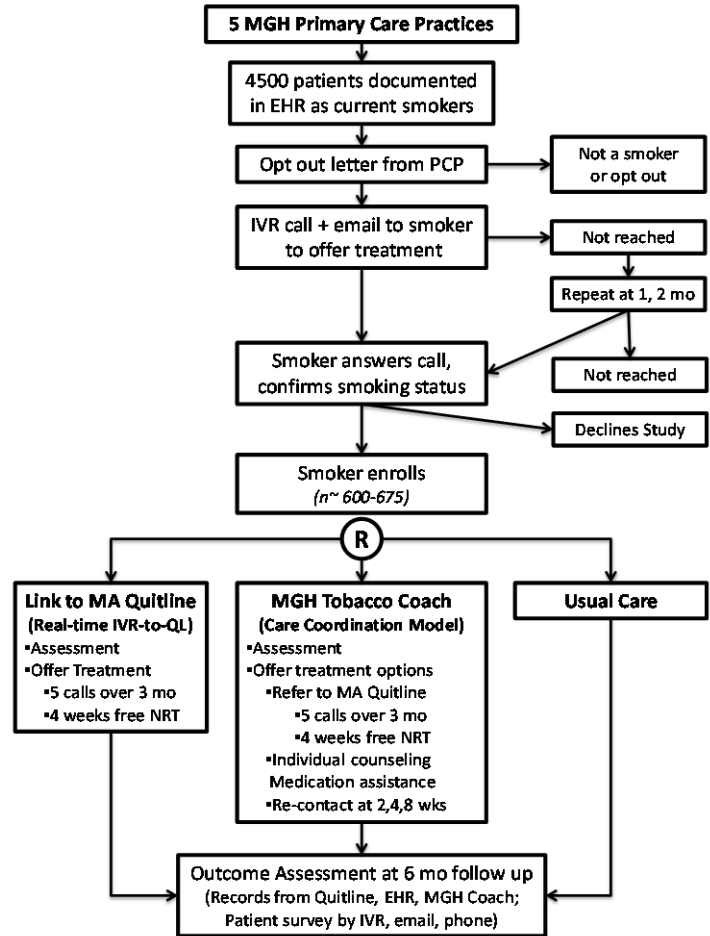
Target Audience

Adult patients enrolled for primary care at the 5 MGH Primary Care PBRN practices with the highest smoking prevalence comprise the target population (n=5233 smokers). All are located in MGH-affiliated community health centers. Administrative staff working under the direction of Dr. Steven Atlas, Director of the MGH PC-PBRN, will use the PC-PBRN's infrastructure to identify all patients who were seen at a participating MGH Primary Care practice in 2014, were identified as a current smoker in the EHR's smoking status field at their most recent office visit, and who have a listed telephone number. We will randomly sample 4500 smokers from this population to recruit for the study.

Outreach and Patient Engagement (=Trial recruitment and randomization)

During a one-year period, study staff will proactively reach out to recruit smokers in the month of their birthday. Targeting birthdays distributes the workload evenly over one year. It also contacts smokers at the time of an event that might make them more receptive to changing a health-related behavior. Current smokers in each month's cohort will receive a letter signed by their PCP informing them that they will be contacted by telephone and email about a free new opportunity for smokers. Recipients who are not smokers or do not want to be contacted will be provided a phone number to call study staff to opt out of further communications. Recipients whose telephone contact has changed will be asked to call or email study staff to update contact information.

Two weeks later, smokers who have not opted out will receive an automated telephone call using an interactive voice response (IVR) system developed and operated by TelAsk Technologies. A total of 15 call attempts will be made at different times of day and days of week. Smokers who do not answer IVR calls and have e-mail contact will then receive an email message that describes the study opportunity and asks them to reply to the email to learn more or to opt out. They will indicate the preferred day and time for an IVR call in the reply or they can initiate an in-bound call to the IVR system to indicate interest or learn more about the project. Because smokers' readiness to address tobacco use varies over time, patients who do not respond to this outreach in the month of their birthday will be contacted in the same manner 1 and 2 months later.



When patients answer the IVR call, the automated system will describe the study, confirm the patient's eligibility as a current smoker, obtain oral informed consent, administer a brief survey to collect baseline smoking history and randomly assign study participants to 1 of 3 study groups, as described below. TelAsk Technologies will create a web-based interface that will allow study staff to monitor the progress of the IVR recruitment and enrollment. The study team has previously worked with TelAsk Technologies to deliver IVR-based interventions to smokers, and we have confidence that they have the capacity to accomplish these tasks.^{8,9,22} Due to resource limitations in the grant, the program will be offered only in English, which 95% of smokers in the target population speak. If successful, the program could be adapted for delivery in other languages when funds permit.

Interventions

Once a smoker responds to the proactive outreach and enrolls in the study, the project will compare two strategies for providing evidence-based tobacco cessation treatment with usual clinical care. Both intervention strategies attempt to connect the smoker to comprehensive treatment that includes both pharmacotherapy and counseling support, as recommended by the U.S. Public Health Service clinical treatment guidelines.²³

Intervention 1: Tobacco Care Coordination (Chronic Disease Management Model)

The smoker will be connected to a Tobacco Care Coordinator who is based centrally within the health care system but has ready access via EHR, email, and telephone with staff in each primary care practice. The Coordinator will be introduced to practice staff as their partner in managing the practice's smokers. The Tobacco Care Coordinator will be introduced to smokers as the "MGH Tobacco Coach." This individual will primarily initiate, guide, and optimize adherence to the care that others deliver, rather than providing direct care herself.

The Coach will be alerted as soon as a smoker is randomly assigned to this condition. TelAsk will communicate this information with an entry into the web-based interface developed for project management. The Coach will monitor this interface daily. She will call the smoker to conduct a brief assessment of tobacco use and readiness to quit, offer brief counseling and motivational intervention (5-10 min), describe the available pharmacologic and behavioral options, help the smoker to choose among them, and link the smoker to chosen resources. The resources offered will include both internal (health care system based) and external (community based) tobacco cessation resources, as previously described (*see p. 7*). Internal resources include connecting the smoker to the in-person individual tobacco counselor and to the smoker's PCP or practice to facilitate the prescription of tobacco cessation pharmacotherapy, especially for patients with a Medicaid benefit for OTC NRT. This benefit requires a physician's prescription. It is our experience that smokers with Medicaid (and some of their PCPs) do not know that MA Medicaid covers all FDA-approved pharmacotherapy, including OTC NRT. External resources include QuitWorks fax-referral to the MA Smokers Helpline. The Coach will be able to initiate referral to QuitWorks by either fax or email. The Coach will document the outcome of the initial interaction with a note in the EHR and an email to the PCP.

Successful care coordination requires ongoing contact with the patient to encourage treatment adherence and to coordinate care with the primary care practices. Consequently, we will re-

contact participants proactively at 2 weeks, 1, 2, and 3 months after the initial contact to assess the smoker's use of tobacco treatment and smoking status. To minimize workload, these contacts will be done with automated IVR telephone calls and email messages. Each contact will offer smokers the option of a call back from the Tobacco Coach for more intensive assistance or for medication management (e.g., managing side effects or obtaining refills). If the IVR system does not reach the smoker for a scheduled call and the smoker does not respond to the email message, the MGH Tobacco Coach will make up to 3 attempts to reach the smokers by phone. All of these contacts will be documented in the web-based interface. To maintain contact with the PCP, the Tobacco Coach will also document all follow-up contacts as a note in the EHR and will send an email directly to the PCP if clinically appropriate. The EHR documentation step could be automated in the future to enhance its sustainability. As noted above, the Tobacco Care Coordinator is intentionally designed to resemble Partners' existing Population Health Managers and will coordinate with their activities.

Intervention 2: Direct Referral to Community Resources (MA Smokers Helpline)

This intervention will connect the smoker directly to a community-based resource, the Massachusetts Smokers Helpline, which will provide its standard services to smokers. MA Helpline services include an assessment of smoking history and readiness to quit, advice to quit, self-help materials and telephone counseling.²⁰ For smokers who set a quit date in the next 30 days, the Helpline offers up to 5 proactive telephone counseling calls with options for text messaging and web-based resources if patients prefer not to take calls, educational materials, insurance plan information and suggested questions to ask about coverage. It also provides eligible smokers 4 weeks of free nicotine patch or gum mailed to their home. For those patients not ready to quit in 30 days, the Helpline offers educational materials, a Tips telephone line, and texting and website options that are tailored for people not yet ready to make a quit attempt. The Helpline provides feedback to referring providers in a written report of the outcome of each referral made by the provider via fax. The Helpline also makes a 6-month follow-up telephone call to assess smoking status of all smokers referred from a healthcare system.²⁰ For the proposed research program, the Helpline will send the feedback report to study staff, who will enter it into the patient's EHR. This process of incorporating feedback into the EHR could be automated in the future.

A novel aspect of this intervention is how a smoker is connected to the Helpline. Typically, in the MA QuitWorks system, a clinician sends a fax to refer a smoker to the Helpline. Helpline staff then initiates a telephone call to the smoker. They reach 45-50% of referrals (personal communication, Anna Landau). For the proposed program, in order to maximize the likelihood that a smoker is successfully connected to the Helpline, the smoker will be connected in real time from TelAsk, the IVR service provider, directly to the Helpline via a "warm transfer."

We have demonstrated the feasibility of an IVR-to-quitline connection in our ongoing NIH-funded clinical trial (#NCT01714323) that is testing a strategy for keeping smokers smoke-free after hospital discharge. For that project, the IVR vendor, TelAsk Technologies, worked with a different quitline provider, Alere Wellbeing, Inc., to transfer smokers directly from an IVR call to Alere in real time. In our experience, 69% of transfers were successfully transferred to Alere via the "warm transfer" system. The "warm transfer" failed if a smoker could not remain on the

telephone long enough to complete the connection or for other technical issues. In this case, the IVR provider (TelAsk) routinely informed the quitline provider (Alere) of any failed transfers, and Alere proactively called these individuals. Most of these individuals were reached, so that 91% of attempted transfers ultimately reached Alere staff. For the proposed project, TelAsk will work with the Massachusetts Helpline service provider, National Jewish Health. Both organizations have committed to building the capacity for make real-time transfers of callers from the IVR call to the MA Helpline in a similar manner (*See Landau letter*). If a warm transfer from TelAsk to the Helpline is not successful, TelAsk will inform the Helpline staff by email. The Helpline will treat the case as a QuitWorks fax-referral from a physician's office and make proactive calls to attempt to engage the patient in treatment.

Control condition: Usual care

At the end of the IVR enrollment call, smokers who are assigned to usual care will be given the number for the MA Smokers Helpline and advised to contact their PCP for additional assistance in quitting smoking. This condition represents a passive referral to the Helpline, in contrast to the active referral that the two intervention conditions provide. The PCP will not be expected or prompted to do anything other than provide usual clinical care for patients in this study condition. If a smoker has a routine office visit during the study period, the PCP may provide the stop-smoking assistance or referrals, but this will be independent of the interventions provided by this program.

c. Evaluation Design

Our goal is to demonstrate the feasibility of implementing the population-based proactive outreach program to current smokers in a health care system's primary care practices. As described, the program aims to (1) proactively contact smokers independent of their health care visits and (2) connect smokers who respond to evidence-based tobacco cessation services available in the health care system and/or community. The evaluation will assess how well these two aims were achieved. After a 3-month start-up period, the program will contact and enroll participants for 1 year. Each smoker will be followed for 6 months after initial outreach.

Aim 1: To determine the feasibility and reach of the program to the targeted population of smokers.

Evaluation Questions:

1.a. What proportion of targeted smokers in the primary care practices will respond to a proactive outreach program?

1.b. What proportion of smokers in the primary care practices who respond will accept the offer of tobacco treatment made independently of office visits?

The product of these two calculations will represent the overall reach of the program.

Q 1.a. will be calculated as the proportion of targeted smokers in the practices who accept the IVR call or respond to the email. Q1.b. will be calculated as the proportion of targeted smokers who agree to access treatment (% who are either transferred to the MA Helpline or are reached by the MGH Tobacco Coach). The denominator for both calculations will be the number of smokers for whom proactive outreach was attempted. These are the individuals who did not opt out or report being a nonsmoker in response to the initial letter from the PCP. Their contact

information was sent to TelAsk for an IVR outreach call and email. We will use records from TelAsk, the MA Helpline, and the MGH Tobacco Coordinator for this analysis. In addition to calculating overall rates, we will determine the proportion of smokers who respond to each modality (IVR vs. email vs. both) and the number of attempts and resources required to make contact. Further, we will compare the demographic, medical history, and provider characteristics of smokers who do and do not respond to the outreach or accept referral for treatment, using variables obtainable from the EHR and TelAsk records (See *Baseline Variables*).

Benchmark: We will compare the rates of contact and of acceptance of tobacco treatment to measures obtained in 2 prior outreach studies conducted in our system.

- In 2009-10, smokers at 1 MGH community health center were mailed 3 monthly letters offering a free telephone consultation with a Tobacco Coordinator and 8 weeks of free NRT; 43 (10%) of 413 smokers responded to mailed offer and enrolled.⁵
- In 2011-2013, low-income, black, or Hispanic smokers in 13 Partners-affiliated practices were contacted by IVR calls and invited to enroll in a randomized study in which they were offered free NRT and telephone counseling or usual care. Of 8089 smokers approached, 3081 (38%) answered the IVR call, and 707 (23% of those reached, 9% of the total approached) enrolled.⁷ The second study is the best benchmark for our project. Adding e-mail to the prior projects' IVR outreach and repeating outreach at 1 and 2 months should improve the response rate.

Goals: Increase the contact rate among smokers approached by 10% (from 38% to 48%). Increase the overall reach (enrollment rate among smokers approached) by 5% (from 9-10% in the prior studies to 15%).

Aim 2: To determine whether the program increases the proportion of smokers in a health care system who use tobacco cessation treatment over a 6-month follow-up, compared to those receiving usual clinical care.

Evaluation Questions:

2.a. Does the proactive offer of tobacco cessation services increase the proportion of smokers who use these services over 6 months, compared to smokers who are offered usual clinical care?

2.b. (Exploratory): Do the two strategies for offering tobacco cessation services differ in the proportion of smokers who used tobacco cessation treatment over 6 months?

2.c. (Exploratory): Do the intervention conditions increase self-reported 7-day tobacco abstinence rates compared to usual care?

Aim 2 will be evaluated in a pragmatic randomized controlled trial that will enroll adult patients enrolled in a participating MGH primary care practice who were documented in the EHR as current smokers at their most recent visit in the past year and who have telephone contact information (See *Target Audience*). A random sample of 4500 individuals meeting these criteria will be selected for proactive outreach, independent of office visits, using a combination of IVR telephone calls and email. Those who are reached will be screened for eligibility and offered participation in a study to help smokers quit. Those who provide oral informed consent will be randomly assigned (1:1:1) to 3 groups, stratified by practice (as described above in *Outreach and Patient Engagement*). Two intervention groups will receive a proactive offer of tobacco

treatment services, each in a different way, while one control group will receive usual care (*See Interventions*). Interventions will last for up to 3 months. Outcomes will be assessed 6 months after study enrollment, using data from the EHR, Helpline records, and program records. The analysis will compare each intervention arm and the pooled intervention arms to the control condition and, in an exploratory analysis, compare the two active groups to each other. The primary outcome is the proportion of participants with any documented use of evidence-based tobacco cessation treatment during the 6-month follow-up period.

Baseline measures

Variables obtainable from the EHR:

Demographic factors: age, sex, race (white, black, Hispanic, Asian, other), education, health insurance (commercial, Medicare, Medicaid, no insurance or other).

Medical history: coronary heart disease, COPD, diabetes, hypertension.

Medication history: active or prior prescription for NRT, varenicline, or bupropion

Practice characteristics: PCP, practice, number of visits to practice in past year, total number of ambulatory visits in past year.

Variables obtainable from TelAsk records:

Contact details: date of initial outreach (to assess seasonal variability), date of successful contact, mode of successful contact (IVR or email)

Smoking status: cigarettes/day, time to first morning cigarette, readiness to quit, past year use of smoking cessation medication or counseling.

Outcome Measures

The primary outcome measure is the proportion of smokers with any documented use of evidence-based tobacco cessation treatment (either counseling or pharmacotherapy) during the 6 months after the initial outreach. Tobacco cessation treatment is defined as any of these:

1. Completion of ≥ 1 Helpline counseling call (excluding the initial call transferred from the IVR system)
2. An in-person visit with the MGH Health Center's tobacco counselor
3. Telephone contact with the MGH Tobacco coach (excluding initial assessment call)
4. Prescription of nicotine replacement, bupropion, or varenicline in the EHR
5. Provision of nicotine patch or gum by the MA Helpline

In addition to this composite outcome, additional outcome measures include (1) documented use of pharmacotherapy (#4 or #5); (2) documented use of cessation counseling (#1- #3), and (3) documented use of both counseling and medication. We will also examine the intensity of counseling treatment, defined as number of contacts. For treatment use outcomes, we will assume that patients with no documentation of treatment have not received it.

Sources of data: Review of EHR records, program records of the MGH Tobacco Coach, health center tobacco counselor, and MA Helpline. The Helpline provider, National Jewish Health, will provide us patient-level data of the outcomes of all QuitWorks referrals sent from all MGH physicians and practices during the study period.

Patient-level smoking status is the optimal outcome measure. We will attempt to collect it, but we regard this effort as exploratory in this pilot project due to limits on the available funds in this grant. The primary smoking status outcome measure is self-reported past 7-day tobacco

abstinence, with past 30-day abstinence as a secondary measure. These will be assessed by patient survey at 6-month follow-up. To conserve resources, it will be done by IVR and email, with phone calls and mail as back-up for non-responders to the extent that funds permit. A strategy of IVR calls with telephone follow-up produced a 66% response rate in our prior survey.⁷ Patients who do not respond to the survey will be counted as smokers for the primary analysis but we will also explore the use of multiple imputation to fully use available baseline information. We will supplement patient survey with 6-month follow-up data from the MA Helpline and explore whether follow-up smoking status outcomes can be collected from the EHR. We will measure the proportion of enrollees who are documented as nonsmokers in the EHR at their most recent entry during the 6-month follow up period. The feasibility depends on how many enrolled smokers make an office visit during their 6 month follow-up period and whether their smoking status is updated in the EHR at that visit. If feasible, we will compare the patient survey and EHR review results to determine the similarity of the results obtained by these two methods. The EHR record review is far less expensive than a patient survey. If it produces comparable results, that result would lower the cost of assessing smoking status outcomes for future quality improvement efforts at Partners HealthCare System.

Data Management and Analysis

At the start of the project, MGH Primary Care Practice Based Research Network staff will identify the target population and create a project database that includes the baseline variables from the EHR. Each patient can accumulate outcome measures for 6 months after the date of the initial study IVR outreach. At the end of the study, records from the Helpline, IVR system, MGH Tobacco Care Coordinator, and Health Center coach will be merged into the database for analysis.

Data Analysis

The sample of smokers enrolled in the study will be characterized on baseline measures and compared to the population of smokers whom we attempted to contact in order to determine the sample's representativeness to the target population. Variables include demographics, smoking history, medical history, cessation medication use, and practice characteristics (See *Baseline Measures*). We will also compare baseline characteristics of the 3 randomized groups to determine the success of randomization. The primary outcome analysis will be conducted as intention-to-treat, comparing the control condition to the pooled intervention conditions, using multiple logistic regression analysis that includes study group, practice, and any baseline factor that is significantly imbalanced by group ($p < .05$) as independent variables. As secondary analyses, we will compare each of the 2 intervention groups to usual care and compare the 2 interventions to each other. We will follow the same approach to testing the smoking status outcome measure. We will explore potential interactions between smoker characteristics and use of treatment by group.

Sample size

Aim 2a. We will randomly select 4500 smokers for proactive outreach from the participating practices. We estimate that 13-15% will respond to the proactive outreach and participate in the trial, generating a total enrolled sample of 600-675 smokers or 200-225 smokers in each of 3 randomized study arms. Without the program, we estimate that 3% of the overall sample of

4500 smokers approached would have achieved the primary outcome (any use of cessation treatment over 6 months). We base this estimate on data that 1.2% of smokers were referred to the MA Helpline from MGH practices in CY 2013 and on the results of a previous MGH practice-based study in which 2% of smokers used cessation medication over 1 year.²⁴ We further assume that the sample of smokers who accept the outreach call will use treatment at a higher rate even if they are assigned to usual care. For the sample of 600-675 who enroll, we estimate that the rates of treatment use will be 10% for usual care and an average of 25% for the 2 intervention groups. With a sample of 200 per group and assuming a two-sided alpha of .05, there is >90% power to detect a 15% difference (25% vs 10%) between control and each intervention group. There is also >90% power to detect this difference between control (n=200) and a pooled intervention group (n=400). Finally, we will extrapolate treatment use back to the entire population of 4500 who were selected for outreach. We will assume that the 85% of patients who do not respond to outreach would have a 3% rate of treatment use. Thus, at the population level (n=1500/group), we expect that treatment will have been used by 4.0% ($= [.15 \times .10] + [.85 \times .03]$) in the usual care arm and by 6.3% ($= [.15 \times .25] + [.85 \times .03]$) in each intervention group. With 1500 per group, there is 81% power to detect this difference.

Aim 2.b. We have insufficient information to estimate the difference between the two intervention groups in treatment use rates; therefore, this comparison is exploratory.

Aim 2.c. The effect of the intervention on tobacco abstinence at 6 mo follow-up is an exploratory aim because we do not expect to have sufficient power to detect a statistically significant difference in this outcome. A sample of 225 per group can detect, with 80% power, an 8% difference between intervention groups (e.g., from 6% to 14%). If the true difference is smaller, the project can generate estimates of effect size for a future large study to demonstrate the impact of population outreach on tobacco abstinence rates. If the results of this project are promising, we anticipate applying for NIH funding to conduct a larger trial with sufficient size to detect a difference in tobacco abstinence rates.

Cost-effectiveness

If the intervention is effective, a cost-effectiveness analysis (CEA) could help make the case for its sustainability. Resources available in this grant cannot support the analysis, but we will collect the data systematically and prospectively for a future CEA. MGH colleague Douglas Levy, PhD, has conducted CEA's for our prior projects^{5,9} and will advise us on the collection of cost data. He will conduct the CEA when resources are identified. The CEA will take the perspective of Partners Health Care System and assess (1) the incremental cost-per-connection to tobacco treatment and (2) the incremental cost-per-quit during the 6 months of follow-up. The major direct costs are 1) staff time to create the registry of smokers and develop IVR and enrollment protocols; 2) Tobacco Coach time to deliver that arm, and 3) IVR implementation. Research costs will be excluded. Helpline costs will be excluded because they are not borne by Partners.

Dissemination of project outcomes

We will present the program results at national conferences of research and professional organizations and report the results in manuscripts in peer reviewed journals. We will offer to conduct a webinar sponsored by the UCSF Smoking Cessation Leadership Center and other organizations. We can disseminate to tobacco treatment clinicians through list-serves of organizations like ATTUD or the Action-2-Quit Network.

5. Detailed Workplan and Deliverables Schedule

Workplan

Project duration – 2 years (May 1, 2015 – April 30, 2017)

Months 1-3: Obtain IRB approval. Project start up to develop IVR systems, query PBRN registry to identify smokers to be targeted, create Tobacco Coach protocols.

Month 4: Train staff, pilot test IVR system, link to Helpline, and Tobacco Coach protocols. Mail first batch of monthly opt-out letters to patients.

Months 5-16: Recruit, enroll smokers by direct outreach in the month of their birthday. Randomize to group, link to treatment resources (intervention groups).

Months 11-22: Collect outcome measures from data sources (EHR, Helpline, program records, patient survey)

Months 21-24: Conduct data analysis, prepare reports and presentations, transfer operations to Population Health Management.

Year	2015								2016												2017			
	m	j	j	a	s	o	n	d	j	f	m	a	m	j	j	a	s	o	N	d	j	f	m	a
Study Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
IRB approval	x																							
Identify cohort of smokers		x																						
Build IVR outreach	x	x	x	x																				
Build IVR to Helpline transfer	x	x	x	x																				
Create Tob. Coach protocols	x	x	x	x																				
Test IVR system, train Tob Coach					x																			
Recruit smokers						x	x	x	x	x	x	x	x	x	x	x								
6-month f/up surveys											x	x	x	x	x	x	x	X	x	x	x	x		
Obtain data for outcomes (EHR, Helpline)											x	x	x	x	x	x	x	X	x	x	x			
Data analysis																					x	x	x	x
Prepare reports																						x	x	x

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See Appendix for

- E. Detailed Budget**
- F. Staff Biosketches**
- G. Letters of Commitment**