Proactive Tobacco Cessation Outreach to Smokers of Low Socioeconomic Status

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Original Investigation

Proactive Tobacco Cessation Outreach to Smokers of Low Socioeconomic Status
A Randomized Clinical Trial

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IMPORTANCE Widening socioeconomic disparities in mortality in the United States are largely explained by slower declines in tobacco use among smokers of low socioeconomic status (SES) than among those of higher SES, which points to the need for targeted tobacco cessation interventions. Documentation of smoking status in electronic health records (EHRs) provides the tools for health systems to proactively offer tobacco treatment to socioeconomically disadvantaged smokers.

OBJECTIVE To evaluate a proactive tobacco cessation strategy that addresses sociocontextual mediators of tobacco use for low-SES smokers.

DESIGN, SETTING, AND PARTICIPANTS This prospective, randomized clinical trial included low-SES adult smokers who described their race and/or ethnicity as black, Hispanic, or white and received primary care at 1 of 13 practices in the greater Boston area (intervention group, n = 399; control group, n = 308).

INTERVENTIONS We analyzed EHRs to identify potentially eligible participants and then used interactive voice response (IVR) techniques to reach out to them. Consenting patients were randomized to either receive usual care from their own health care team or enter an intervention program that included (1) telephone-based motivational counseling, (2) free nicotine replacement therapy (NRT) for 6 weeks, (3) access to community-based referrals to address sociocontextual mediators of tobacco use, and (4) integration of all these components into their normal health care through the EHR system.

MAIN OUTCOMES AND MEASURES Self-reported past-7-day tobacco abstinence 9 months after randomization ("quitting"), assessed by automated caller or blinded study staff.

RESULTS The intervention group had a higher quit rate than the usual care group (17.8% vs 8.1%; odds ratio, 2.5; 95% CI, 1.5-4.0; number needed to treat, 10). We examined whether use of intervention components was associated with quitting among individuals in the intervention group: individuals who participated in the telephone counseling were more likely to quit than those who did not (21.2% vs 10.4%; *P* < .001). There was no difference in quitting by use of NRT. Quitting did not differ by a request for a community referral, but individuals who used their referral were more likely to quit than those who did not (43.6% vs 15.3%; *P* < .001).

CONCLUSIONS AND RELEVANCE Proactive, IVR-facilitated outreach enables engagement with low-SES smokers. Providing counseling, NRT, and access to community-based resources to address sociocontextual mediators among smokers reached in this setting is effective.

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Although tobacco use in the United States has declined,[1] substantial socioeconomic and racial and/or ethnic disparities in smoking prevalence, risk of addiction, and tobacco-related disease remain.[2,3] Despite relatively similar rates of tobacco use, blacks experience a higher burden of tobacco-related disease, particularly lung cancer, than whites.[3] Importantly, smokers of low socioeconomic status (SES) and/or of a racial or ethnic minority also have more difficulty quitting for several reasons, including more limited access to treatment,[4-7] misinformation about risks and benefits of nicotine replacement therapy (NRT),[8] lack of social support,[9] neighborhood disadvantage,[10] discrimination,[11] and other life stressors.[12,13] Widening socioeconomic disparities in mortality in the United States are largely explained by slower declines in tobacco use among low-SES smokers than among higher-SES smokers.[14,15]

While the majority of smokers visit a primary care clinician (PCC) each year, PCCs do not have adequate time or training to provide tobacco treatment[16]; therefore, it is important to offer systematic opportunities for tobacco treatment beyond the clinician's office. The broad dissemination of electronic health records (EHRs), with coded data about smoking status, represents an important tool to help reach out to smokers.[17,18] Another important tool, interactive voice response (IVR), is a telephone technology that allows a computer to detect voice responses during a call and so provides an efficient way to proactively reach large populations, such as patients identified in the EHRs as smokers. The IVR scripts can be translated into other languages, facilitating outreach to diverse populations. Researchers have used IVR as part of multicomponent smoking cessation programs to provide reminders and to facilitate or sustain treatment delivery.[19-21] This technology can also be used to engage smokers by providing direct linkage to a tobacco treatment specialists (TTS) and other resources.

Despite growing disparities in tobacco use and tobacco-related disease, few trials have specifically examined smoking cessation interventions in low-SES populations.[22] Because of the substantial burden of tobacco in these populations, the objective of the present study was to develop and evaluate a proactive approach to tobacco treatment for low-SES smokers that addressed broader sociocontextual mediators of tobacco use. While conceptual models of smoking cessation stress the importance of addressing the broader context of smoking,[23] we do not know of other empirical studies that have incorporated referrals to community resources as part of a cessation program. The intervention was designed so that it could be incorporated into the health system through IVR outreach and EHR documentation.

Methods

Overview

The protocol for the present study, Project CLIQ (Community LInk to Quit), was reviewed and approved by the institutional review board (IRB) of Partners HealthCare. The IRB waived written informed consent and instead approved review of a letter describing the study and how to opt out. The baseline IVR call briefly reviewed the study purpose and protocol; oral, implied consent was presumed if subjects completed the IVR call. Participants were informed that they could withdraw from participation at any time.

We undertook this prospective, randomized clinical trial (RCT) enrolling low-SES smokers to compare usual care delivered by a patient's health care team with a proactive treatment program that included (1) a series of telephone-based motivational counseling calls with a TTS based in the health care system, (2) access to free NRT patches, (3) personalized, community-based referrals to reduce sociocontextual mediators of tobacco use, and (4) integration of all these components into the participants' normal health care through updated documentation in the EHR system. The EHR system was used to identify low-SES smokers who described their race and/or ethnicity as white, black, or Hispanic; IVR was used for recruitment.

Setting

Smokers were recruited from 13 primary care practices affiliated with Partners HealthCare, a large health care delivery system in eastern Massachusetts. Participating primary care practices included 6 community health centers, 2 community-based practices, 4 hospital-based practices, and 1 medical home. These sites did not have on-site tobacco treatment programs during the study period, but clinicians could refer patients to the Massachusetts Smokers' Helpline (http://makesmokinghistory.org). Practices shared a web-based, fully functional EHR that allowed coded documentation of smoking status; this allowed identification of smokers by querying a data repository, thus providing an opportunity for outreach. These tools and services provided the basis for "usual care" for tobacco treatment in these practices.

Eligibility

Persons eligible for study participation were adults (age ≥18 years) who visited a PCC at a participating clinic in the month before outreach. Eligibility also required smoker coding in the EHR, race and/or ethnicity documented as white, black, or Hispanic, English or Spanish language preference noted, and residence in a low (<$45 000) or moderate ($45 000-$67 050) median household income census tract. These income thresholds were chosen to reflect the income characteristics of Massachusetts. In the 2008-2012 period, the median household income in Massachusetts was $66 658.[24] These income thresholds also divided our population into thirds; the highest income group (>$67 050) was not eligible. We used ArcMap 10.0 (Esri) to geocode participants' mailing addresses to append median household income estimates based on 2010 census tract as a proxy for socioeconomic status, since income is not captured in the EHR.[25] We targeted individuals shortly after a clinic visit to ensure current documentation of smoking status and contact information. Because of the proactive, population-based design, we reached out to all individuals who met these eligibility criteria regardless of their interest in quitting. We excluded patients without a telephone number.

Figure 1. CONSORT Diagram
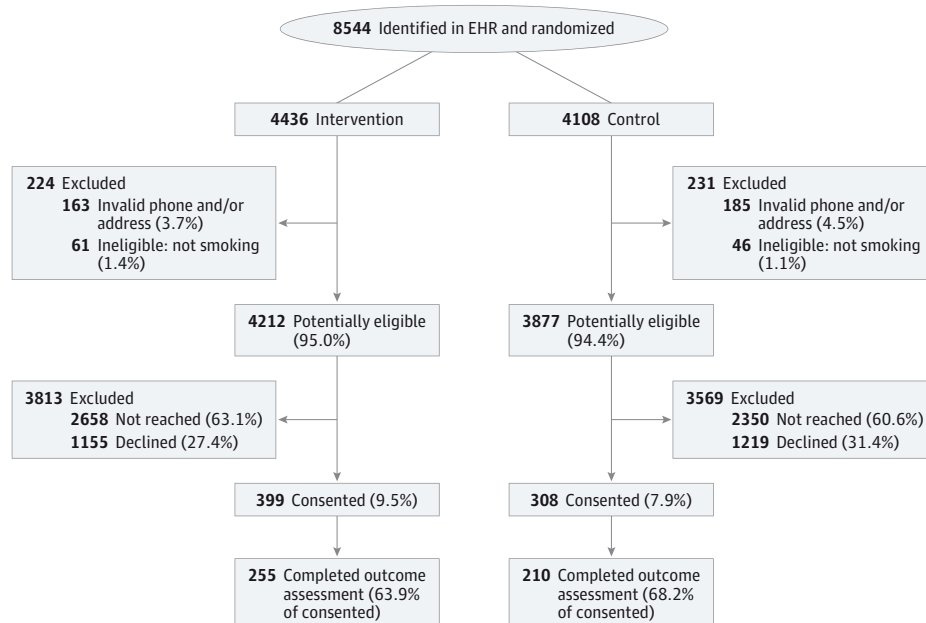
Smokers identified from the electronic health record (EHR) were randomly allocated at a ratio of roughly 1:1 to intervention or control status. The number of individuals who consented served as the denominator for our analyses.

Recruitment and Randomization

Recruitment for this study occurred between November 7, 2011, and June 3, 2013. Every 2 weeks, the EHR generated a list of individuals who met the eligibility criteria. Within 1 month of a PCC visit, EHR-identified smokers received an informational letter that described the study and included a toll-free telephone number to call if they wished to opt out. Patients in both study groups received identical mailings. We contacted patients who did not opt out within 2 weeks using an IVR script that called up to 15 times over a 2-week period on different days of the week and times of the day. Patients could choose to hear the IVR script in English or Spanish. The IVR platform did not leave messages. If all initial call attempts failed to make contact, patients remained eligible for an additional attempt at contact 4 months later. Participants were recruited solely by automated telephone scripts.

Smokers identified through EHRs were randomly allocated to intervention or control status at roughly a 1:1 ratio. Randomization was performed in batches based on the date of the clinic visit. The first patient randomized in each batch was randomized to intervention status; batches with an odd number of participants therefore resulted in an imbalance in the size of the intervention and control groups (**Figure 1**). Randomization occurred before consent for logistical reasons (IVR caller could not randomize in real time).

Baseline Call

After patients who answered the IVR call confirmed their identity, they heard a standard informed consent script. All individuals who agreed to participate then completed a brief smoking history. We excluded patients who reported that they had not smoked even a puff of a cigarette in the prior week or who had not smoked at least 100 cigarettes in their lifetime (ie, they

were considered to be a nonsmoker). The baseline IVR call was identical for intervention and control groups until the final question. After completion of the smoking history, participants in the intervention group were asked if they wanted to speak with a TTS for advice about how to quit smoking and to receive a free 6-week supply of NRT patches. Participants in the control group were not offered treatment.

Intervention

We designed the intervention based on the Chronic Care Model[26,27] and the Social Contextual Model for Reducing Tobacco Use.[23] The IVR system sent an automated e-mail to the TTS when a participant requested contact. Participants in the intervention group were eligible for up to 4 counseling calls (a total of approximately 75-100 minutes for all calls over 8-10 weeks), with additional calls scheduled between the participant and TTS at the request of the participant. The TTS used motivational interviewing techniques, which help a participant resolve ambivalence about behavior change regardless of readiness to quit.[28] The counseling calls included standard content as well as content tailored to the individual based on intent and confidence to quit, and participants could select optional modules based on their needs (eg, stress, weight gain, menthol use).

The TTS encouraged participants to receive a 6-week supply of free NRT patches. Participants who smoked 10 or more cigarettes per day were offered a 2 weeks' supply of 21-mg/d patches, 2 weeks of 14-mg/d patches, and 2 weeks of 7-mg/d patches; participants who smoked fewer than 10 cigarettes per day offered 4 weeks of 14-mg/d patches and 2 weeks of 7-mg/d patches. The TTS instructed participants on the use of NRT and addressed knowledge gaps around safety and efficacy.

To address the sociocontextual mediators of tobacco use, the TTS also encouraged participants to receive a personalized referral from a community resource database, HelpSteps.com, a web-based referral system for the greater Boston area. HelpSteps.com is designed to help users select referrals to over 1700 local health and human service agencies categorized into 13 social resource domains (eg, food, education, employment) and has resources related to over 90 different types of services (eg, literacy classes, domestic violence hotline).[29,30] At each call, the TTS encouraged participants to pick 2 domains and then selected referrals near the participant's address and mailed a personalized referral document to the participant. Costs for these referrals, if any, were determined by the particular agency or service and were paid for by the participants (ie, not paid for by the study). The majority of these resources are free. Finally the TTS coordinated additional treatment needs (eg, prescription medications) with the participant's PCC. We tracked use of intervention components (speaking with the TTS, use of NRT, request for and use of a HelpSteps.com referral).

Outcome Assessment

Our primary outcome measure was self-reported 7-day tobacco abstinence at 9 months following randomization.[31] We assessed outcomes by IVR call with live follow-up of nonrespondents (52.9% of outcome calls were completed by IVR with the remainder completed by blinded study staff). Participants were considered to have quit smoking if they responded "no" to the question "Have you smoked a cigarette, even a puff, in the past 7 days?" The IVR platform automatically sent updated information about smoking status to the EHR for the clinician's review. We also obtained self-reported information about the use of tobacco treatment during the study period by asking: "Did you use any counseling over the phone or in person to help you to quit smoking?" and "Have you used any nicotine products to help you to quit smoking, like the patch, gum, or inhaler?" Participants in both the intervention and the control group who completed the outcome assessment were eligible for a monthly drawing for 1 of 2 $100 gift cards.

Data Analysis

The primary analysis used an intent-to-treat approach. We compared participants' characteristics by group using 2-sample *t* tests, Wilcoxon tests, and χ^2 tests. For the primary analysis, we assumed that nonrespondents at follow-up were smokers. We conducted a sensitivity analysis using multiple imputation of both baseline characteristics and the outcome variable using the FCS option (fully conditional specification) in SAS PROC MI (version 9.3; SAS Institute Inc).[32] We explored the effect of the intervention in subgroups based on sex, race and/or ethnicity, SES, and baseline tobacco use. To assess whether there was a differential effect of the intervention for subgroups based on race and/or ethnicity and SES, we constructed logistic regression models that included interaction terms between variables representing the subgroups and intervention status.

Results

Recruitment and Retention

During the enrollment period, we attempted to contact 8544 individuals identified by EHR data as smokers (Figure 1). Of these, 455 were not eligible for the study (348 did not have a valid telephone number or address, and 107 reported that they were not a smoker when reached). Of the 8089 potentially eligible adults, 5008 (61.9%) were never reached by the IVR system (no answer and/or answering machine to all of the call attempts) and 2374 (29.3%) declined participation. Overall, 707 (8.3% of those eligible) agreed to participate; 66% of participants completed the outcome assessment call 9 months after enrollment.

Study Population

Overall, the median age of the participants was 50 years; 68% were women, 20% self-reported Hispanic ethnicity, and 28% black; 36% reported their highest level of educational attainment to be high school or less, and 35% had Medicaid (**Table 1**). Common comorbidities included hypertension (10%), depression or anxiety (8%), high cholesterol levels (5%), and diabetes (5%). At enrollment, participants were daily smokers, a median of 15 cigarettes per day; 88% reported smoking within 30 minutes of waking, and 77% said that they planned to quit in the next 30 days. The majority had made a quit attempt within the prior year. There were no significant differences between the enrolled intervention and control smokers in demographic, comorbidity, or baseline tobacco use characteristics. Demographic information from the EHR allowed us to compare the participants with nonparticipants: compared with participants, nonparticipants were younger (median age, 47 years), less likely female (54.9%), more likely Hispanic (24.7%), and less likely black (17.1%) (*P* < .001 for all comparisons).

Effect of the Intervention on Quit Rates and Use of Tobacco Treatment

Individuals in the intervention group were significantly more likely to report quitting at the time of outcome assessment than individuals in the control group (**Figure 2**). In the primary intention-to-treat analysis, 17.8% of intervention participants quit compared with 8.1% in the control group (*P* < .001; odds ratio [OR], 2.5; 95% CI, 1.5-4.0). The number needed to treat (NNT) was 10. The sensitivity analysis, using multiple imputation, confirmed these findings, with quit rates of 26.8% and 12.4% respectively (*P* < .001; OR, 2.6; 95% CI, 1.7-3.9; NNT, 7). Intervention participants were more likely than control participants to respond affirmatively that they had used any counseling for tobacco treatment during the follow-up period (49.6% vs 8.4%; *P* < .001) or had used NRT (63.6% vs 41.8%; *P* < .001).

Quit Rates for Subgroups

We examined the odds of quitting for intervention vs control participants for subgroups specified by demographic characteristics and baseline tobacco use (**Figure 3**). Women (OR, 3.0; 95% CI, 1.6-5.4; *P* < .001), blacks (OR, 3.9; 95% CI, 1.4-10.8; *P* = .001), whites (OR, 2.1; 95% CI, 1.2-3.9; *P* = .02), individu-

Table 1. Characteristics of the Participants[a]

Characteristic	Intervention	Control	P Value
All participants, No.	399	308	NA
Age, median (range), y	49 (19-82)	51 (21-77)	.98
Women	271 (67.9)	211 (68.5)	.87
Self-reported race or ethnicity[b]			
Hispanic	85 (21.3)	58 (18.8)	.42
White	245 (61.4)	191 (62.0)	.87
Black	107 (26.8)	89 (28.9)	.54
Other	55 (13.8)	36 (11.7)	.41
Born in the United States[c]	265 (85.2)	214 (85.3)	.99
High school education or less[c]	113 (35.8)	89 (35.3)	.91
Health insurance[c]			
Medicare	101 (26.2)	80 (26.6)	
Medicaid	139 (36.1)	101 (33.5)	.08
Private	135 (35.1)	119 (39.5)	
Self-pay	10 (2.6)	1 (0.3)	
Census tract median household income			
Low	197 (49.4)	139 (45.1)	.26
Moderate	202 (50.6)	169 (54.9)	
Married[c]	104 (27.1)	78 (26.3)	.81
Comorbidity[d]			
Hypertension	44 (11.0)	30 (9.7)	.58
Depression or anxiety	36 (9.0)	23 (7.5)	.46
High cholesterol	21 (5.3)	14 (4.6)	.66
Diabetes	23 (5.8)	12 (3.9)	.26
Chronic lung disease[e]	16 (4.0)	14 (4.6)	.73
Cardiovascular disease	13 (3.3)	10 (3.3)	.99
Smoking-related cancer[f]	1 (0.25)	0	.99
Non-smoking-related cancer[g]	6 (1.5)	4 (1.3)	.82
Baseline smoking characteristics			
Median smoking days per week, No.[c]	7	7	.35
Median cigarettes per day, No.[c]	15	15	.38
Quit attempt in the last 12 months[c]	206 (60.6)	171 (64.0)	.38
Used NRT in the last 12 months[c]	133 (40.8)	109 (40.8)	.99
Smokes within 30 minutes of waking[c]	299 (89.3)	228 (86.4)	.28
Allows smoking in car or home[c]	219 (65.8)	166 (63.1)	.50
Lives with someone who smokes[c]	117 (35.5)	95 (36.7)	.76
Plans to quit in next 30 days[c]	265 (78.6)	201 (74.7)	.26

Abbreviations: EHR, electronic health record; NRT, nicotine replacement therapy.

[a] Unless otherwise noted, data are reported as number (percentage) of participants.

[b] Race or ethnicity from the EHR is reported where self-reported race is missing.

[c] Missing data for the following numbers of participants: education, n = 139; born in the United States, n = 145; married, n = 26; health insurance, n = 21; median number of smoking days per week, n = 56; median number of cigarettes per day, n = 96; quit attempt in the last 12 months, n = 100; used NRT in the last 12 months, n = 114; smokes within 30 minutes of waking, n = 108; allows smoking in car or home, n = 111; lives with someone who smokes, n = 118; plans to quit in the next 30 days, n = 101.

[d] Comorbidities reported in the EHR problem list.

[e] Chronic lung disease included chronic obstructive pulmonary disease, chronic bronchitis, asthma, and reactive airways disease.

[f] Smoking-related cancers included lung, throat, esophagus, head, neck, larynx, kidney, and bladder cancers.

[g] Non–smoking-related cancers included all other cancers excluding skin cancers.

als with more than a high school education (OR, 2.7; 95% CI, 1.4-5.0; P = .002), and those who lived in a low-income census tract (OR, 3.5; 95% CI, 1.7-7.2; P = .001) were all significantly more likely to quit in the intervention vs control group. The odds of Hispanics quitting in the intervention vs control groups were not significant. The intervention was effective in all baseline tobacco use subgroups, whether or not the participant planned to quit in the next 30 days. There were no significant interactions between intervention status and any of the demographic or baseline smoking characteristics.

Effect of Intervention Components
Among individuals in the intervention group, we examined use of each intervention component (ie, speaking to the TTS, receiving NRT, request or use of a community referral)

and whether use of a specific component of the intervention was associated with quitting (**Table 2**). Of those in the intervention arm (n = 399), 274 (68.7%) spoke with the TTS at least once. Of these 274 individuals, 79.6% received NRT; 46.7% requested a HelpSteps.com referral; and 20.1% reported using this referral. The domains most commonly requested for community resources included physical activity (n = 379), educational opportunities (n = 235), and job counseling (n = 69).

Among individuals in the intervention arm, those who spoke to the TTS were more likely to quit than those who did not (21.2% vs 10.4%; P = .01). There was no difference in quitting by use of NRT. Quitting status did not differ by a request for a community referral, but individuals who reported using their referral for the community resource were much more

likely to quit than those who did not (43.6% vs 15.3%; P < .001). In a multivariate model that included the intervention components, the only intervention component associated with quitting was use of a community referral (OR, 5.4; 95% CI, 2.5-12.0).

Discussion

Project CLIQ, one of the first RCTs that specifically targets low-SES smokers, demonstrates that a proactive, systematic, telephone-based intervention including counseling, NRT, and referrals to community resources to address sociocontextual mediators of tobacco use doubles smoking cessation rates compared with usual care for this population with access to primary care. Among participants, use of counseling and the community referrals were important components of this intervention; referral to community resources was one of the novel aspects of this treatment program.

We designed our intervention to take advantage of effective strategies for smoking cessation and address individual sociocontextual mediators that promote tobacco use. First, we recruited individuals from primary care. While 70% of smokers see a PCC each year, minority and low-SES smokers are less likely to report tobacco counseling.[4,5] The use of a common EHR allowed us to identify smokers outside of the context of a visit, independent of their interest in quitting.

Second, the intervention used automated calls to provide a systematic, proactive outreach to link interested smokers to treatment. Third, the telephone-based program allowed for the delivery of established effective treatments, including personalized counseling and subsidized NRT.[33]

Figure 2. Self-Reported 7-Day Tobacco Abstinence 9 Months After Randomization
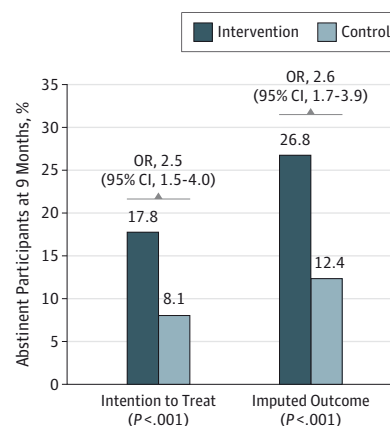
Primary outcome was intention to treat; sensitivity analysis used multiple imputation of both baseline characteristics and the outcome variable. OR indicates odds ratio.

Figure 3. Quit Rates by Subgroups of the Intervention Group
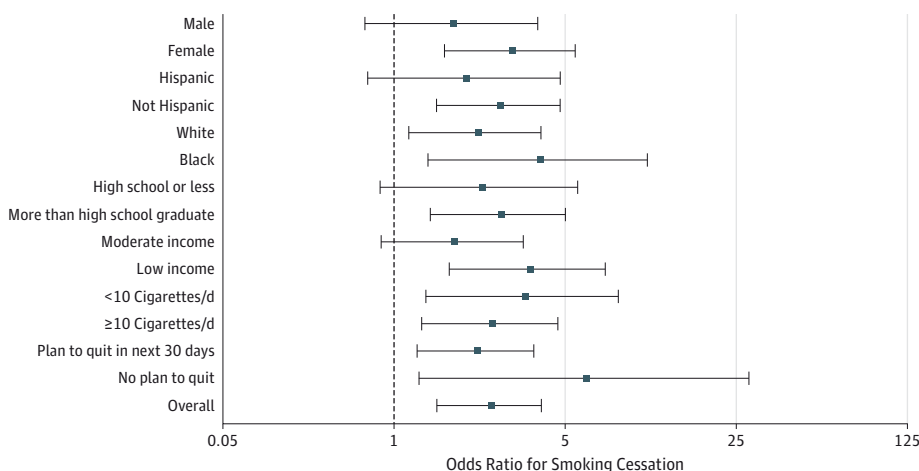
Odds ratios (95% CIs) compared with controls are displayed for selected subgroups. There were no significant interactions between subgroups and intervention status.

Table 2. Use of the Intervention Components Among Individuals in the Intervention Group and Smoking Cessation Rates by Component

Component Use	Individuals in the Intervention Group Who Quit Smoking, No. (%) (n = 399)		
	Used Intervention Component	Did Not Use Intervention Component	P Value
Spoke to the tobacco treatment specialist	58/274 (21.2)	13/125 (10.4)	.01
Received nicotine replacement patches[a]	50/218 (22.9)	8/56 (14.3)	.16
Received a HelpSteps.com referral[a]	30/128 (23.4)	28/146 (19.2)	.39
Reported using a HelpSteps.com referral[b]	24/55 (43.6)	34/219 (15.3)	<.001

[a] Among intervention participants who spoke to the tobacco treatment specialist.

[b] Among intervention participants who spoke to the tobacco treatment specialist and received a HelpSteps.com referral.

Finally, our intervention was designed to consider the sociocontextual challenges to tobacco cessation faced by minority and low-SES smokers.[34] Among participants, community resources for physical activity, educational opportunities, and job counseling were the most common referrals requested, and use of these referrals was associated with quitting among participants, which suggests that attempts to address the broader life experiences of smokers was an important component of our intervention. Our findings suggest that the use of these community resources was one of the important mediators of the effectiveness of our program.

For the 8554 registry-identified smokers in our clinics, the design and implementation of this intervention was estimated to cost $283 023 ($33.13 per registry-identified smoker).

The rates of tobacco abstinence in the present study were similar to those measured in other proactive treatment programs not specifically targeting low-SES smokers[35] and higher than those found in interventions involving visit-based clinician advice for smoking cessation.[36] The Veterans Victory over Tobacco Study (VVTS),[37] a pragmatic RCT, used a registry of current smokers at 4 Veterans Affairs medical centers to test a proactive outreach with either telephone or in-person cessation services compared with usual care. At 12 months after randomization, the 6-month abstinence rate was 13.5% in the outreach group vs 10.9% in the usual care group. The VVTS Project CLIQ had a similar proportion of black participants, but VVTS included few Hispanics, and most VVTS participants were men. Project CLIQ extends the result of a previous study[38] in which smokers from 1 health center were proactively contacted by mail to offer telephone counseling and free NRT; that study found increased self-reported quit rates at 3-month follow-up compared with usual care (5.3% vs 1.1%).[38]

Electronic health records allow for identification and management of a population of smokers in a health system.[17,39] Coupled with IVR or other technology for systematic outreach (eg, texting), this infrastructure allows for the possibility of large-scale linkage to care teams for tobacco treatment.[40] Systematic intervention facilitated by EHRs may be particularly important for low-SES smokers who experience substantial barriers to treatment.[19,41] While only 8.3% of the potentially eligible population in Project CLIQ responded to the proactive outreach, this is not surprising because only a minority of smokers may be interested in hearing about cessation at any given time, and there are difficulties inherent in reaching people by telephone (eg, screening of calls, intermittent service particularly among low-SES groups). Our participation rate was higher than that of quitlines,[42] which achieve, at best, 1% to 2% reach into populations.

Population-based approaches may reach a relatively small proportion of smokers, but settings with a large number of smokers will still realize a large number of quits. Future implementation of this type of program could consider an ongoing schedule of outreach informed by qualitative work to understand how to better engage men, younger participants, and Hispanics, the groups that proved less likely to participate in this study. This model could be generalized to other health systems with EHRs, which are increasingly promoted to improve the safety and quality of health care.

This study has several limitations. It was a pragmatic trial, conducted within a primary care network. However, this is also a strength in that our findings speak more directly to clinical effectiveness. Our randomization protocol led to an imbalance of the group sizes; despite this limitation, the groups were well balanced on measured characteristics.

Our outcome was measured by self-report and was not biochemically verified, an approach similar to other population-based interventions.[31] Project CLIQ was designed to be generalizable to clinical care where clinicians use self-reported smoking status to guide treatment and risk assessment.

While our outcome survey completion rate was good (66%), there is the potential for nonresponse bias. Because we had a higher outcome assessment rate in the control group, the assumption that nonrespondents were smokers would bias against finding an effect. Our sensitivity analysis also suggests that our findings are robust.

Our intervention was designed to address barriers to smoking cessation experienced by low-SES participants, but we needed to use a census tract–based proxy for income assessment. Electronic health records should include measures of individual SES to enable interventions to reduce health disparities. Widening socioeconomic disparities in tobacco use and mortality support the importance of the broad collection of individual socioeconomic measures in EHRs to support interventions designed to promote health equity.[14]

Conclusions

Project CLIQ demonstrates that proactive, systematic, telephone-based interventions to provide counseling, pharmacotherapy, and access to community-based resources to address the social context of smoking can promote tobacco cessation in disadvantaged populations. Interventions to reduce tobacco use for these populations may reduce disparities in preventable deaths in the United States, an important public health goal.

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Invited Commentary

Proactive Outreach Strategies to Connect Smokers With Tobacco Cessation Treatment

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Most smokers want to quit smoking but try to stop without using tobacco cessation treatment. Because abundant evidence supports the efficacy of behavioral, pharmacologic, and combination treatment for tobacco dependence, it is important to increase the proportion of smokers who take advantage of therapy. Evidence confirms that current tobacco treatment models that rely on the patient or clinician to initiate treatment fail to reach all smokers interested in quitting. Proactive outreach strategies are increasingly being evaluated as a systematic approach to engage "hard-to-reach" smokers to increase the use of evidence-based tobacco treatments.

In this issue of *JAMA Internal Medicine*, Haas et al[1] describe results of a randomized clinical trial (RCT) testing an innovative intervention to reach out to all smokers in a health care system that included 13 primary care practices. Two tools were instrumental to the intervention design: the electronic health record (EHR) to identify smokers, and (IVR) to deliver telephone outreach and connection to a tobacco treatment specialist. In addition to typical smoking cessation counseling content, the specialist promoted referral to community resources to try to address some of the social determinants that contribute to tobacco use and might stand in the way of quitting, such as unemployment and education needs. The authors report a statistically significant improvement in 7-day point-prevalent abstinence in the intervention group compared with usual care (control): 17.8% vs 8.1% (odds ratio [OR], 2.5; 95% CI, 1.5-4.0) (*P* < .001). Of note, the intervention was similarly effective for those who planned and did not plan to quit.[1]

Routine recording of smoking status in the EHR affords an important opportunity for systematic identification of smokers. The use of coded data to instigate smoking cessation intervention without relying on clinician action is a strategic method to address significant disparities in delivery and utilization of tobacco dependence treatment among low-income smokers. Existing literature documents important barriers to accessing treatment in this population at the patient level (eg, lack of knowledge about effective treatments, low self-

efficacy), clinician level (eg, lack of time, bias about interest in quitting and likelihood of quitting), and systems level (eg, access to appointments, insurance coverage).[2] Automated electronic systems to identify smokers and deliver outreach have the considerable advantage of being blind to estimations of interest in and capacity to quit, which are subject to bias. In spite of low rates of treatment, numerous studies have documented considerable interest in quitting among low-income smokers.

Advantages of proactive outreach may extend to other populations that experience disparities in tobacco treatment in addition to low-income smokers. For example, because systematic outreach is a robust approach to institutional and clinician bias, it has potential to address low tobacco treatment rates among minority populations, populations with mental health diagnoses, and those with substance abuse diagnoses. More than half of smokers in the United States belong to 1 or more of these groups.[3,4]

There are limitations to this approach. Data from the EHR extend clinical treatment of tobacco dependence[4] but may not be accurate. However, the consequences of incorrect identification of a nonsmoking patient as a smoker are minor, while the incorrect identification of a smoker as a nonsmoker is a missed opportunity for intervention—or it might be the result of the patient recently quitting, in which case the intervention could be adapted for relapse prevention.

The automated nature of IVR makes it an appealing tool for information dissemination and intervention implementation. Although an initial investment in development and programming is required, the downstream costs of extending treatment to large numbers of smokers are low. In addition, the automated contact means that treatment delivery and data collection can occur during the same interaction, as in this study,[1] rather than employing different staff members for each purpose. There may be resistance to IVR, however, that limits this mode of communication. In the current study,[1] 62% of participants in the intervention arm were never reached by the IVR system, and an additional 29% declined to participate, leaving only 8% of eligible patients accessing treatments. In a study by Fu et al,[5] however, 62%

of personal outreach telephone calls were completed, and 30% were interested in counseling. It is therefore possible that this IVR limitation might be mitigated by further tailoring of the message system or by using personal phone calls to follow up with those who do not want to engage with the IVR. This approach would be more resource intensive, but given the highly cost-effective nature of smoking cessation interventions in general, it might still prove efficient.

Haas et al[1] describe a multicomponent intervention, and although receipt of certain components were more or less associated with abstinence, it is not possible to determine the independent contributions of outreach, counseling, nicotine replacement therapy (NRT), or connection to community resources. Two observations, however, are provocative. The lack of association between success in quitting and use of NRT contrasts with the body of literature, which suggests that NRT is efficacious for smoking cessation.[4] Use of population-based approaches is more likely to bring in smokers who are less motivated to quit, and it is possible that counseling will play a more important role than medication use for those who are less ready to stop smoking, particularly compared with traditional smoking cessation treatment trials that start with a population that is ready to set a quit date. Also, use of the referral system to access health and human service agencies was associated with success, although attributing efficacy to this intervention component may be confounded by other participant characteristics.

The findings are very consistent with the Veterans Victory Over Tobacco Study.[5] This project identified veterans who smoked using the EHR and randomized them to mailed and telephone outreach methods, offering a choice between (1) tele-phone coaching plus NRT or referral to Veterans Affairs smoking cessation services or (2) usual care. The OR for quitting in the intervention group was 1.27 (95% CI, 1.03-1.57), and the quit rate in the intervention group, 13.5%, was in the same range as was found in this proactive outreach study,[1] although in an entirely different population. In aggregate, these RCTs strongly suggest that proactive tobacco treatment will reach more smokers than reactive treatment.

This trial[1] makes an important contribution by focusing on low-income smokers. Data suggest that this is an increasingly large proportion of US smokers. The National Cancer Institute funded a group of RCTs in 2008 that examined novel ways to reach low-income smokers, including residents of public housing, patients receiving subsidized health insurance from the state, those less motivated to quit, people in community correction programs, emergency department patients, low-income veterans, and Native Americans. Results from this diverse group of trial participants will shed further light on the best ways to adapt evidence-based interventions to these priority populations.

The focus on dissemination of treatment to engage smokers is a clear strength of this report.[1] Results support continued investigation of new proactive methods to extend treatment to hard-to-reach populations. Importantly, the results challenge assumptions that low-income smokers are not interested in quitting and that treatment is not effective in this population. A population-based approach that extends tobacco dependence treatment to all income groups, all racial and ethnic groups, and patients with all comorbidities is the only way to effectively reduce the prevalence of smoking in the United States.

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