Helen Ann Halpin
Sara B. McMenamin
Jeffrey Rideout
Gifford Boyce-Smith

The Costs and Effectiveness of Different Benefit Designs for Treating Tobacco Dependence: Results from a Randomized Trial

This research estimated the costs and effectiveness of three different benefit designs for treating tobacco dependence: drugs only (nicotine replacement therapy patch, nasal spray, inhaler, and Zyban); drugs and counseling (drugs and proactive telephone counseling); and drugs if counseling (drugs conditional on enrollment in counseling). A sample of 393 adult smokers enrolled in a California preferred provider organization was randomly assigned to one of three study groups. After eight months, there were no significant increases in quit attempts or quit rates in the groups with covered drugs and counseling compared to the group with drug coverage only. Therefore, costs rose with no increase in quit rates when proactive telephone counseling was added to coverage of pharmacotherapy, regardless of benefit design.

Tobacco use has been identified as the single, largest preventable cause of morbidity and mortality in the United States; it leads to an estimated 440,000 deaths and more than five million years of life lost each year (DHHS 2004). This places a huge burden on society, with an estimated total cost of $158 billion per year (DHHS 2004). This includes both the direct costs to the health care system from the treatment of tobacco-related illness (estimated at $82 billion per year), as well as the societal costs resulting from lost productivity of workers due to premature death and disease (estimated at $76 billion per year). In California, there are approximately 43,000 tobacco-related deaths each year, representing 535,000 years of life lost (Max et al. 2004). This translates into $8.6 billion in direct medical costs and $7.3 billion in lost productivity from illness and premature death (Max et al. 2004).

Recent clinical practice guidelines identify effective treatments for tobacco use and dependence and recommend that all patients who use tobacco be offered at least one of these treatments to help them stop smoking (Fiore et al. 1996, 2000). The 2000 U.S. Public Health Service (PHS) guideline recommends two types of treatment for tobacco dependence: pharmacotherapy and counseling services. The recommended first-line pharmacotherapy treatments include bupropion SR (Zyban) and all Food and Drug Administration (FDA) approved nicotine replacement therapy (NRT) including gum, patch, nasal spray, inhaler, and

Helen Ann Halpin, Ph.D., *is a professor of health policy and director, and* ***Sara B. McMenamin, Ph.D.,*** *is an assistant researcher, both at the Center for Health and Public Policy Studies, School of Public Health, University of California, Berkeley.* ***Jeffrey Rideout, M.D.,*** *is vice president of Cisco Systems, San José, and former medical director of Blue Shield of California.* ***Gifford Boyce-Smith, M.D.,*** *is director of quality at Blue Shield of California, San Francisco.* *This research was funded by a grant (no. 9RT-0096) from the Tobacco-Related Disease Research Program.* *Address correspondence to Prof. Halpin at Center for Health and Public Policy Studies, University of California, Berkeley, 140 Warren Hall, #7360, Berkeley, CA 94720-7360. Email: helenhs@berkeley.edu*

Inquiry 43: 54–65 (Spring 2006).
0046-9580/06/4301–0054
www.inquiryjournal.org

lozenges. Effective counseling services identified in the guideline include proactive telephone counseling, individual face-to-face counseling, and group counseling services. In addition, the PHS guideline recommends that all health insurers provide coverage for these effective treatments. Health insurance coverage of recommended tobacco dependence treatments has been demonstrated to increase quit attempts, use of treatments, and quit rates (Curry, Grothaus, and McAfee 1998; Schauffler et al. 2001a). However, the evidence reviewed in the PHS guideline examines only the effectiveness of each drug or counseling service independently and provides no evidence of the effect of combined pharmacotherapy and counseling or guidance on preferred benefit designs.

While there is widespread agreement in the field of tobacco control that health insurance should cover effective treatments for tobacco dependence, the optimal benefit design for covering these services remains uncertain. In 1999, a survey was conducted of all California health maintenance organizations (HMOs) to document the benefit designs for tobacco dependence treatments offered in their standard employer group health plan benefit packages (Schauffler et al. 2001b). This study found that 31% of HMOs offered coverage for both pharmacotherapy and counseling, 15% offered coverage for pharmacotherapy only, 15% offered coverage for counseling only, and 38% offered coverage for pharmacotherapy conditional on enrollment in a counseling program (Schauffler et al. 2001b). This mix of benefit designs offered in California HMOs raises questions regarding which design is optimal to most effectively and efficiently aid smoking cessation in an enrolled adult population.

Coverage for pharmacotherapy is more prevalent than coverage for behavioral programs to treat tobacco dependence in both the public and private sectors (McPhillips-Tangum et al. 2004; Halpin, McMenamin, and Keeler 2004). Therefore, two of the major questions facing both public and private policymakers are: 1) Is the effect of coverage for pharmacotherapy treatments enhanced if counseling services are also covered? 2) What is the effect of restricting coverage for pharmacotherapy to smokers who enroll in counseling? To this end, this research has four main objectives: 1) to document changes in quitting behaviors among smokers in three treatment groups with different benefit designs (coverage for pharmacotherapy only, pharmacotherapy and counseling, and pharmacotherapy conditional on participation in counseling) with the same cost-sharing requirements; 2) to determine whether adding health insurance coverage for counseling to coverage for pharmacotherapy changes smoking cessation behaviors and outcomes; 3) to determine whether the specific design of the counseling and pharmacotherapy benefit (i.e., pharmacotherapy either conditional on enrollment in counseling programs or not) affects smoking cessation behaviors among adult smokers; and 4) to estimate the relative costs of achieving the major quitting outcomes for each benefit design. The goal of the study was to learn how best to design a package of tobacco dependence treatments for a group of insured adult smokers who are motivated to try to quit.

Methods

Study Design

This case study was an eight-month randomized trial, conducted from May 1, 2001, through December 31, 2001, that compared three different health insurance benefit designs for tobacco dependence treatments. The three treatment groups were designed based on three benefit designs found in California HMOs (pharmacotherapy only, pharmacotherapy and counseling, and pharmacotherapy conditional on counseling) (Schauffler et al. 2001b). According to the findings of the 2000 PHS clinical practice guideline, there is no statistically significant difference in the effectiveness of individual face-to-face, group, and proactive telephone counseling (Fiore et al. 2000). Proactive telephone counseling was chosen as the method of counseling for this study because it has been shown to have the highest participation rates compared to group counseling and face-to-face counseling, it is the most accessible of the three counseling formats, and it is the format of counseling most covered by health plans in the United States (McPhillips-Tangum et al. 2004). Rates of participation in group counseling can be as low as 1% or less, while rates of participation in telephone counseling can be as high as 10% to 25% (Schauffler et al. 2001a). In addition, the physicians in the preferred provider organization (PPO) in the study have not participated in any organized training for smoking cessation,

and most physician offices do not have dedicated personnel to perform such counseling.

While there is a considerable body of literature that demonstrates the efficacy of proactive telephone counseling compared to no interventions on quit attempts and quit rates (Fiore et al. 2000; Stead, Lancaster, and Perera 2003), there is a growing body of literature evaluating the effectiveness of proactive telephone counseling as an adjunct to pharmacotherapy compared to pharmacotherapy alone (Stead, Lancaster, and Perera 2003; Ockene et al. 1991; Lando et al. 1997; Reid, Pipe and Dafoe 1999; Solomon et al. 2000). Four trials have not found any additional effect of telephone counseling for those who use nicotine replacement therapy (Stead, Lancaster, and Perera 2003), but none of these studies specifically evaluated the effect of different benefit designs on smoking cessation.

To recruit participants for this study, informational postcards were mailed to all enrollees in the individual and family plans of a large preferred provider organization operating in California ($n = 113{,}000$ PPO enrollees). This postcard invited smokers to participate in a research study on smoking cessation benefits, requiring them to complete telephone interviews and providing them with access to free or low-cost smoking cessation methods (the pharmacotherapy under all three benefit designs required a $15 co-pay, while the counseling did not require cost sharing). At the time of the study, this PPO offered cessation coverage for pharmacotherapy for enrollees in the group market, but did not provide coverage for any smoking cessation benefits to its individual and family plan members.

Those who responded to the mailing ($n = 803$) were contacted by telephone to determine their eligibility and, if eligible, to conduct the baseline telephone survey. Those who were eligible and completed the baseline interview (71%) were mailed a packet including a complete description of the study, a self-help smoking cessation kit, information on any risks they might face as participants in the study, and two copies of a written consent form (one for their records and one to return to the study). Figure 1 illustrates the disposition of the sample from initial contact through the eight-month follow-up.

Study participants who completed the baseline interview and returned written consent forms (69%) were randomized into three treatment groups. The control group (drugs only, $n = 126$) received tobacco dependence treatment coverage for pharmacotherapy only; the pharmacotherapy included coverage for Zyban and NRT patch, inhaler, and nasal spray.[1] The second group (drugs and counseling, $n = 140$) received tobacco dependence treatment coverage for the aforementioned pharmacotherapy in addition to coverage for proactive telephone counseling provided through a nationally recognized program. The third group (drugs if counseling, $n = 127$) received tobacco dependence treatment coverage for proactive telephone counseling and coverage for pharmacotherapy only if they enrolled in the telephone counseling program. The proportion of subjects lost to follow-up at eight months was 18%; the proportion completing the study was 82%. However, all multivariate analyses included 100% of the original sample in each study group using an intent-to-treat model. All research was conducted with prior approval from, and in accordance with the guidelines set forth by, the Committee for the Protection of Human Subjects at the University of California, Berkeley.

Study participants were under no obligation to use any of the tobacco dependence treatments covered under the study, and they were free to use these benefits just as they would any other covered services. Access to pharmacotherapy benefits required a prescription. Enrollment in the proactive telephone counseling program required calling a toll-free number to register. During the first call, the phone specialist used a formal protocol to assess the smoker's nicotine dependence, readiness to quit, motivation to use behavioral techniques, and self-efficacy regarding cessation.[2] A quitting plan was developed and telephone follow-up calls were scheduled for one year (during which the participant received four additional calls). If the participant relapsed, s/he was sent a "recycle kit" and the specialist re-initiated the quitting process.

Baseline and eight-month follow-up data on smoking and quitting behaviors for all participants were collected by telephone using a computer-administered telephone interview (CATI) system. Participants received $5 for each telephone interview that they completed. Reminder postcards were sent at the midpoint of the study to remind participants of their eligible benefits and to inform them that they had four more months of eligibility. The follow-up was limited

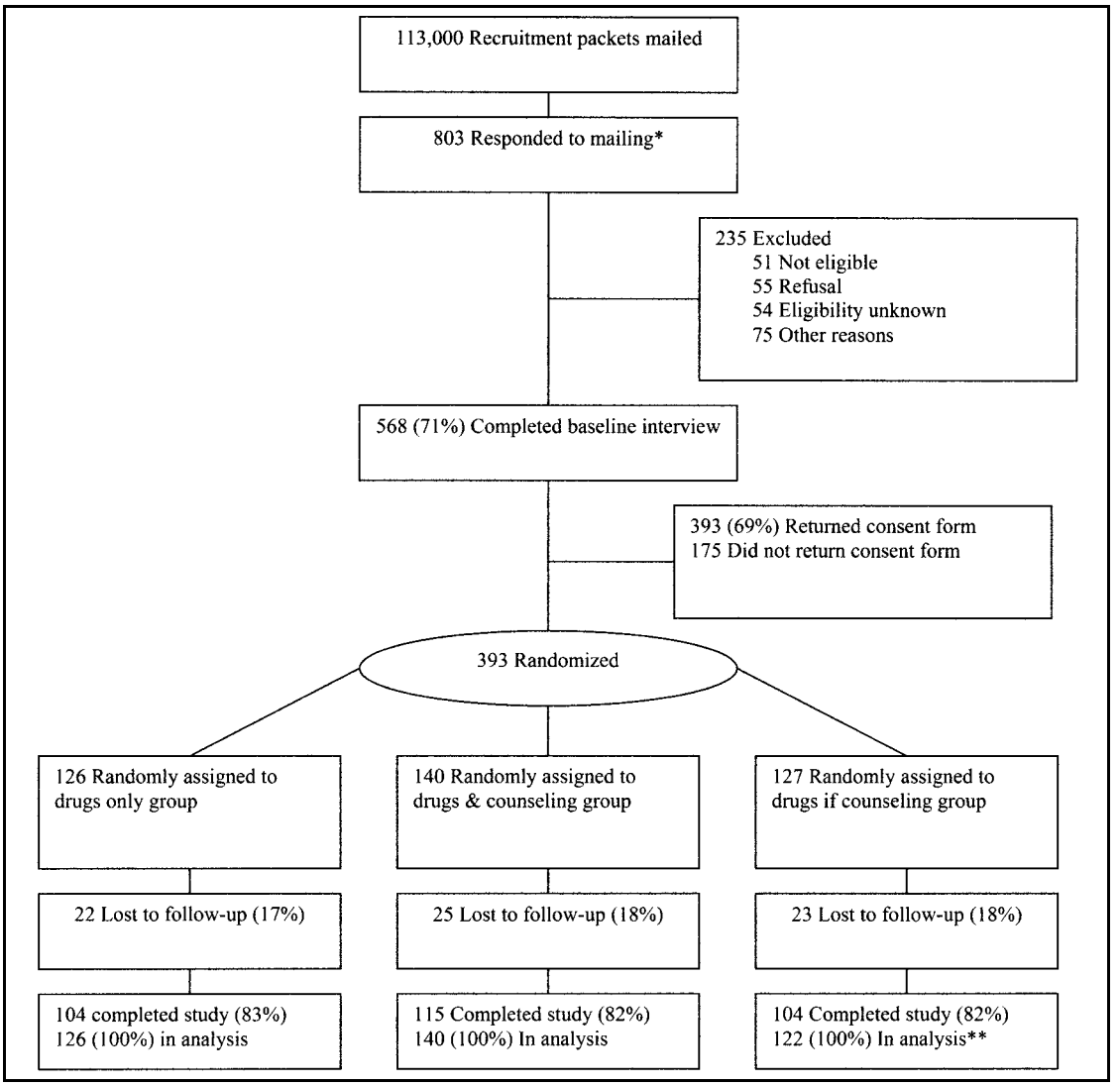

Figure 1. Flow diagram of tobacco dependence treatment randomization (*Recruitment packets mailed to all individual and family members in a large commercial PPO; packets indicated that only smokers should respond to mailing. **Five participants were removed from the analysis because they obtained pharmacotherapy without enrolling in counseling)

to an eight-month time frame, given the timing of the start of the study and the practice of the health insurer to begin each enrollment year on January 1. Ideally, we would have liked to have conducted the study for one full year and to have collected outcome data one year post-intervention.

All physicians enrolled in the PPO network were sent a letter by the health plan informing them about the study in general and the possibility that they may have patients participating. The letter also explained the smoking cessation benefit options with special attention to the drug benefit. The letter required nothing specific of the physicians and was intended only to make them aware of the study and the new benefits offered under the study.

Study Participants

Eligibility for the study required being an adult 18 years of age or older, currently enrolled in

an individual or family (not group) plan in the participating PPO, and a current smoker who had smoked at least one cigarette in the last seven days. Respondents were not eligible to participate in the study if they had any of the following disqualifying health conditions: pregnancy, poor health, coronary artery disease, heart disease, arrhythmia, heart attack or myocardial infarction, cardiovascular disease, angina pectoris, and congestive heart failure.

Thus, the results from this case study are only generalizable to smokers enrolled in individual and family PPOs in the private health insurance market; their applicability to smokers enrolled in other types of health plans is not known. We found several differences between our study participants and a population-based data set of smokers insured in HMOs and PPOs in California.[3] First, the smokers in our study were more likely to be female and more likely to be white than the population of California smokers. And while the smokers in our study were more likely to report wanting to stop smoking and contemplating quitting in the next month, they were actually less likely to have made a quit attempt in the last year and were no more likely to be planning on quitting in the next month compared to all California smokers. We do not know the extent to which these differences are the result of differences in smokers enrolled in individual and family plan PPOs compared to other types of managed care plans, or the result of differences between those who volunteered to be part of a smoking cessation study and the general population of smokers.

Main Outcome Measures

The primary outcomes of interest were: making a quit attempt (stopped smoking for one or more days during the study because they were trying to quit and not for some other reason), quitting during the study (stopped smoking for seven or more days in a row during the study because they were trying to quit and not for some other reason), and prevalent abstinence (had not smoked a cigarette for seven or more days in a row at the eight-month follow-up interview). A second outcome was the total cost of coverage of tobacco dependence treatments under the three different benefit designs and the standardized cost per quitting outcome. Additional outcomes of interest included utilization of the pharmacotherapy benefits and participation in the proactive telephone counseling program.

Data on quitting behaviors were collected by self-report in the follow-up telephone survey. Data on filled prescriptions were provided by the pharmacy manager of the participating PPO to confirm self-reported use of pharmacotherapy benefits for each participant and for estimating the cost of pharmacotherapy coverage for each group. Data confirming participant enrollment in the covered proactive telephone counseling program were provided by a contact at that program and used for estimating the cost of telephone counseling coverage for each group.

Statistical Analysis

For all demographic and control variables, proportions were estimated for the full sample and for each study group. The full sample included those respondents who were lost to follow-up between the baseline and follow-up surveys. Using an intent-to-treat model, these respondents were assumed not to have made a quit attempt, not to have quit during the study period, and not to have prevalent abstinence at eight months. Chi-square tests were performed to estimate whether there were any statistically significant differences in the characteristics of the three study groups at baseline. Bivariate analysis using the chi-square test also was conducted to analyze the associations between treatment group and each outcome measure.

Logistic regression models were estimated for each of the major outcomes of interest to assess the independent association of the two treatment groups covering counseling with each outcome using the "drugs only" group as the referent group. The models were run controlling for: 1) smoking characteristics at baseline (made a quit attempt in lifetime, number of cigarettes smoked per day, age started smoking regularly, stage of readiness to quit, used drugs in a prior quit attempt, prior use of Wellbutrin for non-smoking related diagnosis), 2) demographic characteristics (age, gender, income, race), and 3) doctor visit during the study period. These variables were selected based on previous research on the determinants of quitting smoking (Kabat and Wynder 1987; DHHS 1990). The doctor visit variable measured any doctor visit. While indi-

vidual doctors were not informed regarding which of their patients were participating in the study, prior research finds that more than half of all doctors in California advise their patients to quit smoking during an office visit. Thus it was important to control for physician contact over the study period.

Adjusted odds ratios and 95% confidence intervals were estimated from the coefficients in the logistic models. Costs of treatment for each group were estimated based on utilization of the treatments and the costs of each covered drug (for a 12-week course of treatment) to the PPO, the cost of enrollment in the proactive telephone counseling program, and the cost of the self-help kit sent to all study participants.

Results

Randomization and Demographics

For all demographic, smoking, and control variables, there were no statistically significant differences across the three groups with the exception of income level (Table 1). The drugs and counseling group reported lower incomes compared to the other two study groups, although the participants as a whole had relatively high incomes, reflecting their ability to purchase health insurance in the private individual market. Upon further examination, it appears that this observed difference is a purely random result. The study participants were predominantly white (90%), female (66%), age 40 or older (67%), and smoked less than one pack of cigarettes per day (84%). They were also a highly motivated group with good access to the health care system, with 94% reporting that they would like to stop smoking, 86% having made at least one quit attempt in their lifetime, and 19% reporting using medication in their most recent quit attempt.

Outcomes

A simple bivariate analysis of quitting outcomes by treatment group found no statistically significant differences across the groups in quit attempts, quit rates during the study, or prevalent abstinence rates at eight months (Table 2). The average rate of making a quit attempt across all groups was 48%, ranging from 43% to 55%. Quit rates during the study averaged 31% across all groups, ranging from 26% to 37%. Prevalent abstinence rates at eight months averaged 16% across all groups, ranging from 13% to 19%.

In addition, utilization of the pharmacotherapy benefit did not vary across treatment groups. On average, 20% of subjects filled a prescription for one of the covered medications, with essentially no variation observed across the three study groups. This pattern held true for Zyban (11%), the NRT patch (8%), and NRT nasal spray or inhaler (4%). However, for the two treatment groups for which proactive telephone counseling was covered, statistically significant differences were observed in enrollment in the proactive telephone counseling program. While 8% of the subjects in the drugs and counseling group enrolled in telephone counseling, approximately three times as many subjects in the drugs if counseling group (24%) enrolled in the telephone counseling.

When we examined multiple treatment use among participants in the two study groups who had coverage for counseling in addition to drugs, we found that few chose only counseling. In the drugs and counseling group, of the 34 subjects who used any treatment, 30 chose to use drugs; four chose only counseling. This pattern is similar in the drugs if counseling group; of the 29 subjects who signed up for counseling, just seven used only counseling. In effect, fewer than 3% of the sample across all three study groups used counseling only.

Differences in the characteristics of smokers who did and did not use the covered treatments over the course of the trial suggest that smokers who used covered treatments were more likely: to have been at a higher stage of readiness to quit (planning to quit), to have visited a physician in the past year, and to have reported using drugs in a previous quit attempt (Table 3). In contrast, those who did not use any covered treatments were more likely to report that they did not want to quit and that they were in the pre-contemplation stage of readiness. No differences were observed in the groups who did and did not use covered treatments as measured by age, gender, income and race, or by number of cigarettes smoked per day, age started smoking regularly, if they had ever made a quit attempt in their lifetime, and their use of Wellbutrin prior to the study period.

We also were interested in knowing whether certain smokers preferred one type of treatment over the other and what characteristics were

Table 1. Baseline characteristics by treatment group

	Total ($n = 388$)		Drugs only ($n = 126$)		Drugs and counseling ($n = 140$)		Drugs if counseling ($n = 122$)		
	Number	%	Number	%	Number	%	Number	%	**Chi-square**
Demographic characteristics									
Age									3.9 (.7)
18 to 39	127	33	38	30	51	36	38	31	
40 to 49	113	29	41	33	35	25	37	30	
50+	148	38	47	37	54	39	47	39	
Gender (female)	256	66	81	64	90	64	85	70	1.1 (.6)
Income[a]									10.7 (.03)
<$50,000	174	46	51	41	74	54	49	42	
$50,000–$75,000	89	24	26	21	35	26	28	24	
>$75,000	115	30	46	37	28	20	41	35	
Race (white)	351	90	111	88	130	93	110	90	1.8 (.4)
Smoking characteristics									
Number of cigarettes smoked per day									2.9 (.6)
1 to 10	143	37	47	37	53	38	43	35	
11 to 20	183	47	64	51	61	44	58	48	
20+	62	16	15	12	26	19	21	17	
Age started smoking regularly[a]									1.5 (.8)
<16 years old	77	20	21	17	28	20	28	23	
16 to 20 years	217	57	73	58	78	57	66	54	
>20 years	90	23	31	25	31	23	28	23	
Made quit attempt in lifetime	334	86	112	89	116	83	106	87	2.1 (.3)
Tried to quit last year	145	37	48	38	52	37	45	37	.04 (1.0)
Number quit attempts in past year (of those who tried to quit)[a]									2.7 (.8)
1 time	64	44	20	43	27	52	17	38	
2 times	36	25	12	26	10	19	14	31	
3+ times	44	31	15	32	15	29	14	31	
Used medication in most recent quit attempt	75	19	22	17	30	21	23	19	.7 (.7)
Use of Wellbutrin prior to study period	62	16	18	14	27	19	17	14	1.8 (.4)
Visit to doctor within last year[a]	324	84	106	86	113	81	105	86	2.0 (.4)
Stage of readiness									6.7 (.3)
Don't want to quit	22	6	8	6	8	6	6	5	
Pre-contemplation	34	9	14	11	13	9	7	6	
Contemplation	182	50	53	42	74	53	55	45	
Planning	150	39	51	40	45	32	54	44	

Note: The stages of readiness are defined as follows: Planning (planning on quitting in the next 30 days); contemplation (contemplating quitting in the next six months, but not planning on quitting in the next 30 days); pre-contemplation (not contemplating quitting smoking in the next six months, but would like to quit smoking); don't want to quit (does not want to quit smoking). *P* values are in parentheses.

[a] A few variables have some missing responses and therefore have *n*'s that vary from those indicated at the top of the table: Income: total $n = 378$, drugs $n = 123$, drugs and counsel $n = 137$, drugs if counsel $n = 118$. Age started smoking: total $n = 384$, drugs $n = 125$, drugs and counsel $n = 137$, drugs if counsel $n = 122$. Number quit attempts: total $n = 144$, drugs $n = 47$, drugs and counsel $n = 52$, drugs if counsel $n = 45$. Doctor visit: total $n = 385$, drugs $n = 123$, drugs and counsel $n = 140$, drugs if counsel $n = 122$.

associated with different treatment choices. We found that smokers who were taking Wellbutrin prior to the start of the study were more likely to use NRT as a covered benefit, and those who had used drugs in a previous quit attempt were less likely to use bupropion (Zyban) as a covered benefit.

The results of the logistic regressions using

Table 2. Quitting behaviors by treatment group ($n = 388$)

	Total ($n = 388$)		Drugs only ($n = 126$)		Drugs and counseling ($n = 140$)		Drugs if counseling ($n = 122$)		
	Number	%	Number	%	Number	%	Number	%	**Chi-square**
Intermediate outcomes									
Did at least 1 covered treatment (pharmacotherapy or counseling)	89	23	26	21	34	25	29	24	.6 (.8)
Filled Rx for pharmacotherapy	78	20	26	21	30	21	22	18	.5 (.8)
Filled Rx for bupropion (Zyban)	43	11	14	11	15	11	14	12	.04 (1.0)
Filled Rx for NRT patch	30	8	8	6	14	10	8	7	1.6 (.5)
Filled Rx for NRT spray/inhaler	14	4	5	4	5	4	4	3	1.1 (.6)
Enrolled telephone counseling[a]	40	15	NA	NA	11	8	29	24	12.8 (.001)
Final outcomes									
Quit attempt during study	186	48	69	55	60	43	57	47	3.9 (.1)
Quit during study	121	31	46	37	37	26	38	31	3.1 (.2)
Prevalent abstinence	64	16	24	19	18	13	22	18	2.2 (.3)

Note: It was possible for study participants to fill a prescription for more than one type of pharmacotherapy. *P* values are in parentheses. NA = not applicable.
[a] $n = 262$ (excludes drugs only group).

an intent-to-treat model, which included all 393 study subjects originally enrolled in the trial, confirm the findings observed in the bivariate analysis: that neither of the treatment groups with coverage for proactive telephone counseling reported higher quit-attempt rates, higher quit rates during the study or higher prevalent abstinence rates at eight months compared to the drugs only group, regardless of benefit design (Table 4). Using the drugs only group as the referent group, only one of the adjusted odds ratios for the three quitting outcomes was statistically significant for one of the treatment groups with covered counseling. This exception was the drugs and counseling group, which had lower odds of making a quit attempt compared to the drugs only group.

The costs of treating tobacco dependence under each of the benefit designs varied approximately twofold due to the added costs associated with proactive telephone counseling (Table 5). The group with drug coverage only consistently had the lowest standardized costs per study participant ($85) and the lowest costs for achieving each of the major study outcomes.

Discussion

Previous studies have examined the effects of telephone counseling as an adjunct to pharmacotherapy on cessation rates. This case study, however, represents the first randomized trial to assess the effects of different benefit designs that add health insurance coverage of proactive telephone counseling services to pharmacotherapy coverage for treating tobacco dependence on the use of covered services, quitting outcomes, and benefit costs. The findings presented here in the context of a health insurance benefit design are consistent with the previously published studies, which find that the addition of proactive telephone counseling to pharmacotherapy does not positively impact smoking cessation practices and quit rates compared to pharmacotherapy alone (Stead, Lancaster, and Perera 2003; Ockene et al. 1991; Lando et al. 1997; Reid, Pipe, and Dafoe 1999; Solomon et al. 2000). In addition, this is the first study to examine two different benefit designs for covering both pharmacotherapy and counseling to treat tobacco dependence. The results from this study show that although there was an increase in use of proactive telephone counseling among those in the drugs if counseling group, this group did not have any higher quit rates compared to the group with unlinked counseling and pharmacotherapy benefits.

There are three major findings from this case study that are particularly noteworthy. The first is that adding coverage for proactive telephone counseling to coverage for pharmacotherapy for treating tobacco dependence did not increase quit attempts or quit rates among adult smokers. The second is that linking access to drugs to counsel-

ing by restricting drug coverage to those enrolled in proactive telephone counseling did not act as a barrier to use of these medications or as a complement that enhanced the effect of the drugs. Regardless of benefit design, the rates of use of Zyban, the nicotine patch, and nicotine nasal spray did not vary across the three treatment groups. The third finding is that the cost of adding coverage for telephone counseling to a pharmacotherapy benefit was substantial, increasing the costs approximately twofold to achieve each major quitting outcome. Coverage for pharmacotherapy only was clearly the most efficient benefit design for treating tobacco dependence, achieving similar outcomes at a lower cost.

The first major finding raises serious questions about the policies adopted by employers or health plans to add coverage for proactive telephone counseling services to treat tobacco dependence if pharmacotherapy (Zyban and NRT) is covered. In fact, our trial found that quit attempts were lower in the group that received unlinked drug and telephone counseling benefits and no different in the group that received linked telephone counseling benefits compared to those who received coverage for drugs only. In addition, even though the smokers in the treatment group with linked drug and counseling benefits enrolled in the proactive telephone counseling at nearly three times the rate compared to the treatment group with unlinked drug and counseling benefits, there were still no differences observed for these two groups in quit attempts or quit rates compared to the drugs only group after eight months.

The second finding is that, at least for proactive telephone counseling, requiring enrollment in counseling in order to obtain drug coverage does not deter smokers from getting prescriptions for covered tobacco dependence medications. The rates at which smokers filled prescriptions for Zyban and the nicotine patch or nasal spray were no different for those smokers who had to first sign up for telephone counseling compared to those who did not. Many employers and health plans currently structure their smoking cessation benefits such that access to covered pharmacotherapy is linked to enrollment in counseling (Schauffler, Mordavsky, and McMenamin 2001b). There are at least two possible objectives for such policies. The first is the belief that quit rates will be higher if smokers receive both counseling and pharmacotherapy rather than just drugs alone. The second is to establish a barrier to control costs and utilization by limiting access to drugs to only those who demonstrate their willingness and interest in quitting by committing to participate in a proactive telephone counseling program. Our results suggest that there is little reason to believe that linked policies will accomplish either of these objectives.

The third finding that adding coverage for telephone counseling to a pharmacotherapy benefit nearly doubles the cost with no added value in terms of outcomes suggests that the most efficient benefit design is to limit coverage to pharmaco-

Table 3. Comparison of smoking and demographic characteristics of study participants who used treatments and those who did not use treatments

	Used no treatments	Used treatments
Sample size (*n*)	299	89
Smoking characteristics at baseline		
Number of cigarettes smoked per day (mean)	15	20
Age started smoking regularly	19	18
Made a quit attempt in lifetime (%)	84	92
Stage of readiness to quit*		
Don't want to quit (%)	7	1
Pre-contemplation (%)	10	4
Contemplation (%)	47	47
Planning (%)	36	47
Used drugs to quit in previous quit (self-report)* (%)	16	31
Use of Wellbutrin prior to study period (pharm. records) (%)	16	17
Visit to doctor during study period* (%)	65	81
Demographic characteristics		
Age	44	48
Female	65	70
Income		
<$50,000 (%)	47	42
$50,000–$75,000 (%)	23	24
>$75,000 (%)	29	34
Race		
White, non-Hispanic (%)	91	90
Hispanic (%)	4	1
Other (%)	5	9

* There is a difference at the $p < .05$ level.

Table 4. Adjusted odds ratios (ORs) of quitting behaviors by treatment group

	Quit attempt		Quit during study		Prevalent abstinence	
	OR	*P*-value	OR	*P*-value	OR	*P*-value
Group: Drugs only (referent)	1.0		1.0		1.0	
Group: Drugs and counseling	.5 (.3–.9)	.02	.6 (.3–1.0)	.06	.7 (.3–1.4)	.3
Group: Drugs if counseling	.7 (.4–1.1)	.1	.7 (.4–1.2)	.2	1.0 (.5–1.9)	1.0

Note: Analysis controls for smoking characteristics at baseline (number of cigarettes smoked per day, age started smoking regularly, made a quit attempt in lifetime, stage of readiness, used drugs in prior quit attempt, used Wellbutrin prior to study period), demographic characteristics (age, gender, income, race), and doctor visit during the study period. In parentheses are 95% confidence intervals.

therapy, including Zyban and nicotine replacement therapy, except for those smokers for whom pharmacotherapy is not indicated or desired. The cost of enrollment in the proactive telephone counseling program was $185 per smoker, which added more than $2,000 to the total costs of coverage for the drugs and counseling group, and more than $5,000 to the total costs of coverage for the drugs if counseling group; there were no added benefits observed for either group in terms of increased quit attempts or quit rates compared to the drugs only group.

These findings indicate that employers and health plans may achieve a significant impact on quitting behaviors and smoking rates at a relatively low cost by covering pharmacotherapy only. Our results suggest that rather than adding coverage for proactive telephone counseling to a pharmacotherapy benefit, health care dollars may be more efficiently used if only pharmacotherapy is covered. In addition, employers and health plans may want to cover proactive telephone counseling, but only for those smokers for whom pharmacotherapy is not medically indicated or desired; research studies and meta-analyses have found that proactive telephone counseling interventions alone statistically significantly increase the odds of quitting smoking over less intensive treatments or no treatment (Fiore et al. 2000; Stead, Lancaster, and Perera 2003; Borland et al. 2001). However, the literature to date and the results of this study do not inform the question of whether adding coverage for face-to-face counseling by a health care provider to a pharmacotherapy benefit increases quit and abstinence rates. Additional research is needed to address this question.

An alternative to coverage for employers and health plans that want to provide access to counseling services, particularly for those smokers

Table 5. Costs of tobacco dependence treatment coverage by group ($n = 388$)

	Coverage cost ($)		
	Drugs only ($n = 126$)	Drugs and counseling ($n = 140$)	Drugs if counseling ($n = 122$)
Cost per covered treatment[a]			
Self-help kit ($27)	3,402	3,780	3,294
Zyban ($205)	2,870	3,075	2,870
NRT patch ($295)	2,360	4,130	2,360
NRT nasal spray/inhaler ($427)	2,135	2,135	1,708
Proactive telephone counseling ($185)	—	2,035	5,365
Total cost of treatments	10,767	15,155	15,597
Standardized cost/outcome			
Cost/study participant	85	108	128
Cost/quit attempt during study	156	253	274
Cost/quit during study	234	410	410
Cost/prevalent abstinence	449	842	709

[a] Pharmacy costs are based on a 12-week course of treatment. All costs are based on actual utilization of treatments by study participants in each group over the eight months of the study.

who cannot or do not want to use pharmacotherapy, is to refer them to a state telephone quit line to receive counseling services. In 2003, 34 states offered counseling services through a toll-free telephone quit line to assist smokers in their cessation attempts (Center for Tobacco Cessation 2004).

In light of the heterogeneity of tobacco dependence treatment benefit designs that are offered in practice today, it is important that employers and health plans take into account the relative impacts of different benefit designs for smoking cessation to most efficiently and effectively increase quit attempts and quit rates, and ultimately improve the overall health status of their populations. Our findings add to the growing body of literature on tobacco dependence treatment indicating that it is a drug benefit which produces the observed increases in quit attempts and quit rates at the lowest cost to employers and health plans, with no value added by covering proactive telephone counseling (Stead, Lancaster, and Perera 2003), regardless of benefit design, when Zyban and nicotine replacement therapy are covered.

Finally, these findings suggest that national guidelines for tobacco dependence treatments need to be updated and revised to address the effectiveness of combined therapies. The 2000 PHS clinical practice guideline was silent on the effectiveness of treatments combining pharmacotherapy and counseling. At present, more than half of the Medicaid programs and health maintenance organizations in the United States cover treatments for tobacco dependence (McPhillips-Tangum et al. 2004; Halpin, McMenamin, and Keeler 2004). The continued development of both public and private health insurance benefits for smoking cessation would be greatly aided by a comprehensive review of the evidence of the effectiveness of combined pharmacotherapy and counseling services. This is particularly important given pressures to control rising health care costs. It is in the interests of employers, health plans, and state and federal governments to design cost-effective benefits that achieve desired outcomes at the lowest cost.

Notes

The funder of this research, the California Tobacco-Related Disease Research Program (TRDRP), was established after the passage of California's Proposition 99 in November 1988. Proposition 99 instituted a $.25 per pack cigarette tax, of which 5% was earmarked for research on tobacco-related disease. This led the California State Legislature to authorize the creation of TRDRP, which is administered by the University of California.

1 The PHS 2000 Clinical Practice Guideline (Fiore et al. 2000) defines Bupropion SR and NRT as follows: Bupropion SR (bupropion sustained-release) is a non-nicotine aid to smoking cessation originally developed and marketed as an antidepressant. Its mechanism of action is presumed to be mediated through its capacity to block the re-uptake of dopamine and norepinephrine centrally. It is available as Zyban (used for smoking cessation) or Wellbutrin (used for depression). Nicotine replacement therapy refers to a medication containing nicotine that is intended to promote smoking cessation. There are four nicotine replacement therapy delivery systems currently approved for use in the United States. These include nicotine chewing gum, nicotine inhaler, nicotine patch, and nicotine nasal spray. The side effects, dosages, duration, and availability of the pharmaceuticals used in this study are as follows:

A. Bupropion SR—Contraindications: history of seizure or history of eating disorder; Side effects: insomnia, dry mouth; Dosage: 150 mg every morning for three days, then 150 mg twice daily (begin treatment one to two weeks pre-quit); Duration: seven to 12 weeks, maintenance up to six months; Available as: Zyban.
B. Nicotine patch—Side effects: local skin reaction, insomnia; Dosage and duration: 21 mg/24 hours (two weeks), 14 mg/24 hours (two weeks), 7 mg/24 hours (four weeks), or 15 mg/16 hours (eight weeks); Available as: Nicoderm CQ (over the counter [OTC] only), generic patches (prescription and OTC), Nicotrol (OTC only).
C. Nicotine inhaler—Side effects: local irritation of mouth and throat; Dosage: six to 16 cartridges/day; Duration: up to six months; Available as: Nicotrol Inhaler (prescription only).
D. Nicotine nasal spray—Side effects: nasal irritation; Dosage: eight to 40 doses/day; Duration: three to six months; Available as: Nicotrol NS (prescription only).

Taken from the *Suggestions for the Clinical Use of Pharmacotherapies for Smoking Cessation*. U.S. Public Health Service. http://www.surgeongeneral.gov/tobacco/clinicaluse.htm

2 The proactive telephone counseling was conducted by a nationally recognized firm using standard pro-

tocols accepted in the field. Nicotine dependence was assessed using a modified Fagerstrom Tolerance Scale. Readiness to quit was measured using Prochasksa's (Prochaska, DiClemente, and Norcross 1992) five stages of change. Motivation to use behavioral techniques and self–efficacy regarding cessation were assessed using a 1–10 scale.

3 Data from the 2000 California Behavioral Risk Factor Survey were used as a comparison for our sample. This data is available at http://www.surveyresearchgroup.com.

References

Borland, R., C.J. Segan, P.M. Livingston, and N. Owen. 2001. The Effectiveness of Callback Counseling for Smoking Cessation: A Randomized Trial. *Addication* 96(6):881–889.

Center for Tobacco Cessation. 2004. Quitting Isn't Easy, Getting Help Is. Washington, D.C.: Center for Tobacco Cessation. Available at: http://www.ctcinfo.org/five_things/smokers.asp

Curry, S.J., L.C. Grothaus, and T. McAfee. 1998. Use and Cost Effectiveness of Smoking-Cessation Services Under Four Insurance Plans in a Health Maintenance Organization. *New England Journal of Medicine* 339(10):673–679.

Department of Health and Human Services (DHHS). 1990. The Health Benefits of Smoking Cessation: A Report of the Surgeon General. Atlanta, Ga.: Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office of Smoking and Health.

———. 2004. The Health Consequences of Smoking: A Report of the Surgeon General. Atlanta, Ga.: Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health.

Fagerstrom, K.O., and N.G. Schneider. 1989. Measuring Nicotine Dependence: A Review of the Fagerstrom Tolerance Questionnaire. *Journal of Behavioral Medicine* 12(2):159–182.

Fiore, M.C., W.C. Bailey, S.J. Cohen, et al. 1996. Smoking Cessation. Clinical Practice Guideline No. 18. AHCPR Publication No. 96-0692. Rockville, Md.: U.S. Department of Health and Human Services, Public Health Service, Agency for Health Care Policy and Research.

———. 2000. Treating Tobacco Use and Dependence. Clinical Practice Guideline. Rockville, Md.: U.S. Department of Health and Human Services, Public Health Service.

Halpin, H.A., S.B. McMenamin, and C.L. Keeler. 2004. State Medicaid Coverage for Tobacco Dependence Treatments—United States, 1994–2002. *Morbidity and Mortality Weekly Report* 53(3):54–57.

Kabat, G.C., and E.L. Wynder. 1987. Determinants of Quitting Smoking. *American Journal of Public Health* 77(10):1301–1305.

Lando, H.A., S. Rolnick, D. Klevan, et al. 1997. Telephone Support as an Adjunct to Transdermal Nicotine in Smoking Cessation. *American Journal of Public Health* 87(10):1670–1674.

Max, W., D.P. Rice, H-Y Sung, et al. 2004. The Economic Burden of Smoking in California. *Tobacco Control* 13(3):264–267.

McPhillips-Tangum, C., C. Bocchino, R. Carreon, et al. 2004. Addressing Tobacco in Managed Care: Results of the 2002 Survey. *Public Health Research Practice and Policy* 1:1–11.

Ockene, J.K., J. Kristeller, R. Goldberg, et al. 1991. Increasing the Efficacy of Physician-Delivered Smoking Interventions. *Journal of General Internal Medicine* 6(January/February):1–8.

Prochaska, J.O., C.C. DiClemente, and J.C. Norcross. 1992. In Search of How People Change. Applications to Addictive Behaviors. *American Psychologist* 47:1102–1114.

Reid, R.D., A. Pipe, and W.A. Dafoe. 1999. Is Telephone Counseling a Useful Addition to Physician Advice and Nicotine Replacement Therapy in Helping Patients to Stop Smoking? A Randomized Controlled Trial. *Canadian Medical Association Journal* 160(11):1577–1581.

Schauffler, H.H., S.B. McMenamin, K. Olson, et al. 2001a. Variations in Treatment Benefits Influence Smoking Cessation: Results of a Randomised Controlled Trial. *Tobacco Control* 10:175–180.

Schauffler, H.H., J.K. Mordavsky, and S.B. McMenamin. 2001b. Adoption of the AHCPR Clinical Practice Guideline for Smoking Cessation: A Survey of California's HMOs. *American Journal of Preventive Medicine* 21(3):153–161.

Solomon, L.J., G.M. Scharoun, B.S. Flynn, et al. 2000. Free Nicotine Patches Plus Proactive Telephone Peer Support to Help Low-Income Women Stop Smoking. *Preventive Medicine* 31(1):68–74.

Stead, L.F., T. Lancaster, and R. Perera. 2003. Telephone Counseling for Smoking Cessation. *Cochrane Database Systematic Review* (1): CD002850.