

Variations in treatment benefits influence smoking cessation: results of a randomised controlled trial

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Abstract

Objective—To assess the impact and costs of coverage for tobacco dependence treatment benefits with no patient cost sharing for smokers with employer sponsored coverage in two large independent practice association (IPA) model health maintenance organisations (HMOs) in California, USA.

Methods—A randomised experimental design was used. 1204 eligible smokers were randomly assigned either to the control group, which received a self-help kit (video and pamphlet), or to the treatment group, which received the self-help kit and fully covered benefits for over the counter (OTC) nicotine replacement therapy (NRT) gum and patch, and participation in a group behavioural cessation programme with no patient cost sharing.

Results—The quit rates after one year of follow up were 18% in the treatment group and 13% in the control group (adjusted odd ratio (OR) 1.6, 95% confidence interval (CI) 1.1 to 2.4), controlling for health plan, sociodemographics, baseline smoking characteristics, and use of bupropion. Rates of quit attempts (adjusted OR 1.4, 95% CI 1.1 to 1.8) and use of nicotine gum or patch (adjusted OR 2.3, 95% CI 1.6 to 3.2) were also higher in the treatment group. The annual cost of the benefit per user who quit ranged from \$1495 to \$965 or from \$0.73 to \$0.47 per HMO member per month.

Conclusions—Full coverage of a tobacco dependence treatment benefit implemented in two IPA model HMOs in California has been shown to be an effective and relatively low cost strategy for significantly increasing quit rates, quit attempts, and use of nicotine gum and patch in adult smokers.

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Keywords: health insurance; cessation treatments; health maintenance organisations

The objective of our research was to assess the impact of health insurance coverage for tobacco dependence treatments on quit attempts and quit rates in a randomised controlled trial of smokers enrolled in health maintenance organizations (HMOs). HMOs receive a fixed monthly payment per capita to arrange for or provide all covered services for an enrolled population, regardless of actual

utilization of services. HMO members are covered only for services delivered by physicians in the HMO's provider network.

The specific research questions are: do the tobacco dependence treatment benefits increase quit rates, quit attempts, and use of tobacco dependence treatments in the treatment group compared to the control group; and at what cost per benefit user who quits smoking?

In 1996, the Agency for Health Care Policy and Research (AHCPR) published a clinical practice guideline for smoking cessation that identified the most effective, experimentally validated tobacco dependence treatments based on a comprehensive review of the scientific literature.¹ The guideline concludes that effective tobacco dependence treatments are available and should be included as "paid service for all [insured] subscribers."¹⁻³

We conducted our research in independent practice association (IPA) and network model HMOs because they are the fastest growing health plans in the USA. In IPA and network model HMOs, physicians, individually, in groups, and in loosely organised networks, contract with health plans to provide comprehensive primary and preventive care to enrolled members in return for a fixed monthly capitation payment or discounted fee-for-service payments. Physicians practising in IPA and network model HMOs see patients in different health plans, including HMO and non-HMO enrollees. Thus, the ability of any one health plan to influence physician behaviour is limited under this type of managed care. As of July 1998, 62.4% of all HMOs operating in the USA were independent practice association (IPA) or network model HMOs, and 50% of all HMO members nationwide were enrolled in IPA and network model HMOs.⁴

Many health plans in the USA do not routinely cover tobacco dependence treatments, and in many cases access to pharmacological benefits is tied to participation in a behavioural programme. In 1999 in California, only 36% of HMO enrollees with employer sponsored health insurance were covered for any nicotine replacement therapy (NRT), 30% were covered for any behavioural treatment, and 10% were covered for bupropion.⁴ In addition, in nearly all cases, covered nicotine dependence treatments required patient cost sharing.⁴

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Methods

SUBJECTS AND RANDOMISATION

Large employers offering health benefits through CIGNA's HMO or Blue Cross of California's HMO, CaliforniaCare, were contacted by the HMO medical directors about participating in the study. Only those employers who did not cover any NRT or behavioural programmes in their HMO contracts with CIGNA and Blue Cross in 1997, and who agreed not to offer any new tobacco dependence treatment benefits in 1998, other than those defined for the treatment group as part of the study, were eligible for participation. Sixteen large employers agreed to participate.

A survey research firm recruited the study population by telephone using lists of the covered employees and dependents of the participating employers who were enrolled in the two HMOs. Eligibility for study participants was prospectively determined by telephone. Eligibility criteria included at least one family member living in the household 18 years and older who currently smoked cigarettes and who was covered by CIGNA's or Blue Cross of California's HMO in December 1997. Smokers were defined as those who had smoked at least 100 cigarettes in their lifetime and who smoked cigarettes every day or some days at the time of the screening interview. Smokers were ineligible for the study if they were pregnant or their overall health status was poor. The sample also excluded smokers who had ever been told by a physician that they should not use NRT because of health concerns, and/or had ever been told by a physician that they have coronary artery disease, heart disease, arrhythmia, cardiovascular

disease, angina pectoris, congestive heart failure, and/or a heart attack or myocardial infarction (because of concerns over potential adverse effects of nicotine replacement on cardiovascular disease). Only one smoker per household was allowed in the study. If two or more adults in a household smoked, one was randomly selected to be eligible for the study.

The target sample size was based on the ability to detect a difference between the treatment and control groups given a projected quit rate of 5% in the control group and 10% in the treatment group. To ensure an adequate sample to detect such a difference with a two sided α level of 0.05 and power of 80%, anticipating 85% participation in follow up interviews, approximately 600 subjects were initially enrolled in each group. Identification of the sample began on 7 October 1997 and was completed on 17 December 1997 when we reached our target sample. Figure 1 summarises the disposition of the sample.

Qualified smokers were told that they were being asked to participate in a research study on smoking behaviour conducted by the University of California, Berkeley in cooperation with their health plan. They were told that they would be asked to complete a baseline interview and two more 10 minute telephone interviews over the next year. We also informed them that they were under no obligation to try to quit during the study, that all information they provided was confidential, and they were assured that their participation in the research would not in any way affect their health insurance coverage or premium. At the baseline interview, subjects were randomly assigned to the control or treatment group.

STUDY DESIGN AND TIMELINE

The research uses a randomised experimental design in the form of a pretest-post-test control group design.⁵ The control group (n = 603) and experimental group (n = 601) were mailed letters explaining their new benefits. The control group's "benefit" was a free self-help kit (videotape and AHCPR pamphlet). The evidence on the efficacy of self-help treatment alone is that the odds of quitting for smokers who receive self-help videotapes and pamphlets is no different than for smokers who receive no self-help treatments.¹⁻⁶⁻⁹ Thus, provision of two self-help formats effectively served as a placebo for the control group. To control for any influence the video and pamphlet might have on quit attempts or quit rates, the treatment group was sent the same self-help kit.

The difficulty of coordinating a physician component for the intervention within IPA model HMOs was critical to the benefit design. In the two HMOs participating in the study, physicians and patients were spread out over 40 counties in California. To overcome the difficulties of trying to influence individual physician behaviour in IPAs and medical groups, we designed the benefit to activate patients by stimulating smoker demand for NRT and behavioural interventions.¹⁰⁻¹³ The benefit was

Eligible smokers n = 2385	
Not randomised n = 839 Refused to participate n = 762 Call back not completed n = 77	
Randomisation n = 1546 Did not return consent form n = 342	
Treatment group Received notification of benefits and self-help kit n = 601	Control group Received self-help kit n = 603
Follow up 6 months n = 505 Over 12 months n = 484	Follow up 6 months n = 494 Over 12 months n = 503
Lost to follow up n = 92	Lost to follow up n = 87
Other reasons n = 73 Quit before benefit in effect n = 4 No longer covered by plan n = 35 New health problem n = 4 Unavailable due to illness n = 5 Refusal = 25	Other reasons n = 71 Quit before benefit in effect n = 3 No longer covered by plan n = 38 New health problem n = 4 Unavailable due to illness n = 8 Refusal = 18
Completed trial n = 436	Completed trial n = 445

Figure 1 Sampling disposition for the randomised controlled trial of tobacco dependence treatments.

designed to minimise barriers to access, including removing all patient cost sharing.

A letter was mailed to the treatment group explaining how to access their benefits. Orders for the nicotine patch and gum was filled by telephoning a toll free number. The patch or gum was mailed to the participant's home, much the same way that pharmacy benefits are handled by mail order. The treatment for the covered OTC gum and patch was defined based on the AHCPR guideline (table 1). Smokers requesting NRT were asked the number of cigarettes they smoked per day and other information about their smoking behaviour and quitting history to determine the proper dosage.¹ The treatment group was limited to filling two orders of nicotine patch or gum every six months, and was eligible for the benefit for one year beginning 1 January 1998.

After reviewing the content and structure of existing behavioural group programmes, the American Lung Association (ALA) programme was selected for coverage based on its conformance with the AHCPR guideline and its availability across the state. The criteria for programme selection included 4–7 sessions delivered over 2–4 weeks. Arrangements for billing were made by the HMOs with all of the local ALA branches in California.

By calling the toll free number, the treatment group could request a referral to an ALA class, and they were given a contact name and phone number for the programme most convenient to them. The study team contacted local ALA programmes to alert them when a study participant had been referred for a class. Only when a participant registered did the ALA bill the health plan.

A study notification letter and a copy of the physician guide to smoking cessation treatment produced by AHCPR were sent to the 2600 primary care physicians in CIGNA's California HMO network and the 11 700 primary care physicians in Blue Cross of California's HMO network. The letter informed physicians that study participants may be on their panels and that those in the treatment group may be contacting them before using the nicotine gum or patch. Unless patients contacted or visited their physicians, individual physicians had no way of knowing which, if any, of their patients were participating in the study. A similar letter was sent to the medical director of each medical group and IPA contracting with each HMO.

Table 1 Nicotine replacement therapy (NRT) benefit for the treatment group based on AHCPR guideline¹

NRT benefit	Number of cigarettes smoked per day	Duration and dosage
Nicotine patch		
Nicoderm	15 or more/day	4 weeks @ 21 mg 2 weeks @ 14 mg 2 weeks @ 7 mg
Nicoderm	Less than 15/day	6 weeks @ 14 mg 2 weeks @ 7 mg
Nicotine gum		
Nicorette	If answer yes to any of the following: ● smoke more than 20 per day ● smoke within 30 minutes of waking ● tried and failed with 2 mg gum	8 weeks @ 4 mg (864 pieces)
Nicorette	If answer no to all of the above	8 weeks @ 2 mg (864 pieces)

Four of the large employers participating in the study agreed to cover the cost of the tobacco dependence treatment benefit for their employees and dependents who were assigned to the treatment group. Purchaser support was also critical to our effort to simulate the "real world." The only way that tobacco dependence treatments will be covered as standard benefits is if they are paid for by the purchaser as part of the premium. CIGNA and Blue Cross covered the cost of the benefit for the employees in the treatment group for other participating employer groups.

SURVEY DATA COLLECTION

Data were collected by computer assisted telephone interview. Baseline data were collected between October and December 1997, before the introduction of the benefit on 1 January 1998. Two follow up interviews were conducted, one during July 1998 six months following the introduction of the benefit, and the other at 12 months in January 1999 after the benefit ended on 31 December 1998. For both follow up surveys, participants were mailed a postcard approximately one week in advance reminding them of the interview, along with a toll-free number to call for questions or to update their phone contact information if it had changed. Each participant who completed each of the three telephone interviews was mailed a check for \$5.00 thanking them for their continued participation. At least eight attempts were made to reach participants for each follow up interview.

Data collected at baseline included sociodemographic characteristics, smoking behaviours, prior quit history, readiness to quit, and health services use in the last 12 months. Outcome data collected in the follow up interviews included smoking status, quit attempts, and use of tobacco dependence treatments. At the time the study was about to go into the field, the US Federal Food and Drug Administration (FDA) approved bupropion as a prescription drug for quitting smoking. To control for potential confounding associated with the use of bupropion, which was not covered in the defined benefit, we collected data on bupropion use over the study period.

STATISTICAL ANALYSIS

Outcomes included one or more self-reported quit attempts, use of specific tobacco dependence treatments (gum, patch, class, bupropion), and quit rates. Subjects were classified as having made a quit attempt if they had quit smoking for one or more days over the 12 months because they were trying to quit and not for some other reason. Subjects were classified as having quit smoking if they reported no smoking during the previous seven days and indicated that they had quit smoking because they were trying to quit and not for some other reason.

The effects of the benefit were assessed in two ways. Differences in the unadjusted rates for the treatment and control groups over 12 months were estimated using χ^2 . The effects of the benefit on smoking behaviours were also

modelled using logistic regression analysis controlling for covariates including health plan, demographics (age, sex, race, annual household income), baseline smoking characteristics (number cigarettes smoke per day, ever tried to quit in life, number of years as a smoker, if started smoking before age 17), and use of bupropion over the study period. We calculated adjusted odds ratios (ORs) and 95% confidence intervals (CIs) for outcomes in the treatment group compared to the control group based on the results of the logistic models. All analyses were performed using Logistic procedures in PC SAS Version 6.12 (SAS Inc, Cary, North Carolina, USA).

Results

STUDY POPULATION

At baseline there were no significant differences ($p < 0.05$) among the treatment and control groups in demographics, smoking behaviours, quit history, readiness to quit, service utilization, or physician advice to quit rates.

USE OF THE BENEFIT

Over the course of the 1998 benefit year (table 2), a total of 148 orders for the NRT benefit were filled for 106 subjects in the treatment group. In addition, 18 subjects reported using the gum or patch over the study period, which they purchased OTC. In all, 113 subjects used the patch and 35 used the gum in the treatment group (25%), compared to 14% of the control group who reported using the nicotine gum or patch over the study period ($p = 0.001$). In both the experimental ($p = 0.001$) and control ($p = 0.02$) groups, those who reported a higher level of readiness to quit (planning to quit in the next 30 days, contemplating quitting in the next six months) were more likely to have used NRT compared to those who reported a low level of readiness (do not want to stop) (data not shown).

Only 21 subjects in the treatment group requested a referral to a behavioural programme over the benefit year, and claims were processed for only four subjects, with two subjects in the treatment group reporting they had participated in programmes not covered by the benefit. Thus, only 1.2% of the smokers in the treatment group participated in a behavioural programme compared to five smokers (1.1%) in the control group ($p = 0.8$).

The treatment group was more likely to have watched the video or read the pamphlet over the first six months of the benefit period ($p = 0.001$, data not shown). However, by the

Table 3 Adjusted odds ratios (OR) of smoking outcomes and behaviours for smokers in the treatment group (compared to the control group) over 12 months*

Smoking outcomes and behaviours	OR (95% CI) *
Quit smoking	1.6 (1.1 to 2.4)
Attempt to quit $\geq 1\times$	1.4 (1.1 to 1.8)
Attempt to quit $\geq 2\times$	1.3 (1.0 to 1.8)
Watched video/read pamphlet	1.4 (1.0 to 1.8)
Used nicotine gum and/or patch	2.3 (1.6 to 3.2)
Used nicotine gum	1.8 (1.1 to 2.9)
Used nicotine patch	1.7 (1.2 to 2.5)

*Controlling for health plan, number of cigarettes smoked per day at baseline, race, sex, income, ever made a serious attempt to quit in lifetime, started smoking at age 17 or younger, total number of years as a smoker, doctor recommended quitting smoking in 12 months before baseline, and used bupropion over study period.

end of 12 months, the rates at which smokers in each group had watched the video or read the pamphlet were not different ($p = 0.09$).

Use of bupropion over the 12 month study period, which was not covered in the benefit, was higher in the control group (7%) than in the treatment group (4.4%), but the difference was not significant ($p = 0.07$).

SMOKING BEHAVIOUR OUTCOMES

The unadjusted rates of quitting smoking (18% v 13%, $p = 0.04$), quit attempts (55% v 48%, $p = 0.03$), using any nicotine gum or patch (25% v 14%, $p = 0.001$), nicotine gum (8.6% v 5.2%, $p = 0.04$), and the nicotine patch (18% v 11%, $p = 0.005$) were higher in the treatment group compared to the control group over 12 months. In addition, those in both the experimental ($p = 0.001$) and control ($p = 0.06$) groups who reported a higher level of readiness to quit were more likely to have quit over 12 months compared to those with a low level of readiness (data not shown).

The adjusted OR that subjects in the treatment compared to the control group quit smoking over 12 months was 1.6 (95% CI 1.1 to 2.4) (table 3). The OR that the treatment compared to the control group attempted to quit smoking one or more times over the benefit year was 1.4 (95% CI 1.1 to 1.8), and used NRT (gum and/or patch) was 2.3 (95% CI 1.6 to 3.2).

We observed no change in the rates of physician counselling for smoking cessation in the last year for either the experimental or control group from baseline to the 12 month follow up (data not shown).

BENEFIT COSTS

The total cost of the NRT and behavioural programmes for the treatment group was \$32 487. The additional cost of the self-help kit was \$17 225 for the treatment group. Based on a smoking prevalence rate of 11% in the study population (estimated from the sampling screening interviews), the total annual cost per HMO member associated with covering the nicotine gum and patch, the behavioural programme benefit, and the self-help video and pamphlet is estimated to be \$8.76 or \$0.73 per member per month (pmpm). The cost of the nicotine gum and patch and the behavioural programme (not including the self-help kit) for the treatment group is

Table 2 Unadjusted rates of smoking outcomes and behaviours over 12 months by group

Smoking outcomes and behaviours	Control group (n = 484)	Treatment group (n = 503)	p Value
Quit smoking	65 (13%)	91 (18%)	0.04
Attempt to quit $\geq 1\times$	232 (48%)	275 (55%)	0.03
Attempt to quit $\geq 2\times$	130 (27%)	162 (32%)	0.07
Watched video/read pamphlet	131 (27%)	161 (32%)	0.09
Used nicotine gum and/or patch	70 (14%)	124 (25%)	0.001
Used nicotine gum	25 (5.2%)	43 (8.6%)	0.04
Used nicotine patch	55 (11%)	89 (18%)	0.005
Used bupropion	34 (7%)	22 (4.4%)	0.07
Participated in behavioural programme	5 (1.1%)	6 (1.2%)	0.8

estimated to be \$5.60 per HMO member per year or \$0.47 pmpm. The average cost per benefit user who quit smoking ranged from \$1495 (self-help kit and other benefits) to \$965.34 (benefits only). The costs of bupropion are not included in these estimates, as they were not covered benefits in the study.

LIMITATIONS

The most important limitation to this study was our inability (because of budget constraints) to follow our cohort of smokers for a year following the termination of the benefit to assess long term quit rates and recidivism.

Another limitation was the selection of the ALA programme for the behavioural component of the benefit. We know that participation in behavioural health education classes is low, even when they are free. While linking access to the NRT benefit to participation in a behavioural programme may have increased programme participation rates, we feared that linking the benefits would have an even greater impact on reducing access to the NRT benefit. Not surprisingly, less than 2% of the treatment group took advantage of the behavioural benefit. This finding is consistent with other surveys that have found very low rates of participation in health promotion programmes offered by HMOs.^{14 15} Additional research is needed to determine what type of behavioural counselling benefit is most effective in reaching the highest proportion of smokers and is most cost-effective in increasing quit rates.

The third limitation is that the participants in the study were all volunteers, and use of the NRT or participation in the ALA programme for study members in the treatment group was also voluntary. Thus, the impact of the benefit is only generalisable to those who volunteer to use it. Interest in trying to quit smoking may have been higher among study participants than among those smokers who chose not to participate. However, the entire process of using health insurance benefits is a voluntary one. Health plans cover specific treatments and enrollees use those they need or want. For example, a health plan may cover annual mammograms, yet 20–30% of women covered for this service may not choose to get one, even if their physician has given them a referral.

In addition, the results may not be generalisable to all smokers in California or to smokers outside of California. Of the eligible smokers identified in California, 32% refused to participate in the baseline interview, and of those who completed the baseline survey, 18% did not return a signed informed consent form. Among those who returned their consent forms, 26% of the control group and 27% of the experimental group were lost to follow up over 12 months. While we found no differences between our experimental and control groups at baseline, we do not know if those who refused to participate were different in some important way, such as being more addicted to nicotine or less ready to quit. In addition, California has implemented a strong anti-tobacco media campaign, as well as community based

anti-tobacco activities, increasing cigarette excise taxes, and a social climate that is not welcoming to smokers. Thus, California's smokers may be more receptive to using tobacco treatment benefits when offered by their health plan compared to smokers in other states. Additional research, to demonstrate the validity and reliability of our findings in other states, will be important.

Discussion

This study suggests that coverage of a tobacco dependence treatment benefit with no patient cost sharing implemented in IPA model HMOs is an effective strategy for increasing quit rates and quit attempts in an adult population of smokers with employer based health insurance. The results suggest that coverage of OTC NRT and elimination of all cost barriers to NRT treatment not only increase the proportion of the smokers that will try to quit, but enables them to use the most effective means, and increases the proportion that will quit successfully.

The study is also important because it suggests that health insurance plans, through a change in their benefit designs, can increase quit rates without requiring that providers make referrals to or write prescriptions for tobacco dependence treatments. However, both HMOs participating in our experiment recognise the added value of physician counselling in smoking cessation and have offered the physicians in their networks opportunities for smoking cessation training, and encouraged them to advise and assist their patients to quit smoking. However, adding the benefit for 600 smokers had no measurable effect on physician smoking counselling rates.

There are several advantages to the design of this research over previous studies. First, this is the first study conducted on the impact of coverage for tobacco dependence treatments on quit rates in the fastest growing segment of the health insurance market in the USA, IPA and network model HMOs. Most research on coverage of tobacco dependence treatments in managed care has been conducted in staff or group model HMOs, the results of which are generalisable to only about 10% of the US population in managed care.⁶ Our study is also the first to use a randomised controlled trial to assess the impact of coverage for tobacco dependence treatments in HMOs. Finally, our study uncouples coverage of pharmacotherapy from participation in a behavioural programme and removes all patient cost sharing.

Prior research on smoking cessation benefits in a staff model HMO reported average costs to the health plan per benefit user who quit smoking ranging from \$928 to \$1192 (in 1993/1994 dollars).¹⁶ Our average cost estimates of \$965 to \$1495 per benefit user who quit smoking (in 1998 dollars) are quite similar to the prior estimate. The estimated additional cost of the tobacco dependence treatment benefit to the HMO monthly premium is between \$0.47 and \$0.73.

The AHCPR guideline recommends that health insurance carriers and HMOs cover the

What this paper adds

While one observational study in a health maintenance organisation (HMO) suggested that covering treatments for tobacco use and dependence are effective in helping smokers to quit, until now evidence from randomised controlled trials on the effect of insurance coverage on quit attempts and quit rates in HMOs has been lacking.

This randomised study suggests that full health insurance coverage, with no patient cost sharing, for nicotine patch and gum and group smoking cessation classes increases quit attempts, use of nicotine replacement therapy, and quit rates among smokers in HMOs. The findings suggest insurance coverage for tobacco use and dependence treatments is relatively low cost and can significantly reduce smoking rates among populations covered by HMOs.

nicotine gum and patch.¹ Our results suggest that such coverage is not only feasible, but that it is effective in helping patients to quit smoking at a relatively low cost per member per month in IPA model HMOs, through which the majority of Americans in HMOs receive their medical care.

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