Evaluating a Primary Care Tobacco Cessation Program

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Clinicians at this VA facility explore new ways to meet the needs of tobacco users who are unable to commit to a time-intensive quit program.

Tobacco dependence is a leading cause of morbidity and mortality in the United States. Smoking, in particular, is a known cause of cancer, chronic obstructive pulmonary disease, cardiovascular disease, cerebrovascular disease, and pregnancy complications. Tobacco use is responsible for nearly a half million premature deaths annually.[1] Nevertheless, it is estimated that 25% of adult Americans[1] and 33% of VA patients[2] smoke. Furthermore, despite the availability of effective smoking cessation strategies, more than one third of smokers report that they have never been asked about smoking or encouraged to quit by a health care provider.[1] In the absence of such intervention, tobacco users are left to attempt to quit on their own, without the benefit of evidence-based treatment options.[1]

To address the problems of tobacco dependence and lack of provider intervention, the HHS recommends that institutions adopt a procedure for identifying, documenting, and treating every tobacco user.[1] In a similar vein, VHA Directive 2003-042 calls for VA medical facilities to make tobacco cessation medications available to all tobacco dependent patients who show an interest in quitting, regardless of whether or not the patient is willing to attend an intensive tobacco cessation program.[2]

In this article, we present a performance improvement project undertaken to evaluate a primary care tobacco cessation program developed at the Erie VA Medical Center in Erie, PA specifically for patients who want to quit but cannot commit to a time-intensive cessation program. The primary objective of the study was to determine the tobacco use quit rate of program participants after six to 12 months. Secondary objectives involved determining the influence of various factors—such as the pattern of tobacco use, pharmacologic intervention used, patient education, use of non-VA resources, and number of previous quit attempts—on the quit rate.

EVIDENCE-BASED INTERVENTIONS

It's well established that appropriate use of pharmacologic agents—such as sustained-release bupropion and nicotine replacement gum, inhalers, nasal sprays, and patches—promotes long-term smoking abstinence. As second-line pharmacologic treatments, clonidine and nortriptyline have proven safe, efficacious, and cost-effective relative to other routinely reimbursed medical interventions. Counseling and behavioral therapies that have proven effective include practical counseling techniques (such as problem solving and skills training), the incorporation of social support into therapy, and assistance in securing social support outside of the therapy setting. Research has demonstrated a direct correlation between the intensity of tobacco dependence counseling and its effectiveness.[1]

Independently, both behavioral therapy and pharmacotherapy can produce long-term or permanent tobacco abstinence. Current data, however, suggest that optimal tobacco cessation outcomes may require the combined use of both.[1]

EVOLUTION OF A PROGRAM

For over 10 years, the Erie VA Medical Center has administered a tobacco cessation program through its behavioral health clinic. This intensive, 10-week program is available to all medical center patients who screen positive for tobacco use and are willing to quit. The program provides comprehensive services (including group support, individual counseling as needed, and pharmacologic therapy) to help patients stop using any sort of tobacco product. Unfortunately, time constraints and travel distances have prevented many patients from participating.

Subsequent to the publication of VHA Directive 2003-042, the medical center introduced an interdisciplinary, evidence-based program to screen and treat patients for tobacco dependence in the primary care setting. Under

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this program, all patients are assessed for tobacco use in primary care. Current tobacco users are advised to quit, and their readiness to quit is assessed by the provider. For those patients unwilling to quit, clinicians provide guidance and encouragement using the four "Rs": relevance, risks, rewards, and repetition.[3]

Patients who can commit to tobacco cessation and set a quit date, but are unable or unwilling to attend the intensive counseling and behavioral therapy program at the medical center's behavioral health clinic, are treated in the primary care clinic. Patients are encouraged to select a quit date that falls within one month of the decision to cease tobacco use. Upon making this commitment, patients are given a list of local (non-VA) tobacco cessation resources and a packet of written patient education that discusses the health benefits of tobacco cessation, provides tips for quitting and for minimizing withdrawal symptoms, and includes information on pharmacologic tobacco cessation aids. Along with this standardized, written patient education, clinicians are encouraged to provide spoken patient education and to document this education in the medical record. The spoken education is not standardized and may be delivered by any of a number of health care professionals, including nurses, primary care providers (physicians or nurse practitioners), health care technicians, pharmacists, or behavioral health therapists.

At the time of this performance improvement project, pharmacologic aids for tobacco cessation used in the primary care program included immediate-release bupropion, the nicotine patch, and nicotine gum. (Although the majority of evidence regarding efficacy in tobacco cessation is with the sustained-release formulation of bupropion, the immediate-release formulation was considered a suitable alternative due to its pharmacokinetic properties and cost considerations.) The recommended dosage of immediate-release bupropion was 75 mg twice daily for three days, followed by 150 mg twice daily for 12 weeks. A "heavy dependence" nicotine patch regimen (21 mg/24 hr for the first six weeks, followed by 14 mg/24 hr for two weeks and 7 mg/24 hr for two weeks) was recommended for patients smoking 25 or more cigarettes per day. A "mild dependence" nicotine patch regimen (14 mg/24 hr for six weeks, followed by 7 mg/24 hr for two weeks) was recommended for patients smoking less than 25 cigarettes per day. Two strengths of nicotine gum (2 or 4 mg) also were available to treat either mild or heavy tobacco dependence. In either case, the recommended regimen was 1 piece every one to two hours for six weeks, followed by a six-week tapering period.

Pharmacologic interventions are prescribed at the primary care provider's discretion, with consideration of the patient's preferences, level of nicotine dependence, concurrent medications, and comorbid medical conditions. Guidelines for prescribing tobacco cessation pharmacotherapy are readily available to assist providers. Specifically, links on the computerized physician order entry menus contain information on advantages and disadvantages, contraindications, and precautions for each product.

Patients treated for tobacco cessation in primary care are contacted by telephone at two weeks and three months after the quit date to document patient abstinence or relapse. During each of these follow-up calls, patients who are tobacco free are congratulated on their success and encouraged to continue their abstinence. Patients who have relapsed are encouraged to resume their efforts and are referred back to the primary care provider.

Table 1. Patterns of tobacco use at enrollment

Characteristic of tobacco use	% of participants (no./total)
Tobacco product	
Cigarettes	86% (203/236)
Chewing tobacco	11% (27/236)
Pipe/cigar	3% (6/236)
Quantity of cigarettes smoked[a]	
< 1 pack per day	32% (64/201)
1 pack per day	42% (85/201)
1–2 packs per day	15% (31/201)
> 2 packs per day	10% (21/201)

[a]Data on the quantity of cigarettes smoked were unavailable for two of the 203 program participants who smoked cigarettes.

DATA COLLECTION AND ANALYSIS

For this performance improvement project, all patients who were treated in primary care for tobacco use disorder within the first three months of the program were included in the analysis. Individuals who were iden-

Table 2. Use of pharmacologic tobacco cessation aids

Pharmacologic agent	% using monotherapy (no./total)	% using combination therapy (no./total)
Bupropion	11% (27/236)	13% (30/236)
Nicotine gum 2 mg	8% (19/236)	1% (3/236)
Nicotine gum 4 mg	3% (6/236)	0% (0/236)
Mild patch regimen	26% (62/236)	2% (5/236)
Heavy patch regimen	39% (92/236)	10% (23/236)
Total	87% (206/236)	13% (30/236)

tified as tobacco users but were not willing to quit were excluded.

In addition to the routine follow-up at two weeks and three months, the long-term quit rate was assessed through another telephone contact at six to 12 months after the quit date. This follow-up call included a question about patients' use of tobacco cessation resources outside of the VA health care system.

To achieve 85% power at the level of $P < .05$, it was necessary to assess a sample size of at least 171 patients. Assuming that 10% of patients would be lost to follow-up, enrollment was set at a minimum of 188 patients.

Descriptive statistics were used to compare the quit rate of the primary care tobacco cessation program to that of the behavioral health clinic's intensive counseling and behavioral therapy program and other, similar programs. The impact of tobacco use pattern, choice of pharmacologic intervention, presence or absence of spoken patient education, profession of the clinician delivering the spoken patient education, use of non-VA tobacco cessation resources, and number of previous quit attempts was assessed initially through contingency table analysis using either chi-square or Fisher's exact tests as screening tools. Thereafter, factors with associated *P* values of less than .2 were loaded into a binary logistic regression analysis using a forward conditional approach to establish predictors of success. Data analysis was performed using the Statistical Package for the Social Sciences (SPSS) version 12.0 (SPSS Inc., Chicago, IL).

OUR FINDINGS

During the first three months of the program, 336 patients were treated for tobacco use disorder in primary care clinics and, thus, were eligible for inclusion in the analysis. Of these, 56 were prescribed pharmacotherapy without a documented quit date or subsequent patient follow-up. (This was identified as a problem early in the implementation of the program, and providers were instructed, thereafter, not to prescribe pharmacotherapy without a documented quit date and scheduled follow-up.) In addition, 44 patients were lost to follow-up: 30 were unreachable by telephone, seven died, and seven moved away. The remaining 236 patients were included in the analysis.

The majority (95%) of these patients were men. The mean age of the group was 58.5 years (range, 24 to 84 years). For most patients, racial information was not included in the electronic medical record.

The tobacco product used by the majority of patients was cigarettes (Table 1). There were no statistically significant differences in successful tobacco cessation based on the tobacco product used or the quantity of cigarettes smoked.

The nicotine patch was the pharmacologic agent prescribed most frequently—to 77% of patients, either alone or in combination with other pharmacologic aids (Table 2). At two-week follow-up, a statistically significant difference favored combination therapy with bupropion and either nicotine gum or a nicotine patch over monotherapy with any of these agents (Table 3). Six to 12 months after the quit date, 17% of all enrollees and 27% of those using nicotine replacement therapy plus bupropion were still tobacco free.

Spoken patient education regarding tobacco cessation was documented for 137 (58%) of the 236 patients. Nurses delivered this education most frequently (27%), followed by primary care providers (16%), health care technicians (13%), pharmacists (1%), and behavioral health therapists (1%). There were no significant associations, however, between the tobacco cessation rate and either the presence or absence of spoken patient education or the profession of the clinician delivering the education.

Approximately 5% of patients reported using non-VA tobacco cessation resources. These patients tended to be less successful over the course of follow-up, though this effect was

statistically significant only at the two-week point (Table 4).

The number of previous quit attempts varied widely, with 66% of patients having made fewer than five, 14% having made five to eight, and 15% having made more than eight. (The number of previous quit attempts was unknown for the remaining 5%.) At two-week follow-up, abstinence rates differed significantly between these groups, with the highest abstinence rate achieved by those who had made fewer than five previous quit attempts.

Table 3. Effects of pharmacotherapy type and dosages on the success of tobacco cessation

Pharmacologic intervention	Cessation rate, by follow-up point (no./total)		
	2 weeks	3 months	6–12 months
Agent(s)			
Bupropion	17% (4/24)	17% (4/23)	7% (2/27)
NRT[a]	58% (91/157)	36% (54/152)	16% (29/179)
Both	76% (19/25)	43% (10/23)	27% (8/30)
P value	< .0001	.144	.144[b]
NRT dosage form			
Gum	42% (10/24)	32% (8/25)	11% (3/27)
Patch	63% (100/158)	37% (56/150)	19% (34/182)
P value	.071	.661	.427[b]
Gum strength			
2 mg	37% (7/19)	30% (6/20)	14% (3/22)
4 mg	50% (3/6)	33% (2/6)	0% (0/6)
P value	.653[b]	> .999[b]	.999[b]
Patch regimen			
Mild	70% (41/59)	32% (18/56)	13% (9/67)
Heavy	60% (59/99)	40% (38/94)	22% (25/115)
P value	.236	.383	.236

[a]NRT = nicotine replacement therapy. [b]Approximate *P* values only; at least one assumption violated in test.

INTERPRETING THE RESULTS

When Larson and colleagues followed up on veterans enrolled in a tobacco cessation program 12 months after their quit dates, they found that all patients who had relapsed had done so within the first six months.[4] Our analysis at six to 12 months, therefore, likely provides an accurate reflection of the program's success.

The six- to 12-month quit rate of our primary care tobacco cessation program (17%) was substantially lower than that of the intensive program offered within our medical center's behavioral health clinic (33%), though it should be noted that these two patient cohorts were not randomized and that confounding variables prevent a valid comparison. Although the quit rate for our primary care program falls within the 9% to 22% range reported by most smoking cessation programs provided to the general public, it leaves substantial room for improvement. Some studies have reported six-month tobacco abstinence rates as high as 66%.[4]

A factor contributing to the low quit rate observed in our analysis may have been a failure on the part of providers to determine accurately a patient's readiness to quit. Some tobacco cessation clinics have successfully applied the transtheoretical model for behavioral change to the assessment of patients' readiness to quit.[5,6] This model relies upon several stages of change, including precontemplation, contemplation, preparation (determination), action, maintenance, and termination.[5,6] Implementation of such a model in our program might help to improve its success.

Optimizing pharmacotherapy

Further study may be warranted to establish the role of bupropion and combination therapy for tobacco cessation. In the current study, combination therapy with immediate-release bupropion and nicotine replacement (gum or patch) was more effective than monotherapy with either agent at two-week follow-up, but the difference was not sustained throughout the evaluation period. In a previous study by Simon and colleagues, the addition of sustained-release bupropion to nicotine replacement therapy and counseling did not increase rates of smoking cessation significantly.[7] By contrast, Jorenby and colleagues found that sustained-release bupropion alone or in combination with a nicotine patch resulted in significantly higher rates of tobacco cessation than use of either the nicotine patch alone or placebo.[8]

In May 2006, the FDA approved varenicline for use as an aid to smoking cessation. This approval gives patients and clinicians a novel therapeutic option—and provides an opportunity for further study to define its place in tobacco cessation therapy.[9] Investigation of the role played

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by the brain's insula may provide yet another basis for developing therapeutic interventions.[10]

Patient education

All patients identified as tobacco users should receive the fundamental intervention of patient education. Education provided by various health care professionals has been shown to be effective in increasing rates of tobacco cessation, and involving multiple clinical professionals may further enhance these rates.[1]

In the current study, the receipt of spoken patient education about tobacco cessation was documented in the electronic medical records of only 58% of patients. Whether this finding represents poor documentation or inconsistent provision of patient education is unclear.

The presence or absence of spoken patient education, however, did not appear to affect outcomes. A potential explanation for this finding is that these brief, oral interventions were insufficient to reinforce patient momentum and, thereby, stimulate the greater success observed with more intensive interventions. Another possibility is that statistical power was lost due to inadequate documentation of patient education, resulting in a type II error.

The role of behavioral therapy

Evidence favors the use of pharmacotherapy in conjunction with counseling and behavioral therapy over the sole use of any one component.[1] Few patients sought tobacco cessation counseling resources outside of the VA to augment provided pharmacotherapy. Paradoxically, those patients who used non-VA resources were less likely to be abstinent at two-week follow-up. This difference, however, was not sustained throughout the six- to 12-month evaluation, and the number of patients evaluated in this regard was small. In addition, our project did not assess characteristics of veterans who accessed outside resources or the nature of the resources used. Perhaps those who sought outside resources did so because they were having more difficulty remaining abstinent from tobacco products.

Table 4. Effects of use of non-VA resources and number of previous quit attempts on the success of tobacco cessation

Variable	Cessation rate, by follow-up point (no./total)		
	2 weeks	3 months	6–12 months
Non-VA tobacco cessation resources used?			
Yes	23% (3/13)	8% (1/12)	0% (0/15)
No	57% (106/186)	36% (65/180)	18% (38/210)
P value	.022	.061[a]	.081[a]
No. of previous quit attempts			
< 5	62% (85/138)	38% (49/129)	19% (29/155)
5–8	35% (9/26)	22% (6/27)	6% (2/33)
> 8	45% (15/33)	35% (12/34)	20% (7/35)
P value	.018	.297	.189

[a]Approximate *P* values only; at least one assumption violated in test.

Based on these data, it is unclear whether VA patients being treated for tobacco use disorders should be encouraged to participate in additional, non-VA tobacco cessation programs. Available medical literature suggests that increasing the convenience of counseling and behavioral therapy sessions and expanding their reach to rural areas may improve tobacco cessation rates.[1,11,12]

The impact of quit attempts

It has been suggested that there is need for greater recognition of tobacco dependence as a chronic condition, requiring ongoing assessment and repeated intervention.[1] The average smoker attempts to quit five to eight times before succeeding.[13] In our project, only 29% of participants had attempted to quit five times or more.

The statistically significant higher abstinence rates noted at two-week follow-up among patients with fewer than five previous quit attempts could possibly point to a higher degree of motivation among such patients early in the attempt to quit. Over the six- to 12-month study period, abstinence rates fell in all groups, independent of the number of previous quit attempts.

STUDY LIMITATIONS

The current analysis is limited in that it did not measure or standardize the content of patient education. Other limitations include the loss of 44 program enrollees to follow-up and the lack of information on patient adherence to prescribed pharmacotherapies. Self-reports of tobacco abstinence were used due to the unavailability of such objective measures as serum nicotine levels. Furthermore, the unique profile of the VA's patient population may render these results applicable only to patients with similar demographic characteristics. A randomized, controlled trial would have provided greater control over factors that potentially contribute to or detract from the success of tobacco cessation.

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MAXIMIZING IMPACT

The CDC estimates the costs of smoking to be about $3,391 per smoker per year.[14] Each pack of cigarettes sold in the United States costs the nation an estimated $7.18 in medical care and lost productivity.[14] In addition, smoking accounts for roughly 6% to 14% of personal health care expenditures.[15]

In 2005, Lee and Volpp concluded that there was an underinvestment in smoking cessation within VISN 4.[15] According to the U.S. Preventive Services Task Force, smoking cessation treatment was one of the highest-ranked services in terms of both cost-effectiveness and potential to reduce disease burden.[16]

The current analysis demonstrates that some patients may be treated for tobacco dependence successfully in a primary care setting. While modest, the 17% quit rate achieved by the primary care tobacco cessation program at six to 12 months could be expected to result in a significant cost savings if these patients are able to maintain abstinence.

To increase patients' chances of long-term success, the results of this performance improvement project are being used to enhance the design of the primary care tobacco cessation program. Providers have been educated on assessing readiness to quit, based on the transtheoretical model for behavioral change. A means of standardizing both the content and delivery of spoken patient education is being addressed. In addition, the program has implemented a single-session group educational class that involves a pharmacist and a behavioral health therapist to enhance education, provide support to the patient, and promote involvement in more intensive counseling and behavioral therapy sessions (either within or outside the VA). Tobacco cessation educational classes also have been incorporated at some of the medical center's community-based outpatient clinics located in rural areas.

Another recent change to the program has been updated recommendations regarding pharmacologic aids for tobacco cessation. The recommended bupropion dosage for tobacco cessation is now 100 mg once daily for three days, followed by 100 mg three times daily for a total of 12 weeks. The quantity of cigarettes used to assign the two nicotine patch regimens has been changed to 10 or fewer for the mild dependence regimen and greater than 10 for the heavy dependence regimen. And the nicotine lozenge has been added as an additional treatment option. These changes underscore the need for tobacco cessation therapies to evolve constantly in response to advances in our understanding of this challenging condition.

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