# Effect of Cost on the Self-Administration and Efficacy of Nicotine Gum: A Preliminary Study<sup>1</sup>

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Methods. One hundred six smokers seen in a family practice received brief physician advice and a prescription for nicotine gum. Smokers were randomly assigned to pay \$20, \$6, or \$0/box of nicotine gum and followed for 6 months.

Results. Decreased cost increased the incidence of obtaining gum, the amount of gum used, and the incidence of long-term use (P < 0.05). Decreased cost also increased cessation attempts and 1-week cessation (P < 0.05) and appeared to increase abstinence at 6-month follow-up (19% vs 6% vs 8%, P < 0.10). Cost-benefit estimates suggest that an insurance plan, HMO, etc., would recoup any costs in subsidizing nicotine gum and perhaps incur a net financial gain. © 1991 Academic Press, Inc.

#### INTRODUCTION

When used with a structured behavioral therapy, nicotine gum is an effective aid to smoking cessation (1, 2). At present, reimbursement for nicotine gum varies widely across health plans, HMOs, etc. For example, some health plans reimburse patients for almost all medications except nicotine gum (e.g., the British system). Some health plans reimburse patients only if they successfully stop smoking. Other plans reimburse patients fully for nicotine gum as with any medication (K. Douse, personal communication, 1990).

The present study had four purposes. The first was to experimentally quantify the effect of decreased cost on the use of nicotine gum. Several nonrandom trials indicate that having to pay for prescriptions is associated with decreased use (3); however, the Rand Health Insurance Experiment is the only study that has experimentally manipulated cost (4). In that study, greater decrements in cost to the consumer increased prescription use.

The effects of decreased cost might be especially important for drugs that patients often do not take. Nicotine gum is one such drug. Less than a third of smokers use more than two boxes of nicotine gum (5). The effect of cost on

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nicotine gum use has not been studied in a controlled experiment; however, a comparison across studies in similar settings (5) and a recent retrospective comparison of smokers who received free nicotine gum and smokers who had to pay for gum (6) found that more smokers obtain nicotine gum when the gum is free (5,6).

A second purpose of the study was to determine whether decreased cost increases the incidence of behavioral dependence on nicotine gum. Among smokers who quit with free nicotine gum, 35–50% become behaviorally dependent on the gum, i.e., use the gum beyond the recommended 3–4 months (5). A recent review concluded that cessation of gum use after the 3 to 4 month period was not associated with an increased rate of relapse to smoking (5); thus, procedures to eliminate use of the gum beyond the recommended period would appear to be indicated. Simply charging for the gum may be enough to prevent or treat such long-term use.

A third purpose was to determine whether decreased cost would increase smoking cessation rates. This could occur through two mechanisms: either increasing quit attempts among smokers ambivalent about cessation or increasing the success rate of the quit attempts made. The first mechanism is plausible because a prescription for nicotine gum prompts cessation attempts (7). The second mechanism is plausible because most smokers use too little gum and increased gum use is associated with increased cessation (5). On the other hand, one could hypothesize that decreased cost for the gum would not increase quit rates. Charging for the gum may be beneficial in that it eliminates the less motivated smokers who might not benefit from the gum. In addition, having to pay for a treatment may increase its efficacy (8). The only test of the effect of the price of nicotine gum on outcome was the recent retrospective study cited earlier. This study found that smokers who received free gum had higher quit rates than those who had to pay for the gum (38% vs 27%) (6).

A fourth purpose of the study was to determine whether decreased cost would be cost-beneficial; i.e., what is the relative cost-benefit to an HMO, insurance plan, etc., of full reimbursement vs partial reimbursement vs no reimbursement for nicotine gum? For example, suppose free nicotine gum increases quit rates. Would an HMO recoup the expenditure for nicotine gum in health-care savings?

#### **METHODS**

Subjects

Smokers were recruited from two rural family practices run by the Department of Family Practice, University of Vermont College of Medicine. As patients were registered they were asked to be in a study of "physician advice about smoking cessation." Patients were told they did not have to be interested in quitting to be in the study. Upon entry, subjects were not told that they might receive free gum. This was done to avoid recruiting smokers who would enter the study specifically to have a chance to get free gum. Only after patients consented to be in the study were they told they would be randomly assigned to price groups. If patients were still interested, they read and signed an informed consent document and at that

point were considered enrolled. Subject recruitment and completion of forms occurred prior to seeing the physician for the purposes of the visit.

Inclusion criteria were (a) smoke daily, (b) at least 18 years old, (c) not have used nicotine gum before, (d) no contraindication to nicotine gum, (e) pay for all prescriptions, (f) not an emergency, and (g) no family member already enrolled. This last criterion was to prevent smokers assigned to pay for the gum from borrowing free or less expensive gum from a family member who might be assigned to the free or reduced cost groups.

Over a 6-month period 368 smokers were screened and 106 entered. The major reasons for exclusion were (a) not interested (54%) and (b) insurance covered prescription (26%). Medical contraindications excluded 5%. This sample size was thought to be adequate to detect changes in gum use. The sample size was small to detect our secondary aim of examining changes in smoking cessation rates.

The sample was similar to the national average in demographics and smoking history except for a higher incidence of subjects who completed high school and a higher rate of smoking (Table 1). Subject characteristics did not differ across the cost groups.

### **Procedures**

Physicians (6 faculty and 12 residents) were trained in the brief advice, gum instructions, and data collection procedures in two 1-hr sessions.

After the physician had seen the patient for the purpose of the visit, he/she spent 10 min giving brief advice on smoking cessation according to a protocol outlined elsewhere (9), instructing subjects in the use of nicotine gum as outlined

| SUBJECT CHARACTERISTICS |                 |                  |                     |                                  |
|-------------------------|-----------------|------------------|---------------------|----------------------------------|
|                         | Free $(n = 32)$ | 6/box $(n = 36)$ | \$20/box $(n = 38)$ | Average U.S. smoker <sup>b</sup> |
| Demographics            |                 |                  |                     |                                  |
| Age                     | 37.2            | 36.6             | 39.2                | 35-44                            |
|                         | (12.1)          | (9.8)            | (12.2)              |                                  |
| % Men                   | 55              | 64               | 55                  | 54                               |
| % Completed high school | 87              | 89               | 71                  | 69                               |
| % Unemployed            | 16              | 20               | 16                  | _                                |
| % White collar          | 26              | 17               | 24                  | _                                |
| % Earning <\$15,000     | 26              | 29               | 21                  | _                                |
| Smoking habits          |                 |                  |                     |                                  |
| Cigarettes/day          | 24.8            | 27.9             | 25.8                | 20                               |
| ,                       | (10.6)          | (10.4)           | (10.0)              |                                  |
| Nicotine yield          | 0.75            | 0.76             | 0.80                |                                  |
| •                       | (0.32)          | (0.36)           | (0.31)              |                                  |
| Years smoking           | 17.4            | 20.3             | 20.8                | 21                               |
| Č                       | (11.2)          | (4.8)            | (10.5)              |                                  |

TABLE 1
Subject Characteristics<sup>a</sup>

<sup>&</sup>lt;sup>a</sup> Mean (SD) unless otherwise stated.

<sup>&</sup>lt;sup>b</sup> From the Office on Smoking and Health (J. Pierce, Ph.D., October 1989, written communication). Data on income, occupation, and nicotine yield not presented, as these data are 4 years old.

in the package insert, and handing out a stop-smoking booklet. Subjects were told that if they were using gum 3 months after the quit date, to gradually stop use of the gum over the following month. If patients made a commitment to quit on a certain date, they were given a follow-up appointment 1–2 weeks after their quit date.

After the advice had been given, the physician opened a sealed envelope and signed a prescription that indicated the price group to which the smoker had been assigned. The prescription was valid for 6 months and was valid only at the four local pharmacies. At the time of the study, nicotine gum cost an average of \$24/box in our locale. Patients were randomly assigned to three cost groups: free gum, \$6/box, or \$20/box. Patients were not charged for the extra time for smoking cessation advice nor for the follow-up visit.

At the 1- to 2-week follow-up for those who set a quit date, patients were seen for 5-10 min by the physician for more advice and to check on use of and side effects from the gum. Physician compliance to the protocol was checked with exit interviews of patients at both the initial and the follow-up appointments.

Each box of gum contained 96 pieces of the 2-mg dose of nicotine gum (Marion-Merrell Dow Pharmaceuticals). Patients could obtain gum one box at a time at the local pharmacy. To obtain refills, patients had to return each old box (to verify use of gum) and had to wait at least 48 hr between boxes (to prevent stockpiling).

## Measures

Gum use was measured for 6 months after each subject entered the study via dates of prescriptions and number of gum pieces in the returned boxes. Self-reported quit attempts and smoking status at 1-week and 6-month follow-ups were collected. In addition, observers were named by subjects to verify self-reports of smoking status. Among subjects who reported cessation, 77% had an observer available to verify cessation.

## Data Analysis

Self-administration. Boxes of gum were the unit of analysis for two reasons. First, in a random sample of 60 returned boxes of nicotine gum, the number of gum pieces left in the boxes did not differ across the price groups. Second, obtaining a box of gum was the response most likely to show effects of cost.

Analyses were first conducted among all subjects. Three self-administration variables were used: (a) incidence of obtaining any gum during the 6 months of the study, (b) number of boxes of gum used, and (c) incidence of filling a prescription after the recommended 4-month period. To examine the effect of cost independent of its effect on initiation of gum use, analyses (b) and (c) were repeated among only those who obtained gum.

The effect of cost on the use of the nicotine gum was further quantified by calculating a demand curve (i.e., cost vs use) and its associated elasticity. Elasticity refers to the degree to which consumption is sensitive to price changes (i.e., the slope of the effect of cost on use (10)). The formula for its calculation can be found in Hursch and Bauman (10). A greater elasticity refers to a greater decrement in use for a given increase in price or a greater increase in use for a

given decrease in price. Elasticities range from 0 to 1 and refer to the proportionate change in use with cost. For example, an elasticity of 0.10 indicates that a 20% decrease in price will increase use by 2%. Elasticities were calculated for a change from \$20 to \$6 and for a change from \$6 to \$20.

Smoking behavior. Smoking behavior variables were the incidence of (a) attempting to quit during the 6 months after entry, (b) abstinence at 1 week, and (c) abstinence at 6 months. Subjects who could not be located or whose observer disagreed with self-reported abstinence were considered to have not tried to quit smoking and/or to be smokers. Analyses were first conducted among all smokers. To examine the effect of cost independent of its effect on prompting a quit attempt, analyses (a) and (b) were repeated only among those who tried to quit.

Effect of income. To determine whether income modulated the influence of cost on gum use or smoking cessation, we divided subjects into three income groups, <\$15,000, \$15,000-\$30,000, and >\$30,000, and reran the analyses.

Cost-benefit analyses. We estimated cost-benefit even though our sample size was small, as we believed readers would be interested in this outcome. The methods of analysis and assumptions made are described in the Appendix. The results of this analysis should be considered tentative and are illustrative rather than definitive.

Statistical analyses. Dichotomous values (e.g., ever-filled prescription, rates of cessation) were entered into a three-cell Bartholomew's test for order (11). This is similar to a  $\chi^2$  test but it tests directly for an a priori order of results (e.g., \$20 > \$6 > \$0). Continuous variables were entered into a three-cell one-way ANOVA comparing cost groups with an a priori contrast of the same hypothesis. Several of the continuous variables were highly skewed, with many zeros and small values. Log-transformation analyses showed results similar to those of analyses of the raw scores. Only the latter are presented.

#### RESULTS

#### Compliance

Physicians were to tell or ask patients 11 items during their visit (e.g, chew gum slowly, are you willing to set a quit date?). Patient exit interviews indicated that physicians gave these instructions on 82-100% of occasions, depending on the item. Across the three price groups, 91-92% of patients agreed to a specific date to stop smoking prior to finding out the price of their gum.

#### Gum Use

Decreased cost of gum increased the incidence of obtaining gum (Table 2). Decreased cost also increased the total number of boxes of gum obtained and the incidence of long-term use both among all subjects and among the subset of subjects who had ever obtained gum. Among those who used the gum for 1 month or more, the mean (and SD) number of boxes of gum used/month was 1.32 (0.9), 0.93 (0.9), and 0.66 (0.8) for the \$0, \$6, and \$20 groups (P = 0.05). Decreased cost appeared to especially increase the proportion who used  $\ge 2$  boxes of gum (Fig. 1).

| TABLE 2 |      |     |     |       |
|---------|------|-----|-----|-------|
| GUM USE | OVED | THE | 6 M | ONTHE |

|                               | Free $(n = 32)$ | 6/box $(n = 36)$ | 20/box $(n = 38)$ | Analysis                 |
|-------------------------------|-----------------|------------------|-------------------|--------------------------|
| Among all subjects            |                 |                  |                   |                          |
| Percentage (and No.) obtained |                 |                  |                   |                          |
| gum                           | 75 (24)         | 58 (21)          | 47 (18)           | $\chi^2 = 5.5, P < 0.03$ |
| Mean (and SD) No. of          |                 |                  |                   | •                        |
| boxes of gum                  | 3.3 (4.6)       | 1.6 (3.6)        | 0.8 (1.7)         | F = 8.5, P < 0.006       |
| Percentage (and No.) obtained |                 |                  |                   |                          |
| gum after 4 months            | 25 (8)          | 11 (4)           | 3 (1)             | $\chi^2 = 7.7, P < 0.01$ |
| Among those who obtained gum  |                 |                  |                   |                          |
| Mean (and SD) No. of          |                 |                  |                   |                          |
| boxes of gum                  | 4.3 (4.9)       | 2.8 (4.4)        | 1.7 (2.1)         | F = 5.9, P < 0.025       |
| Percentage (and No.) obtained | , ,             | , ,              | , ,               | ,                        |
| gum after 4 months            | 38 (9)          | 24 (5)           | 11 (2)            | $\chi^2 = 4.0, P < 0.05$ |

Elasticity for total number of boxes obtained appeared to be greater for the \$6 vs \$20 price difference than for the \$0 vs \$6 difference, but these elasticities were not significantly different (Table 3). Substantial elasticity occurred even after initiation effects were eliminated (i.e., when examined among only those who obtained the gum).

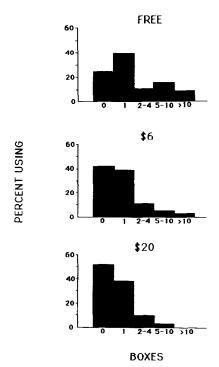


Fig. 1. Boxes of gum used among all subjects.

TABLE 3
POINT ELASTICITIES FOR TOTAL NUMBER OF BOXES OF GUM

|   | \$0 vs \$6 | \$6 vs \$20 |
|---|------------|-------------|
| Use among all subjects given prescription | 0.21       | 0.45        |
| Use among those who obtained the gum      | 0.35       | 0.62        |

## Smoking Behavior

Among the 35 self-reported abstainers at 1-week follow-up, observers verified cessation in 13, observer data were missing in 8, and observers refuted 3. Decreased cost of gum increased the incidence of attempting to stop and abstinence at 1 week among all subjects. A similar nonsignificant trend occurred among only those who tried to quit and among only those who obtained the gum (Table 4).

At the 6-month follow-up, 21 smokers could not be located and were counted as currently still smoking. Among the 11 subjects who stated they were not smoking at 6-month follow-up, all had an observer who verified their abstinence. Decreased cost showed a nonsignificant trend to increase quit rates at 6-month follow-up among all subjects and among only those who tried to quit. A similar but statistically significant effect occurred among only subjects who had obtained the gum.

## Income and the Effects of Cost

Decreased cost did not appear to have a significantly larger effect on gum use or smoking behavior among lower income groups than among higher income groups.

## Cost-Benefit

The financial gain to an HMO, insurance company, etc., for each group was

TABLE 4
PERCENTAGE (AND NO.) OF SUBJECTS WHO QUIT OR TRIED TO QUIT OVER THE 6 MONTHS

|                                  | Free $(n = 32)$ | 6/box $(n = 36)$ | 20/box $(n = 38)$ | Analysis                 |
|----------------------------------|-----------------|------------------|-------------------|--------------------------|
| Among all subjects               |                 |                  |                   |                          |
| Tried to quit                    | 85 (27)         | 78 (28)          | 66 (25)           | $\chi^2 = 6.8, P < 0.03$ |
| Quit at 1 week                   | 47 (15)         | 33 (12)          | 21 (8)            | $\chi^2 = 5.3, P < 0.03$ |
| Quit at 6 months                 | 19 (6)          | 6 (2)            | 8 (3)             | $\chi^2 = 3.5, P < 0.10$ |
| Among those who tried to quit    |                 |                  |                   |                          |
| Ouit at 1 week                   | 55 (15)         | 43 (12)          | 32 (8)            | $\chi^2 = 2.9, P < 0.10$ |
| Ouit at 6 months                 | 22 (6)          | 7 (2)            | 12 (3)            | $\chi^2 = 2.4, P = NS$   |
| Among those who obtained the gum |                 |                  |                   |                          |
| Ouit at 1 week                   | 54 (13)         | 43 (9)           | 33 (68)           | $\chi^2 = 1.9, P = NS$   |
| Ouit at 6 months                 | 21 (5)          | 10 (2)           | 0 (0)             | $\chi^2 = 4.7, P < 0.04$ |

Note. NS, not significant.

calculated by subtracting the cost of the program (including costs for free or \$6/box gum) from the expected financial benefits from cessation (see Appendix). The mean financial gain/subject enrolled was 2-3 times greater in the free-gum group than in the \$6 group or \$20 group (Table 5). Financial gain was similar in the \$6 and \$20 groups.

#### DISCUSSION

## Comparison with Prior Studies

Decreased cost increased the total amount of nicotine gum obtained. Thus, our study provides an experimental replication of the results of the prior retrospective study (6). As in the prior retrospective study, cost was shown to increase the initiation of gum use. In the present study, cost also increased the amount of use among those who obtained the prescriptions and increased the incidence of long-term use. Our results are also consistent with those of the Rand experiment in which the use of all drugs increased as price decreased (4). Our results and those of the Rand experiment suggest that the use of drugs as different as antibiotics and nicotine gum is affected by price.

Nicotine gum use appeared to be relatively elastic (0.35–0.62); i.e., it decreased substantially in response to increased cost. These elasticities appeared to be greater than those found in retrospective studies of prescription drugs (0.10–0.20) (3). The elasticity of use of psychoactive medications has not been reported.

The elasticities for nicotine gum are somewhat similar to those for cigarettes (0.35-0.42) (12, 13). However, the major effect of lower prices for cigarettes has been to increase the initiation of smoking but not the rate of use among existing smokers (12, 13). In the present study lower prices increased both initiation among nonusers and use among existing users.

Although our results suggest that nicotine gum is more sensitive to price than other prescription drugs and similar to that for cigarettes, the comparability of our study and prior studies is unclear for two reasons. First, prior studies used correlational rather than experimental data. Second, in prior studies, changes in price of approximately 10% were studied, whereas price changed 70 and 100% in the present study.

Decreased cost increased use of nicotine gum beyond the recommended period. We are unaware of studies of the effect of cost on the long-term use of drugs typically prescribed *ad libitum* or with dependence potential (e.g., benzodiazepines or opioid analgesics).

TABLE 5
Cost-Benefit Analysis<sup>a</sup>

|                                      | Free | \$6 | \$20 |
|--------------------------------------|------|-----|------|
| Adjusted quit rates (%)              | 9.4  | 3.0 | 4.0  |
| Benefit/subject enrolled (\$)        | 1256 | 372 | 471  |
| Cost/subject enrolled (\$)           | 136  | 92  | 58   |
| Financial gain/subject enrolled (\$) | 1120 | 280 | 413  |

<sup>&</sup>lt;sup>a</sup> See Appendix for calculation.

Decreased cost appeared to increase quit rates. This result replicates that of the prior retrospective survey (6). In fact, the difference in quit rates between free and \$20 gum in our study (+11%) is similar to that in the retrospective study (+13%). To our knowledge, our study is the first experimental demonstration that decreased cost for a medication improves a clinical outcome.

Our estimate of cost-benefit suggested that all the strategies were costbeneficial. Although this result must be considered tentative due to our small sample size, the result is concordant with other studies of physician advice alone (14) and of physician advice plus nicotine gum (15). We are unaware of analyses of the cost-benefit of subsidized prescriptions for nonsmoking conditions.

## Methodological Adequacy of the Study

Our study had several assets: (a) minimal inclusion criteria, (b) experimental manipulation of cost, (c) objective measure of medication use, (d) consideration of family income, etc. Nevertheless, our results must be considered preliminary for at least five reasons. First, we did not validate gum use via salivary cotinine or other biochemical measures. Second, in terms of generalizability, our sample comprised mostly low- to middle-class patients presenting with problems to a medical practice and who were not a priori motivated to stop smoking. Although, this population is much more common than that usually reported on (i.e., upper-to middle-class healthy smokers already motivated to stop), our results may or may not generalize to other populations. Third, we did not use the standard 1-yr cessation follow-up nor use biochemical verification of abstinence. We did use observer verification; however, whether this increased our validity is debatable (16). Fourth, our sample sizes were too small for adequate power in the nonparametric analyses (e.g., smoking abstinence rates). Fifth, since the physicians knew the price each subject was paying for gum, the physicians could have biased the study by encouraging cessation more in the free-gum group. We have no anecdotal evidence that this occurred.

## Significance

Our results have implications for basic research as well as for clinical practice. In terms of basic research, our results can be restated as an example of the finding that increased response cost decreases drug self-administration (17).

In terms of clinical outcomes, demonstration that cost influences the use, efficacy, and long-term use of nicotine gum is important for at least four reasons. First, although studies have shown that decreased cost is associated with increased use of prescription medications (3, 4), no studies have shown that such increased use has an impact on clinical outcomes.

Second, prior studies indicating that nicotine gum is an effective aid to smoking cessation gave subjects free gum (5). If having to pay for nicotine gum decreases gum use and thereby decreases quit rates, then the results of prior studies of nicotine gum may not be generalizable to the "real world" setting.

Third, at present only a few strategies for the treatment of dependence on nicotine gum have been described (18). Our results suggest that increasing the cost to obtain nicotine gum could decrease long-term use but, unfortunately, it also

decreases appropriate use. These results suggest that smokers might be given free gum for the recommended 3- to 4-month period and charged for the gum thereafter.

Fourth, our results suggest that it is cost-effective for prepaid or health insurance plans to reimburse patients for nicotine gum prescriptions. Our estimates are not precise due to our small sample sizes; however, a conservative interpretation of our results would be that prepaid plans, HMOs, etc., will not lose money by dispensing free nicotine gum and may actually have a net financial gain. Further larger studies will be needed to verify whether subsidizing nicotine gum is cost-beneficial.

#### **APPENDIX**

The costs for each payment plan (excluding subject outlays for the gum) were calculated for each group, assuming physician time for all scheduled initial visits and follow-ups at \$150/hr, nicotine gum at \$24/box, smoking cessation booklets at \$2.50 each, and patient time at \$10/hr. Costs for development were not included because the program was already packaged. Costs for evaluation and promotion were not included because the typical medical practice would not likely spend money for these activities.

Cessation rates were corrected for an estimated false self-report rate of 25% and a relapse rate of 20% between 6 months and 1 year and of 18% after 1 year. These assumptions were based on our prior work (19) and that of Midanik *et al.* (20).

Monetary benefits were estimated from Tables 8-7 and 8-8 in Oster *et al.* (21). These tables give discounted total estimates for cost/benefits accruing from avoidance of lung cancer, coronary heart disease, and chronic obstructive pulmonary disease. The tables give the estimates by intensity of smoking, age, and sex. For our sample we calculated a weighted average (0.46 male) of cost-benefit for male and female moderate smokers (15–35 cigarettes/day) in the age range 35–39, as this best matched our sample. Since the effect of decreased cost on cessation in this study did not appear to differ by intensity of smoking, age, or sex, further adjustment in these figures was not made.

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