Proactive Tobacco Treatment and Population-Level Cessation
A Pragmatic Randomized Clinical Trial

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IMPORTANCE Current tobacco use treatment approaches require smokers to request treatment or depend on the provider to initiate smoking cessation care and are therefore reactive. Most smokers do not receive evidence-based treatments for tobacco use that include both behavioral counseling and pharmacotherapy.

OBJECTIVE To assess the effect of a proactive, population-based tobacco cessation care model on use of evidence-based tobacco cessation treatments and on population-level smoking cessation rates (ie, abstinence among all smokers including those who use and do not use treatment) compared with usual care among a diverse population of current smokers.

DESIGN, SETTING, AND PARTICIPANTS The Veterans Victory Over Tobacco Study, a pragmatic randomized clinical trial involving a population-based registry of current smokers aged 18 to 80 years. A total of 6400 current smokers, identified using the Department of Veterans Affairs (VA) electronic medical record, were randomized prior to contact to evaluate both the reach and effectiveness of the proactive care intervention.

INTERVENTIONS Current smokers were randomized to usual care or proactive care. Proactive care combined (1) proactive outreach and (2) offer of choice of smoking cessation services (telephone or in-person). Proactive outreach included mailed invitations followed by telephone outreach to motivate smokers to seek treatment with choice of services.

MAIN OUTCOMES AND MEASURES The primary outcome was 6-month prolonged smoking abstinence at 1 year and was assessed by a follow-up survey among all current smokers regardless of interest in quitting or treatment utilization.

RESULTS A total of 5123 participants were included in the primary analysis. The follow-up survey response rate was 66%. The population-level, 6-month prolonged smoking abstinence rate at 1 year was 13.5% for proactive care compared with 10.9% for usual care (P = .02). Logistic regression mixed model analysis showed a significant effect of the proactive care intervention on 6-month prolonged abstinence (odds ratio [OR], 1.27 [95% CI, 1.03-1.57]). In analyses accounting for nonresponse using likelihood-based not-missing-at-random models, the effect of proactive care on 6-month prolonged abstinence persisted (OR, 1.33 [95% CI, 1.17-1.51]).

CONCLUSIONS AND RELEVANCE Proactive, population-based tobacco cessation care using proactive outreach to connect smokers to evidence-based telephone or in-person smoking cessation services is effective for increasing long-term population-level cessation rates.

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Tobacco use remains the number one cause of premature death and morbidity in the United States, responsible for nearly 443,000 deaths annually.1 Most cigarette smokers want to quit smoking, and about 50% make a quit attempt each year, but only 6% achieve long-term cessation.2 Effective treatments exist, and clinical practice guidelines recommend a combination of behavioral counseling and medication use because this multiple-modality approach is most effective for helping smokers to quit over the long term.3 Unfortunately, in 2010, only 4.3% of smokers had used counseling and medication concurrently in the prior year.4 The population impact of any treatment is the product of the effectiveness of the treatment and the reach of the treatment into the target population.4,5 Effective treatments, if rarely used, have negligible impact.

Despite the high prevalence of interest in quitting and quit attempts without effective treatments, our health care system approach to tobacco cessation is predominantly reactive. Smokers either have to request treatment or have a clinical encounter in which their provider has the initiative, time, and capacity to offer and deliver tobacco cessation care. A proactive, population-based tobacco cessation care model with low barriers to access may greatly increase the reach of evidence-based treatment. Proactive tobacco intervention holds great promise for increasing the population impact of treatment and overcoming disparities in treatment by increasing reach.

We designed a pragmatic randomized clinical trial, the Veterans Victory Over Tobacco Study, to compare the effects of a proactive, population-based tobacco cessation care model vs a traditional cessation care model grounded in episodic clinical encounters on utilization of tobacco treatment and subsequent population-level smoking cessation rates. The intervention used a clinical registry of smokers and proactive telephone counseling.

Methods

Study Design

The Veterans Victory Over Tobacco Study received approval from the participating sites’ institutional review boards: the James A. Haley VA Medical Center (Tampa, Florida), the New York Harbor VA Medical Center (New York, New York), the G.V. (Sonny) Montgomery VA Medical Center (Jackson, Mississippi), and the Minneapolis VA Medical Center (Minneapolis, Minnesota [coordinating site]). Details of the randomized controlled study design and methods have been previously described.6 Participants from the 4 VA medical centers were randomized prior to contact to evaluate both the reach and effectiveness of a cessation-induction intervention within a population-based sample of smokers, including those who were not trying to quit. The study design contained the elements of pragmatic trials,7 including the use of minimal exclusion criteria, the coordination of care with clinicians to deliver medications, the usual care comparison group, the single follow-up at 1 year after randomization, and the analysis of the primary outcome among all current smokers regardless of treatment utilization or interest in quitting. Pragmatic trials compare clinically relevant alternative strategies as they would occur in real-world settings and are designed to more optimally assist clinical and health policy decision makers choose between options for care.8,9

Study Setting and Participants

The study sites were selected to ensure adequate inclusion of racial and ethnic minority veterans. Participants were recruited from October 2009 to September 2010, and follow-up was completed in November 2011. Included participants were all veterans aged 18 to 80 years identified as current smokers during a primary care visit within the prior 3 months. Exclusion criteria were minimal to enhance generalizability to the VA primary care population. Patients with a cognitive disorder or severe persistent mental illness (as identified using International Classification of Diseases, Ninth Revision, Clinical Modification diagnosis codes 290.XX or 331.XX) or having 10 or more mental health clinic visits in the prior year or having no valid contact information (ie, no usable address and telephone number) were ineligible for study participation. These exclusion criteria were applied during the identification process of current smokers using the VA’s electronic medical record (EMR) Health Factors Data set.10

Usual Care (Comparison)

The usual care group (ie, reactive care) received access to tobacco treatment services from their VA hospital. The VA guidelines mandate screening for tobacco use, advising tobacco users to quit, and offering tobacco treatment (ie, pharmacotherapy and counseling). Participants could receive treatment through primary care and/or specialty tobacco treatment clinics and could also access help to quit smoking by calling their state or national quit line (1800QUITNOW). The smoking cessation programs available at these 4 sites are representative of existing programs elsewhere in the VA and are comparable in terms of the availability of pharmacotherapy and in-person counseling services.

Proactive Care (Intervention)

The proactive care intervention combined 2 main components: (1) proactive outreach (mailed invitation materials followed by telephone outreach) and (2) offer of choice of smoking cessation services (telephone care or in-person care). Proactive outreach to participants at all sites was delivered by counselors at the Minneapolis VA Medical Center. Counselors received training in smoking cessation counseling from the California Smoker’s Helpline and training in motivational interviewing. Motivational interviewing is a collaborative, patient-centered, evidence-based counseling practice that is appropriate for addressing tobacco use at varying levels of readiness to quit.11 Counselors mailed smokers invitation materials that described the available VA smoking cessation services. Counselors then contacted smokers for telephone outreach using a protocol including at least 6 attempts at different times of the day and week. The purpose of the outreach call was to provide motivational enhancement to encourage participants to quit smoking and to offer a choice of telephone or
in-person smoking cessation services. Participants who chose telephone care received services from counselors at the Minneapolis VA. For participants who chose in-person (ie, face-to-face) care, the counselors arranged a referral to their local VA facility's smoking cessation program.

Telephone care in this study combined proactive telephone-based counseling with increased access to pharmacological therapy from the VA. Counselors initiated a 7-call protocol scheduled in a manner to minimize likelihood of relapse over a 2-month period (pre-quit, quit day, then 3 days, 1 week, 2 weeks, 1 month, and 2 months after the quit date). Participants who relapsed during the program were encouraged to set new quit dates and were allowed to repeat the counseling protocol (ie, up to 4 months total). Counselors facilitated access to pharmacotherapy by entering electronic progress notes into the VA’s EMR to notify the participant’s VA provider. The participant’s VA provider electronically acknowledged receipt of the note, determined clinical appropriateness, and prescribed smoking cessation medications.

Data Collection
Data collection occurred at baseline and at 12 months after randomization. The VA administrative and health care utilization data were obtained from VA National Patient Care Databases. Survey data were collected at baseline and at 1-year follow-up. As previously described, the baseline and follow-up survey procedures utilized a modified Dillman protocol and included a $10 cash incentive with the first survey mailing. Participants were informed of their group assignment at the time of the baseline survey. Survey staff were blinded to the participants’ group assignment.

Outcome Measures
The primary outcome was 6-month prolonged smoking abstinence 1 year after randomization. Prolonged abstinence was defined as a period of abstinence of 6 months in duration. A participant who smoked at least once on 7 consecutive days or who smoked at least once on 2 consecutive weekends in the 6-month period was defined as a treatment failure. As recommended for cessation-induction trials by the Society for Research on Nicotine and Tobacco Measures Workgroup, follow-up was tied to the onset of the intervention (ie, time of randomization). To assess population-level cessation, 6-month prolonged smoking abstinence was assessed among all current smokers regardless of treatment utilization or interest in quitting. Secondary outcomes included self-reported 7-day point prevalence abstinence (not having smoked part of a cigarette in the past 7 days), use of behavioral counseling, use of smoking cessation medications, and use of combined counseling and medication.

Statistical Analysis
Our primary analysis compared population-level 6-month prolonged smoking abstinence rates and was powered to detect a 2% difference (based on 3000 completed follow-up surveys) between proactive care and usual care. Logistic regression mixed modeling was used to test the effect of treatment on the primary outcome, 6-month prolonged abstinence. The models included, in addition to the treatment effect, site effect and treatment by site interaction. Prior to testing the effect sizes, the success of randomization to create balance between subjects in the different arms was assessed using the observed baseline covariates. The weighted stratified Wald χ² test was used to assess possible lack of balance of categorical demographics and clinical characteristics. Continuous covariates were assessed using weighted stratified z tests. The weights were inverses of the sampling proportions from each facility. We performed intention-to-treat analyses whereby it was assumed that all subjects remained in their treatment arm as randomized. To handle nonresponse, we hypothesized that nonresponse might depend on the unobserved smoking status of the subject; that is, we assumed a not-missing-at-random (NMAR) mechanism. To assess this supposition, we modeled the joint distribution of abstinence status and response status for the logistic regressions using an expectation-maximization (EM) algorithm to find maximum likelihood estimators, as described and modeled by Ibrahim and colleagues. This method is a likelihood-based NMAR method that creates 2 data sets, one that assumes that all nonresponders are smokers, and the other assumes that all nonresponders are quitters. Then, through a series of iterative reweightings, it produces maximum likelihood estimates. Similar analyses were conducted for the secondary outcome of 7-day point prevalence abstinence. All analyses including the macro for likelihood-based NMAR modeling were developed using SAS/STAT software, version 9.2 (SAS Institute Inc).

Results
Study Participants
A total of 10,898 subjects identified as current smokers by the EMR tobacco use clinical reminder were potentially eligible for the study, and 6400 were randomly selected and assigned to either proactive care or usual care and mailed a baseline survey (Figure). At the time of the baseline survey, 1277 subjects were excluded for not meeting eligibility criteria: 428 declined to participate; 201 were misclassified as cigarette smokers (never used cigarettes or smokeless tobacco user); and 478 were former smokers (rather than current smokers); 179 had incorrect mailing addresses; and 25 were deceased. Therefore, the primary analytical sample for the study included 5123 participants who were both randomized and fully eligible. Within this primary analytical sample, 2519 participants received the proactive care intervention and 2604 participants received usual care. The follow-up survey response rate was 66%. Of the 2519 proactive care participants, 1734 completed the 1-year follow-up survey and had complete primary outcome data; and of the 2604 usual care participants, 1734 completed the 1-year follow-up survey and had complete primary outcome data. Post randomization follow-up data from VA National Patient Care Databases were extracted from all participants in both groups (n = 5123).

Baseline Demographic and Clinical Characteristics
Baseline demographic and clinical characteristics were obtained for all participants (n = 5123) using VA National Patient Care Databases.
6% (n = 86) had already quit smoking and 64% (n = 1001) reach call. Of those who participated in the outreach call, 1556 (62%) in the Proactive Care Group

Interest in Smoking Cessation Counseling
In the proactive care group, 2519 were mailed outreach invita-

tion materials. During telephone outreach, 1556 (62%) were successfully contacted and participated in the outreach call. Of those who participated in the outreach call, 6% (n = 86) had already quit smoking and 64% (n = 1001) were not interested in making a quit attempt. Nearly 30% (n = 469) were interested in participating in smoking cessation counseling, and of these, 84% (n = 392) chose telephone care, and 16% (n = 77) chose in-person care.

Tobacco Treatment Utilization
Table 2 details tobacco treatment utilization among follow-up survey respondents. At the 1-year follow-up, 2.2% of usual care participants reported using telephone counseling to quit smoking in the past year. Telephone counseling was 6-fold higher in the proactive care group, with 12.7% reporting using telephone counseling in the past year. The use of in-person counseling and self-reported use of smoking cessation medications (from the VA and outside the VA) in the past year was similar between the 2 groups. However, the proactive care group reported significantly higher rates of use of behavioral counseling combined with medication treatment compared with the usual care group (12.8% vs 5.1%) (P < .001). As determined by consulting VA patient care databases, 3% of participants across both groups attended at least 1 VA smoking cessation clinic visit during the year. There was a significant increase in receipt of a smoking cessation medication from the VA among proactive care participants compared with those receiving usual care (34.5% vs 29.5%) (P = .002). We compared the percentages receiving medications among nonrespondents to the follow-up survey, and 31.9% of the nonrespondents in the proactive care group received VA smoking cessation medication vs 26.5% of the nonrespondents in the usual care group (P = .01). Among the entire study population, regardless of survey response, 33.5% of the proactive care group received VA smoking cessation medication vs 28.5% of the usual care group (P < .01).

Population-Level Smoking Cessation Outcomes
The 6-month prolonged abstinence rate at 1 year among follow-up survey respondents was 13.5% for proactive care compared with 10.9% for usual care (P = .02) (Table 2), an increase in the population-level cessation rate of 2.6% (95% CI, 0.3%-4.8%). Logistic regression mixed modeling analysis demonstrated a significant effect in favor of the proactive care intervention (odds ratio [OR], 1.27 [95% CI, 1.03-1.57]) (Table 3). Results adjusting for anxiety disorder were similar (OR, 1.28 [95% CI, 1.04-1.57]). Analyses accounting for nonresponse using likelihood based NMAR models showed a similar effect of the proactive care intervention on prolonged abstinence (OR, 1.33 [95% CI, 1.17-1.51]). Secondary analyses of 7-day point prevalence abstinence also favored proactive care (Table 3).

To assess the contribution of tobacco treatment utilization to the intervention’s effectiveness, we examined self-reported tobacco treatment utilization variables (use of in-person counseling, telephone counseling, and medication) and all possible 2- and 3-way interactions among treatment utilization variables and treatment group. Telephone counseling was related to 6-month prolonged abstinence (OR, 1.90 [95% CI, 1.36-2.67]) (P < .001), but other utilization variables were not significant.
The intervention activities involved outreach calls to assess interest in smoking cessation and then follow-up telephone counseling for those interested. During the study, there were approximately 8200 outreach call attempts made and another approximately 1960 counseling calls, which yields an average of 3.3 outreach call attempts and 0.8 counseling calls for each of the 2519 patients in the intervention group. Telephone counseling participants received an average of 5 counseling calls. We also observed slightly higher average VA medication costs in the proactive care group compared with the usual care group ($66.78 vs $56.32) \((P = .03)\). However, when...
we looked at overall VA outpatient costs, we found no statistically significant differences between the proactive and usual care groups ($7170 vs $7517) \((P = .26)\).

**Discussion**

This pragmatic randomized clinical trial demonstrates that a proactive, population-based tobacco cessation care model increases the reach of evidence-based tobacco cessation treatments and increases population-level cessation rates compared with usual care. Proactive care primarily increased the use of combination treatment (ie, behavioral counseling combined with the use of smoking cessation medications), which is the most effective form of treatment for helping smokers quit for the long term. Furthermore, a 2.6% increase in the population-level cessation rate is highly significant from a public health perspective because all smokers were included regardless of motivational level to quit smoking. It is also important to note that usual care in the VA was very successful in achieving a population-level cessation rate of 10.9%, which is much higher than the 6.2% population-level cessation rate of the total US population. In addition, a large number of usual care participants (29.5%) received smoking cessation medications. The VA is a national leader in delivery of smoking cessation services and holds facilities accountable using performance measures determined by external audit of medical records. It is possible that a proactive care model effectively implemented in non-VA health care settings might have greater population impact.

The proactive care model may be more effective than usual care models for several reasons. First, proactive care was integrated into the health care system and leveraged the power of the EMR to efficiently identify a complete cohort of current smokers rather than a select sample identified clinically. This approach overcomes known barriers to delivery of smoking cessation treatment such as competing demands during clinical appointments, lack of provider training or interest, and racial/ethnic or other bias about smokers’ interest in quitting. Second, proactive outreach was delivered by counselors trained in motivational interviewing and smoking cessation counseling. Third, counselors were able to communicate and coordinate care with the participant’s VA primary care provider and local smoking cessation clinic.

Our study is one of few studies to specifically address the population impact by increasing the reach of effective treatments and extends the findings of 4 previous randomized trials that included certain components of our proactive care model and demonstrated preliminary support for the benefit of population-based outreach offering evidence-based care. Our results are consistent with a single-site, randomized clinical trial that tested proactive mailed outreach (no telephone) using 3 monthly letters to offer free nicotine replacement therapy (NRT) and telephone counseling (fax referral to state quit line, \(n = 590\)). The use of NRT was significantly higher among the proactive group (11.6% vs 3.9%; OR, 3.47 [95% CI, 1.52-7.92]) compared with usual care, but use of telephone counseling was not increased (1.7% vs 1.1%). Investigators observed a significant effect on 7-day point prevalence abstinence rates at 3 months (5.3% vs 1.1%; OR, 5.35 [95% CI, 1.23-22.32]), but the study did not assess long-term quit rates. In addition, a community-based study in Australia proactively telephoned smokers identified by randomly selecting telephone numbers from the New South Wales White Pages to offer telephone counseling but did not offer medication. Participants who received telephone counseling achieved greater 7-day point prevalence abstinence rates than controls at 7 months (14.3% vs 11.0%) \((P = .02)\) but not at 13 months. Two other trials of mailed outreach also demonstrated increased use of cessation services and quit attempts but limited effects on quit rates. In comparison with prior studies, our protocol used electronic identification of smoking status, both mail and telephone, to accomplish proactive outreach, and offered a combination of counseling and medication tobacco treatment, which may explain the significant effects on long-term abstinence.

This study has several limitations. The pragmatic study design demanded identification of smokers from the EMR, so some participants were excluded after randomization (ie, primarily owing to refusal or misclassification of tobacco use status). This limitation is unlikely to have biased the study results, since baseline participant characteristics (except for a small difference in anxiety) were balanced between the 2 groups. Adjustment for the imbalance in anxiety diagnosis did not alter conclusions. Smoking abstinence was measured by self-report and not biochemically verified; nonetheless, our approach is consistent with recommendations for population-based interventions. Biochemical verification is also not possible for 6-month prolonged abstinence, the study’s primary outcome. The follow-up survey response rate was 66%, and there is the potential for nonresponse bias. We applied the approach of Ibrahim and colleagues to account for nonresponse and observed similar effects between the models accounting for nonresponse and the complete case models. While the study is representative of veterans receiving primary care from the VA who are primarily male and older, results may not be generalizable to the general US population. Finally, it is not possible to determine which specific components of the multiple-component intervention are responsible for the effectiveness of the intervention. However, the inter-

### Table 3. Logistic Regression for Smoking Abstinence at 1-Year Follow-up

<table>
<thead>
<tr>
<th>Model^a</th>
<th>Participants, No.</th>
<th>Odds Ratio (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>6-Month prolonged abstinence^b</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Complete case model</td>
<td>3307</td>
<td>1.27 (1.03-1.57)</td>
</tr>
<tr>
<td>Likelihood based NMAR model accounting for non-response</td>
<td>5123</td>
<td>1.33 (1.17-1.51)</td>
</tr>
<tr>
<td>7-Day point prevalence abstinence</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Complete case</td>
<td>3056</td>
<td>1.16 (0.96-1.41)</td>
</tr>
<tr>
<td>Likelihood based NMAR model accounting for non-response</td>
<td>5123</td>
<td>1.22 (1.08-1.37)</td>
</tr>
</tbody>
</table>

Abbreviation: NMAR, not-missing-at-random.

^a Usual care is the reference group.

^b Primary outcome.
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Original Investigation Research

The design and conduct of the study; collection, development, and Health Services Research and Administration, Office of Research and Department of Veterans Affairs, Veterans Health.

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REFERENCES


In conclusion, this large, randomized clinical trial provided evidence that proactive, population-based tobacco cessation care is effective for increasing use of telephone counseling combined with medications and its significant impact on long-term population quit rates. The observed 2.6% increase in population-level cessation is an important absolute reduction in smoking rate (2600 per 100 000 smokers proactively targeted) with relatively small intervention activities and little to no effect on VA medical care costs. This approach lends itself to dissemination and implementation because of growing capacity to identify tobacco users electronically and because proactive outreach to connect smokers with evidence-based care is not resource intensive. The proactive care intervention evaluated in this study consisted of a single episode to engage smokers in evidence-based treatment. Future studies are needed to test the effect of proactive care using a chronic disease model to ensure delivery of evidence-based tobacco treatment to those who do not quit with a single episode of care. In addition, future research is needed to conduct budget impact analyses for a variety of health care settings to better understand the extent to which this type of proactive model of care might be efficiently incorporated into other VA and non-VA health care settings.

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