# An Adolescent Tobacco-Use Prevention Trial in Orthodontic Offices


## ABSTRACT

*Objectives.* This study examined the effect of an orthodontist-delivered tobacco-use prevention program for adolescents.

*Methods.* Southern California orthodontic offices were randomly assigned to experimental (n = 77) and control (n = 77) groups. Randomly selected adolescents were interviewed at baseline and 2 years later (n = 15 644). Experimental offices received tobacco prevention training, anti-tobacco materials, and 50 cents for each anti-tobacco "prescription" written.

*Results.* The 30-day tobacco use 2-year incidence rates for the control and experimental groups were 12.6% and 12.0%, respectively; incidence rates for using tobacco more than 100 times were 7.6% and 6.8%. Differences between the groups did not reach significance. Mean prescription compliance was 64.4%. A multivariate logistic model, showed a significant dose response: patients who received more prescriptions had lower incidence rates than those who received few or none (10% vs 14%).

*Conclusions.* Training, payment, and support did not ensure clinician compliance with prevention services. The dose effect suggests that replication under conditions that would ensure clinician compliance and statistical power would more thoroughly test clinicians' ability to prevent tobacco use. (*Am J Public Health.* 1996;86:1760–1766)



*Melbourne F. Hovell, PhD, MPH, Donald J. Slymen, PhD, Jennifer A. Jones, MPH, C. Richard Hofstetter, PhD, Susan Burkham-Kreitner, MPH, Terry L. Conway, PhD, Budd Rubin, DDS, MS, and David Noel, DDS, MPH*


## Introduction

Tobacco use is responsible for more than one of every six deaths in the United States and is the most important preventable cause of death in society.[1] More than 50% of tobacco users start before age 18, and almost 90% start by age 21.[2] About 16% of US adolescents are tobacco users.[3] Given the magnitude of the tobacco epidemic in the youth population, along with the limited success of cessation efforts[4–6] and school-based prevention efforts, innovative prevention interventions in alternative settings are needed.[7] One avenue for prevention is for clinicians to advise youth not to start using tobacco, analogous to the National Cancer Institute (NCI) clinician-delivered cessation studies that have demonstrated that physician and dentist advice to quit can increase quit rates.[8–11]

Recommendations have been made for clinicians to expand their role to incorporate prevention of tobacco use initiation among their adolescent patients.[12] Even a small reduction in tobacco use initiation rates during the critical adolescent period could have substantial public health benefits, including the prevention of many premature deaths. Because orthodontists see large numbers of youth repeatedly over 2 or more years, they are especially well suited for testing questions about the effectiveness of clinicians' ability to prevent tobacco use.

This paper presents the results of the first clinician-delivered tobacco-use prevention trial. Trained orthodontists and their office staff delivered the intervention over a 2-year period; they were given incentives for compliance with anti-tobacco "prescription" delivery. The primary objective was to determine the differential 2-year tobacco use incidence rate for youth receiving clinician-delivered advice not to start compared with youth assigned to usual care.

## Methods

### Design

This study was designed to detect a difference of 4% (10% control subjects vs 6% experimental subjects) in the 30-day incidence rate with the assumption of a significance level of .05 (two sided), a power of .80, and a conservative intraclass correlation of .07 to account for the clustering effect of orthodontic offices. Minimum sample requirements suggest a total of 124 offices with an average of 100 patients per office. Blocked random assignment of orthodontic offices to control or experimental conditions was used to ensure that approximately equal numbers were assigned to the two conditions and to ensure balance within a region, since recruitment followed regional patterns. Orthodontic offices (n = 154) from San Diego, Orange, Riverside, and parts of Los Angeles and San Bernardino counties were enrolled in the trial. Orthodontists were identified through the American Association of Orthodontists directory, the California State Society of Orthodontics directory, and the yellow pages. General dentists and orthodontists con-


The authors are with the Center for Behavioral Epidemiology and Community Health, Graduate School of Public Health, San Diego State University, San Diego, Calif.

Requests for reprints should be sent to Melbourne F. Hovell, PhD, MPH, Center for Behavioral Epidemiology and Community Health, Graduate School of Public Health, San Diego State University, San Diego, CA 92182-0405.



This paper was accepted May 17, 1996.

tacted potential participants, described the study, and invited potential participants to an individual meeting at which time those confirmed as eligible were invited to join the study. Orthodontists had to meet the following criteria: (1) be an independent practitioner, (2) practice in an office not controlled by a private practice organization/clinic administration, (3) practice in the participating office at least 2 days a week, (4) have no intention of retiring or selling the practice during the study, and (5) have at least 75 active 11- to 18-year-old patients.

A random sample of 58% of each office's patients were selected for baseline and a 2-year follow-up interview concerning health practices. This proportion represented the average number of age-eligible patients per office required to attain the necessary statistical power. Patients had to meet the following criteria: (1) be 11 to 18 years of age, (2) be in bands or braces, (3) be the only patient from a given household participating, (4) not be the child of a participating orthodontist, and (5) not be changing orthodontists. These procedures resulted in 17 925 eligible adolescent patients.

Youth and parents were sent letters explaining the study and alerting them to a telephone interview. Those not interested in participation were to call the research or orthodontic office to avoid the telephone interview. Youth not reached by telephone were sent questionnaires and asked to complete and return them in postage-paid envelopes. Participants were assured of confidentiality. All patients who completed the survey were entered into a lottery, and one was given a cash award.

### *Experimental Group Training*

After the baseline interviews, the 77 offices assigned to the experimental group were asked to implement a "minimal intervention" designed to be easy, inexpensive, generalizable, and free of side effects.[13] Experimental offices received 1.5 hours of tobacco prevention training based on NCI tobacco cessation workshops for clinicians. Workshops were conducted by health educators at the orthodontic office during lunch, and participants received continuing education credit.

The tobacco prevention workshop included education about youths' rate of tobacco use, financial and health consequences (including oral disease), the addictiveness of nicotine, the extent of tobacco advertising, and the unique role clinicians could play in influencing adolescents' tobacco use. Staff were instructed to create a tobacco-free environment by formalizing a nonsmoking office policy, removing tobacco advertisements, discontinuing magazines with such ads, and displaying tobacco prevention information such as posters, pamphlets, signs, and stickers. Instructions for anti-tobacco counseling and delivery of anti-tobacco "prescriptions" were provided along with a preview of the eight topics covered in the prescriptions. Anti-tobacco counseling using "teachable moments" was similar to that used by general dentists for smokeless-tobacco cessation.[14] Clinicians and staff were to write the patient's name, sign and give the prescription to the patient, briefly discuss the tobacco-related topic printed on the prescription, and request that the patient not start smoking. Offices received 50 cents per prescription delivered to age-eligible youth, who were identified by colored stickers on the charts.

After the workshop, a tobacco prevention coordinator was selected for the program. New prescriptions were delivered and receipts were collected every 3 months to assess compliance with the intervention and to enable accounting for reimbursements. Educators provided consultation to improve prescription delivery during these visits. Between quarterly visits, offices were contacted by phone to encourage compliance with the intervention. During visits and phone contacts, offices were given the opportunity to attain additional tobacco prevention media materials. Each quarterly reimbursement was accompanied by a letter stating the level of prescription delivery compared with the target. At 1 year, offices were provided with graphs of their prescription rates relative to their targets. The accompanying letter provided positive feedback or encouragement to deliver more prescriptions.

The 77 offices assigned to the control condition continued "usual" care. Interim analyses verified that control offices did not alter their offices in the direction of a tobacco-free environment[15] and that unlike the experimental offices, they did not provide anti-tobacco counseling.[16]

### *Prescriptions*

The prescription packages consisted of self-carbon, triple-copy prescription pads with a specific anti-tobacco message preprinted on the form. The eight prescription topics were the following: the announcement of a tobacco-free office, tobacco advertising, tobacco and sports, smokeless tobacco, nicotine and tobacco addiction, passive smoking, tobacco and the patient's teeth, and the negative consequences of tobacco use. Each prescription included a space for the patient's name, a special anti-tobacco message and a space to sign the prescription. One copy was given to the patient, one was kept in the chart, and one was sent to the research office.

### *Measures*

Survey questions covered demographics, health-related behaviors and attitudes, social support for smoking, and intentions to smoke (survey available from the authors). The survey was designed to be quick to administer and easy to comprehend. Responses were structured to provide confidentiality in case a parent was listening to the adolescent's part of the conversation; at baseline and follow-up, primarily dichotomous (yes or no) and some categorical answers were required. Two primary tobacco-related outcome measures were defined as the following: (1) 30-day tobacco use if the youth reported having used tobacco in any form (cigarette, pipe, cigar, or smokeless tobacco) during the past day, week, or month and (2) ever having used any form of tobacco more than 100 times. For consistency with adult tobacco studies, the 30-day measure was used as the primary outcome. The 100-times measure was employed to replicate the 30-day measure and to "capture" youth who had used tobacco, but who might not have done so in the last 30 days. This was considered important because youth do not have as ready access to tobacco products as adults.

Office compliance with the prescription delivery system was measured by quarterly counts of prescription receipts. Individual receipt of prescriptions was documented by tallying by name patients who were given one or more prescriptions with a given anti-tobacco message.

### *Analyses*

Use of tobacco within the past 30 days and ever having used tobacco more than 100 times served as outcome measures. Subjects who at baseline were using tobacco according to either outcome measure were excluded from all analyses. For each outcome, group differences in 2-year incidence rate were computed. Intervention effectiveness was analyzed with the use of a mixed-effects logistic model with and without adjustment for demographic characteristics and the inter-

**TABLE 1—Thirty-Day Tobacco-Use Initiation among Adolescent Orthodontic Patients in Trial, by Selected Baseline Demographic Characteristics**

| | Control Group | | Experimental Group | |
|---|---|---|---|---|
| | Total No. | % Initiated | Total No. | % Initiated |
| Overall | 7626 | 12.6 | 7149 | 12.0 |
| Age | | | | |
| 11–12 | 1128 | 5.2 | 937 | 4.3 |
| 13–14 | 3293 | 11.2 | 3196 | 10.9 |
| 15–16 | 2257 | 16.8 | 2139 | 15.2 |
| 17–19 | 948 | 16.1 | 877 | 16.4 |
| Race/ethnicity | | | | |
| White | 5609 | 13.3 | 5128 | 12.6 |
| Black | 180 | 5.0 | 236 | 6.8 |
| Hispanic | 858 | 12.6 | 991 | 12.1 |
| Asian | 742 | 8.5 | 618 | 8.6 |
| Other | 215 | 15.8 | 160 | 13.1 |
| Gender | | | | |
| Male | 3496 | 13.6 | 3240 | 13.3 |
| Female | 4130 | 11.7 | 3909 | 10.9 |
| Parents' education[a] | | | | |
| Neither a college graduate | 1977 | 13.1 | 2114 | 12.9 |
| One or both a college graduate | 5184 | 12.4 | 4573 | 11.9 |

*Note.* 30-day tobacco users at baseline were not included in this analysis (n = 869).
[a]927 missing observations for parents' education.

actions between group-by-demographic characteristics. Office was included as a random effect to account for the clustering of subjects within an office in all analyses.

Similar mixed-effects logistic analyses were conducted to explore the interaction between the clinician-delivered minimal intervention and various social, environmental, and behavioral variables that contribute to tobacco use among adolescents. Last, exploratory analyses were conducted to assess the impact of anti-tobacco use prescriptions on the incidence rates of youth in the experimental group. Measurement reliability was assessed with test–retest procedures and intraclass correlation tests. Analyses were conducted with SPSS/PC+ and EGRET software.[17,18]

## Results

### *Sample Description and Response Rate*

After being randomly selected from orthodontist's charts, 18 541 adolescents were contacted and 616 of them were determined ineligible. Among the remaining 17 925 patients, baseline surveys were completed by phone or mail with 16 915, over 94% of those eligible. Although most surveys were completed by telephone interview (89%), mail surveys were used for youth or parents requesting them and for patients who could not be contacted by phone. The 1010 adolescents who did not complete the baseline interview either refused or did not respond to the mailed survey.

Two years later, follow-up interviews were completed by phone or mail for 15 644 adolescents (92.3% of the control group and 92.8% of the experimental group). The majority of the interviews were completed by phone (96.1%). Of the 1271 patients who did not complete the follow-up survey, only 7.9% refused; the rest were not located.

The majority of the adolescent sample (mean age of 14.4 at baseline, SD = 1.8) were female (54%), Caucasian (73%), and reported that a parent had graduated from college (70%). About 12%, 9%, and 3% were Hispanic, Asian, and Black, respectively, and 3% did not report their race/ethnicity.

### *Random Assignment*

Orthodontist characteristics were compared with the use of chi-square tests and *t* tests to assess whether those assigned at random to the experimental or control group differed. Orthodontists in both groups were not significantly different across all measured variables: gender, ethnicity, number of years in practice, and number of patients. Similarly, orthodontic patients measured at baseline showed no significant group differences based on mixed-effects models on the following variables: age, gender, parent education, seatbelt use, alcohol use, tobacco use, and attitudes regarding tobacco use. These results confirmed the success of random assignment.

### *Instrument Reliability and Validity*

The reliability of the survey measures was estimated by computing the percentage of agreement between baseline telephone interview responses and responses given 48 hours later on a reinterview for a random subsample (n = 100) of youth. The percentage of agreement was 99% on the 30-day tobacco use variable and 98% on the 100-times tobacco use variable. A similar 48-hour test–retest reliability was conducted during the 2-year follow-up interviews for a random subsample (n = 104) of subjects. The percentage of agreement was 96% on the 30-day tobacco use variable and 98% on the 100-times tobacco use variable. Similar checks on other survey items indicated that the interview measures at both baseline and follow-up were highly reliable (>90% agreement) overall. Kappa coefficients exceed .75 [t(103) 7.0, $P < .001$).[3]

Biological measures, such as saliva testing, were not feasible for over 15 000 patients, the majority of whom were not tobacco users. However, under rigorous research conditions where confidentiality has been assured and accepted, explicit biological validity checks may be omitted without serious risk to reliability or validity.[19] Partial construct validity was apparent in correlates of tobacco use.[20] In light of the overall design, sample size, response completion rates, high reliability, and evidence of construct validity, self-reported measures were interpreted as valid estimates of associations and as satisfactory estimates of incidence.

### *Intervention Effectiveness Evaluation*

*Thirty-day tobacco use measure.* Table 1 presents initiation rates for 30-day tobacco use by group as well as by selected demographic characteristics. A rate of 12.6% in the control versus 12.0% in the experimental group was observed. The observed difference between groups, although in the predicted direction, was not statistically significant ($P = .29$; odds ratio [OR] = .93) after we accounted for the clustering of subjects within an office, with the orthodontic office treated as a random-effects factor. Although there was some variation in the differential between control and experimental groups across various strata, the corresponding interaction

terms in the mixed-effects model were not statistically significant.

The nonsignificant interaction terms indicate that any intervention effect on smoking initiation did not vary significantly with ethnicity, gender, age, or parents' education. Consequently, all interaction terms were dropped from the mixed-effects logistic model shown in Table 2. Table 2 shows the overall results comparing experimental and control groups for 30-day use adjusted for the orthodontic-office random effect and for the demographic variables. The intervention effect for 30-day use, after adjustment, was not significant ($P = .46$). The odds ratio changed only slightly (.93 to .95) after adjustment for demographic variables; this suggests little evidence of confounding.

Ethnicity, gender, and age were significantly related to 30-day tobacco use initiation. Parent education was not significantly related. Blacks and Asians had significantly lower initiation rates than Whites ($P < .001$). The rate for Hispanics was somewhat lower than for Whites, but did not reach statistical significance ($P = .07$). Females had a lower rate of tobacco use initiation than males ($P = .003$). As expected, tobacco use initiation increased with age ($P < .001$).

*More than 100-times tobacco use measure.* We observed a 2-year incidence rate of 7.6% in the control versus 6.8% in the experimental group for use of tobacco more than 100 times. The observed difference between the groups, although in the predicted direction, was not statistically significant ($P = .107$; OR = .88) after we accounted for the clustering of subjects within an office.

Again, the corresponding interaction terms in a mixed-effects model were not statistically significant and were dropped from the model. The group effect for tobacco use more than 100 times was not statistically significant ($P = .15$) after adjustment for selected demographic characteristics. Overall, results for group, ethnicity, gender, and age were consistent with those found with 30-day tobacco use initiation.

### *Interaction of Social, Environmental, and Behavioral Variables with Intervention*

Thirteen nondemographic variables were selected in this second stage of variable assessment. Ten of these variables are included in this report. Three variables—"Would you say yes or no if a friend offered you tobacco?", "Do you think you will smoke in the next 30 days?" and "Would you be more popular if you smoked?"—had distributions that offered little variability within this population of nonsmokers at baseline (e.g., 1% to 3% responded yes) and were not included in regression analyses. Fewer than 1% responded yes to the first two questions, and fewer than 3% responded yes to the third.

The first step was to simultaneously assess the interactions between the behavioral variables and the group variable. To guard against false positive results, given the large number of interaction terms, a Bonferroni correction was applied; this yielded a significance level of .005 (.05/10). The only significant variable was sleeping 8 hours per day ($P = .001$). The trends picked up by the interaction were examined, but were not corroborated by any of the other behavioral variables and were considered a chance result. Therefore, all interaction terms were dropped from the model.

Table 3 displays the mixed-effects logistic model with the main effects of the demographic, social, environmental, and behavioral variables on 30-day tobacco use initiation. This model reports the *P* value for group adjusted for all of the variables that were identified a priori as theoretically important possible determinants. The adjusted odds ratio (.94) and *P* value (.37) changed very little from the unadjusted results previously reported (OR = .93, $P = .29$), further demonstrating that randomization balanced the experimental conditions with respect to social influences of tobacco use.

Table 3 also provides a look at a simultaneous assessment of the relationship between 30-day smoking initiation and each of the baseline factors after adjustment for the residual group effect (as well as all other factors in the model). The results for the demographic variables were similar to those reported previously. However, several of the baseline behavioral variables were highly significantly related to smoking initiation even after adjustment for all other variables. Not flossing at least once per day, getting less than 8 hours of sleep, not usually wearing a seatbelt, drinking alcohol within the past 30 days, living with a smoker, having been offered tobacco in the past 30 days, and having friends who do not avoid people who smoke were associated with smoking initiation. Subjects who had been offered tobacco at baseline were nearly three times as likely to initiate smoking as subjects who had not been offered tobacco. Those who used alcohol were nearly twice as likely to initiate smoking as those who did not use alcohol. Subjects having friends who did not avoid smokers were almost twice as likely to initiate smoking as those having friends who avoided smokers. The results obtained for 100-times tobacco use were essentially

**TABLE 2—Mixed-Effects Logistic Model: Tobacco-Use Incidence with Group, Race/Ethnicity, Gender, Age, and Parents' Education Variables**

| Variable | 30-Day Tobacco Use (n = 13 812, 6.5% Missing) | | |
|---|---|---|---|
| | Odds Ratio | 95% CI | *P* |
| Group | | | |
| Control | 1.0[a] | . . . | |
| Experimental | 0.95 | .83, 1.09 | .46 |
| Race/ethnicity | | | |
| White | 1.0[a] | . . . | |
| Black | 0.42 | .27, .63 | <.001 |
| Hispanic | 0.86 | .73, 1.01 | .07 |
| Asian | 0.58 | .47, .72 | <.001 |
| Other | 1.10 | .81, 1.50 | .53 |
| Gender | | | |
| Male | 1.0[a] | . . . | |
| Female | 0.86 | .77, .95 | .003 |
| Age (continuous) | 1.20 | 1.16, 1.23 | <.001 |
| Parents' education | | | |
| Neither a college graduate | 1.0[a] | . . . | |
| One or both a college graduate | .93 | .83, 1.05 | .23 |

*Note.* CI = confidence interval.
[a]Indicates reference category.

**TABLE 3—Mixed-Effects Logistic Model: Incidence of Tobacco Use with Group and Demographic and Behavioral Characteristics**

| Variable | 30-Day Tobacco Use (n = 12 613, 14.6% Missing) | | |
|---|---|---|---|
| | Odds Ratio | 95% CI | *P* |
| Group | | | |
| Control | 1.0[a] | . . . | |
| Experimental | 0.94 | .82, 1.08 | .37 |
| Race/ethnicity | | | |
| White | 1.0[a] | . . . | |
| Black | 0.45 | .29, .71 | <.001 |
| Hispanic | 0.80 | .67, .96 | .018 |
| Asian | 0.66 | .53, .83 | <.001 |
| Other | 1.01 | .72, 1.42 | .96 |
| Gender | | | |
| Male | 1.0[a] | . . . | |
| Female | 0.88 | .78, .98 | .024 |
| Age (continuous) | 1.04 | 1.01, 1.08 | .020 |
| Parents' education | | | |
| Neither a college graduate | 1.0[a] | . . . | |
| One or both a college graduate | 1.02 | .90, 1.16 | .75 |
| Behavioral characteristics[b] | | | |
| Floss ≥ 1/day | 0.80 | .71, .91 | <.001 |
| ≥ 8 hrs sleep/day | 0.76 | .66, .86 | <.001 |
| Brush teeth 2/day | .95 | .78, 1.17 | .65 |
| Usually wear seatbelt | 0.73 | .59, .89 | .002 |
| 30-day alcohol use | 1.86 | 1.59, 2.17 | <.001 |
| Live with smoker | 1.33 | 1.18, 1.50 | <.001 |
| Been offered tobacco past 30 days | 2.87 | 2.49, 3.31 | <.001 |
| Friends think smokers look cool | 1.05 | .86, 1.29 | .63 |
| Friends make fun of smokers | 1.09 | .96, 1.23 | .17 |
| Friends avoid smokers | .57 | .50, .64 | <.001 |
| Orthodontist office | Random effect | | |

*Note.* CI = confidence interval.
[a]Indicates reference category.
[b]"No" is the reference category for this variable.

**TABLE 4—Association between Tobacco-Use Incidence and Anti-Tobacco Prescriptions Received in the Experimental Group**

| No. Prescriptions Received[a] | 30-Day Tobacco Use | | | | |
|---|---|---|---|---|---|
| | Sample Size | % Incidence | Odds Ratio | 95% CI | *P* |
| 0–1 | 1886 | 14.3 | 1.0 | . . . | |
| 2–3 | 1716 | 12.7 | 0.92 | .75, 1.13 | .43 |
| 4–6 | 1956 | 10.8 | 0.76 | .62, .94 | .012 |
| ≥7 | 1507 | 10.0 | 0.75 | .59, .95 | .016 |

*Note.* CI = confidence interval.
[a]Adjusted for ethnicity, gender, age, parents' education, and orthodontist office (random effect) through a mixed-effects logistic model. The overall test for the relationship between number of prescriptions and 30-day smoking initiation is based on a likelihood ratio test statistic of 9.27 with 3 *df* and *P* of .026.[33]

identical to those found for 30-day tobacco use initiation.

### *Prescription Provision by Clinicians*

Consistent with previous reports of adherence to health promotion,[21,22] adherence to the prescription provision by orthodontic offices during each 3-month interval varied greatly. Overall, prescription compliance across all experimental orthodontic offices for the entire 2-year intervention was 64.4%. Only 14% of the offices provided the target (i.e., eight) number of prescriptions or more every quarter over the 2-year intervention. There were no significant differences between prescription delivery by office for the following variables: office size, geographic location, number of staff members who use tobacco, and use of reimbursement money.

### *Prescription Dose and Tobacco Use*

An exploratory analysis of the relationship between the number of prescriptions received and 30-day tobacco use initiation was examined in the experimental group. Owing to the skewness of the variable, prescription receipt was categorized as 0 to 1, 2 to 3, 4 to 6, and 7 or more prescriptions received by an individual patient. The results from a mixed-effects logistic model with the prescription categories and orthodontic office is shown in Table 4. Overall, a highly significant ($P < .001$) relationship was observed. Patients who received the lowest number of prescriptions (0 to 1) had a 30-day incidence rate of 14.3%; those who received the highest number of prescriptions (7 or more) had the lowest rate, 10.0%. When the demographic characteristics were incorporated into the model, the relationship was not as strong, but remained significant ($P = .026$). The relationship between using tobacco products more than 100 times and the number of prescriptions written was consistent with that found with 30-day tobacco use.

## *Discussion*

The NCI's goal for the year 2000 calls for the reduction of US adolescents' tobacco use to less than 3%.[30] Public school prevention education programs have served as the primary means of tobacco control for youth. The school-based programs subjected to experimental test have been both very expensive and of limited effectiveness. School-based interventions may not be affordable, and they are unlikely to achieve the objectives for the nation.[24–26] Communitywide education and media programs, perhaps best illustrated by the Minnesota multicity multiple risk-factor prevention trial,[27,28] combine numerous interventions, including school education, political action to restrict access to tobacco, and media programs aimed at discouraging tobacco use. These multichannel approaches have yielded promising, but not definitive, reduction in the incidence of tobacco use among adolescents. Both school and

community approaches have the disadvantages of cost and of relying on specialists to implement or coordinate the overall intervention program, and after completion of formal investigations, none have been adopted by school districts or communities, raising questions about generalizability. In this context, the development of additional or alternative means of preventing tobacco use is critical.

NCI-funded clinical trials have demonstrated that physician and dentist recommendations to quit using tobacco result in lower tobacco use among counseled patients.[8–11] These trials have set the stage for studying the effectiveness of clinician-delivered minimal intervention for prevention of tobacco use initiation. In the context of reliable measures, successful random assignment, very high retention rates, and very conservative analyses (including replications), results demonstrated a nonsignificant lower rate of tobacco initiation among youth in the experimental group than in the control group. This result may reflect the limited effectiveness of minimal counseling not to start tobacco use. It could also reflect design limitations that might obscure a true effect.

There were three design features of this study that could not be guaranteed in advance: objective validation of tobacco use, exposure to the correct "dose" of clinician counseling, and clinician compliance with the experimental procedures. The inability to use an objective validation makes this experiment a somewhat conservative estimate of the incidence rate of orthodontic patients' tobacco use. However, this should not compromise the experimental design, because underreporting error should be equally distributed across the two experimental conditions. In addition, the high test–retest reliability and the concordance between predicted and observed associations[18] suggest low measurement error and good construct validity.

The qualitative features of effective counseling were not known. Nor was the duration or frequency of counseling necessary to effect incidence known at the start of this study. The selection of eight different prescriptions was an arbitrary target. However, the dose–response analysis resulted in a highly significant positive relationship. While this may represent sampling bias, it could also represent effects of counseling that is provided often enough. These analyses showed that receipt of four or more prescriptions was associated with a substantially lower rate of tobacco use than receipt of fewer prescriptions. These data provide the best estimate of the minimum number of prescriptions (and counseling episodes) to be recommended as a possible means of decreasing tobacco incidence rates. Since this study targeted eight prescriptions per youth, it appears that adequate frequency was planned. Future studies should confirm this frequency as well as investigate duration and qualitative features of anti-tobacco counseling (i.e., the means of increasing the power of minimal interventions).

Unfortunately, it was not possible to guarantee the office compliance with the recommended prescription provision. Doctors and staff provided an average of 64% of the eight prescriptions. Thus, the greatest limitation for this trial was the incomplete exposure to the experimental intervention. This limitation parallels the experience in the COMMIT study, where overall perception of exposure to tobacco control procedures was low. Formal analyses of the COMMIT intervention "compliance" are underway and may confirm dose–response relationships.[29] In the present study, experimental offices provided more counseling than did controls, which suggests that the training, reimbursement and supervision procedures affected preventive services as expected. However, the overall rate of prescription provision also suggests that more training, supervision, and/or larger reimbursement payments may be needed to attain adequate adherence. Additional studies of clinician adherence to preventive medicine procedures are needed.

An effect-size analysis was conducted to determine the magnitude of the difference between control and experimental groups that could be detected. The approach used was based on the sample size calculations in Donner, Birkitt, and Buck,[23] where the usual sample size estimate to compare two proportions is modified to account for the clustering (i.e., office effects). Given the sample sizes adjusted for mean number of subjects per office and the observed intraclass correlation (0.0089), with a two-sided alpha level of .05 and a power of .80, an absolute difference of 2% (12.6% vs 10.6%) could have been detected with the available sample size. Effects of this size or larger were obtained within the exploratory dose-response analysis. For both the 30-day and the 100-times tobacco use measures, contrasting patients who received 0 to 1 prescription with those who received 4 to 6 prescriptions resulted in a 3.5% (14.3% minus 10.8%) and 4.5% (9.61% minus 5.16%) lower rate, respectively, among those who received greater numbers of prescriptions. These results were based on a subset of the sample and may suffer from sampling bias. For instance, patients who received the most prescriptions may have been the easiest to approach and unlikely to use tobacco even without counseling. However, these results raise the possibility that effects as large as 2% or greater might be attained from clinician-delivered counseling, if adherence to the prescription intervention were established.

Both bivariate and multivariate analyses showed significant associations for dose. The multivariate analyses cannot rule out sampling bias, but because the "dose effect" was apparent even after adjustment for demographic characteristics, cluster effects, and theoretically important possible determinants (e.g., peer models), the credibility of these results reflecting intervention effects is enhanced. Youth receiving four or more prescriptions were 50% to 68% as likely to initiate tobacco use as youth who received none or one prescription. A difference of this magnitude supports the argument for replicating this trial under conditions that ensure clinician adherence.

Orthodontists were selected for this study because they routinely see patients six to eight times a year. However, there are other clinicians who see adolescent patients multiple times during a course of treatment (e.g., for acne, diabetes, allergies). Furthermore, health care providers who see adolescents less frequently could produce a synergistic impact if multiple anti-tobacco messages were provided to the same youth from several health professionals (e.g., for dental hygiene, vision correction, accidents/injury care). The results from this study inform the as yet inadequately explored potential of clinicians to prevent tobacco use initiation.

Although the demographic characteristics of individuals using clinical health services are not representative of the ethnic distribution of the population at large, individuals most likely to initiate tobacco use may be represented. For example, Anglos are at higher risk for tobacco use than Black or Hispanic adolescents.[31,32] Thus, providing tobacco prevention messages to a clinical population that is overrepresented by Anglos may channel resources more efficiently. In the case of tobacco use prevention, skewed demographic characteristics of a popula-

tion receiving clinical services may not be a weakness.

This study also provided important information regarding the possible etiology of tobacco initiation. A number of social and behavioral variables proved strongly and significantly related to incidence. For instance, youth whose friends avoid smokers were almost half as likely to initiate tobacco use, and those who had been offered tobacco were more than twice as likely to start as those who had not been offered. These results are consistent with the theoretical and empirical role of peer influence. The corroboration of these associations suggests that interventions should be directed to changing youths' peer-influence networks with regard to tobacco. Future trials of clinician-delivered counseling might be more effective if the content of counseling were explicitly directed toward enhancing peer relationships that were unlikely to support tobacco use.

The results of this trial suggest the means by which clinician-delivered counseling might be effective in reducing adolescents' tobacco initiation. It is recommended that future studies ensure at least four counseling contacts per year and that some or all of these be directed toward resisting peer pressure for tobacco use and enhancing peer relationships in opposition to tobacco use. Future studies should include procedures designed to increase clinician adherence. These might be larger reimbursement payments, more training in adolescent counseling, and more tracking procedures or "cues" to include counseling in an otherwise busy office routine. Finally, future studies should consider more powerful interventions delivered by clinicians. These might be counseling that is more substantive, longer, or more frequent. □

## Acknowledgments

This study was supported by funds provided by the Cigarette and Tobacco Surtax Fund of the State of California through the Tobacco-Related Disease Research Program of the University of California, grant 2RT0106, awarded to Dr Hovell, and by the Center for Behavioral Epidemiology and Community Health, Graduate School of Public Health, San Diego State University.

Special recognition and thanks go to the following members of the research team whose significant efforts made this study possible: Mary K. Beckhelm, RN, MPH; James H. Dwyer, PhD; Ernest S. Follico, DDS, MS; Robert E. French, DDS, MS; Kristen Keating, MPH; Theodore Morrison, MPH; Daniel S. Mullins, DDS; Stergios Russos, MPH; David Rynearson, DDS; David Schweitzer, DMD; Steven Shepherd, MPH: Julian Singer, DDS, MS; Paul Styrt, DDS, MPH; Dennis Wahlgren, MA; Gerd Wolman, DDS; and Joy Zakarian, MPH. In addition, we would like to thank the California State Society of Orthodontists and the American Association of Orthodontists for their support of the study and assistance with recruitment. Many of the materials for the intervention were provided at cost from the American Cancer Society, the American Lung Association, and the American Heart Association.

## References

1. Centers for Disease Control. *Reducing the Health Consequences of Smoking: 25 Years of Progress—A Report of the Surgeon General.* Rockville, Md: US Public Health Service; 1989. DHHS publication CDC 89-8411.
2. Kreuter MK, Powell KE. Psychosocial predictors of smoking among adolescents. *MMWR.* September 4, 1987;36:1S–2S.
3. Moss AJ, Allen KF, Giovino GA, Mills SL. Recent trends in adolescent smoking, smoking-uptake correlates, and expectations about the future. *Adv Data Vital Health Stat.* December 2, 1992;221.
4. Centers for Disease Control. Smoking cessation during previous year among adults: United States, 1990 and 1991. *MMWR.* July 9, 1993;42(26):504–507.
5. Hatziandreu EJ, Pierce JP, Lefkoloulou M, Fiore MC, Mills SL. Quitting smoking in the United States in 1986. *J Natl Cancer Inst.* 1990;82:1402–1406.
6. Pierce JP, Fiore MC, Novotny TE, Hatziandreu EJ, Davis RM. Trends in cigarette smoking in the United States: projections to the year 2000. *JAMA.* 1989;261(1):61–65.
7. Pierce JP, Evans N, Farkas AJ, et al. *Tobacco Use in California: An Evaluation of the Tobacco Control Program 1989–1993.* Sacramento, Calif: California Department of Health Services; 1994.
8. Fiore MC, Pierce JP, Remington PL, Fiore BJ. Cigarette smoking: the clinician's role in cessation, prevention, and public health. *Dis Mon.* 1990;36(4):181–242.
9. Glynn TJ, Manley MW, Pechacek TF. Physician initiated smoking cessation program: the National Cancer Institute trials. *Progress Clin Biol Res.* 1990;339:11–25.
10. Kottke TE, Battista RN, DeFriese GH, Brekke ML. Attributes of successful smoking cessation interventions in medical practice: a meta-analysis of 39 controlled trials. *JAMA.* 1988;259:2882–2889.
11. Russell MAH, Wilson C, Taylor C, Baker CD. Effect of general practitioners' advice against smoking. *BMJ.* 1979;2(6184):231–235.
12. Epps RP, Manley MW. The clinician's role in preventing smoking initiation. *Med Clin North Am.* 1992;76(2):439–449.
13. Hovell MF, Black DR. Minimal intervention and arthritis treatment: implications for patient and physician compliance. *Arthritis Care Res.* 1989;2(3):S65–S70.
14. Stevens VJ, Severson H, Lichtenstein E, Little SJ, Leben J. Making the most of a teachable moment: a smokeless-tobacco cessation intervention in the dental office. *Am J Public Health.* 1995;85(2):231–235.
15. Hovell MF, Russos S, Beckhelm MK, et al. Compliance with primary prevention in private practice: creating a tobacco-free environment. *Am J Prev Med.* 1995;11(5):288–293.
16. Russos S, Hovell MF, Keating K, et al. Clinician compliance with primary prevention of tobacco use: the impact of social contingencies. *Prev Med.* In press.
17. Norusis MJ. *SPSS/PC + Base Systems User's Guide, Version 5.0.* Chicago, Ill: SPSS Inc; 1992.
18. Statistics and Epidemiology Research Corp. *EGRET reference manual.* Seattle, Wash: Statistics and Epidemiology Research Corp; 1992.
19. Akers RL, Massey J, Clarke W, Lauer RM. Are self-reports of adolescent deviance valid? biochemical measures, randomized response, and the bogus pipeline in smoking behavior. *Soc Forces.* 1983;62:234–251.
20. Hovell M, Slymen DJ, Keating KJ, et al. Tobacco use prevalence and correlates among adolescents in a clinician-initiated prevention trial in California. *J Epidemiol Community Health.* 1996;50:340–346.
21. Becker M, Janz N. Practicing health promotion: the doctor's dilemma. *Ann Intern Med.* 1990;113:419–422.
22. Hovell M, Kaplan R, Hovell F. Analysis of preventive medical services in the United States. In Lamal PA, ed. *Behavioral Analysis of Societies and Cultural Practices.* New York, NY: Hemisphere Publishing Corp; 1991.
23. Donner A, Birkett N, Buck C. Randomization by cluster: sample size requirements and analysis. *Am J Epidemiol.* 1981;114:906–913.
24. Cleary PD, Hitchcock JL, Semmer N, Flinchbaugh LJ, Pinney JM. Adolescent smoking: research and health policy. *Milbank Q.* 1988;66:137–171.
25. Best JA, Thomson SJ, Santi SM, Smith EA, Brown KS. Preventing cigarette smoking among school children. *Annu Rev Public Health.* 1988;9:161–201.
26. Elder JP, Wildey MB, De Moor C, et al. The long-term prevention of tobacco use among junior high school students: classroom and telephone interventions. *Am J Public Health.* 1993;83:1239–1244.
27. Mittelmark MB, Luepker RV, Jacobs DR Jr, et al. Community-wide prevention of cardiovascular disease: education strategies of the Minnesota Heart Health Program. *Prev Med.* 1986;15:1–17.
28. Luepker RV, Murray DM, Jacobs DR Jr, et al. Community education for cardiovascular disease prevention: risk factor changes in the Minnesota Heart Health Program. *Am J Public Health.* 1994;84:1383–1393.
29. The COMMIT Research Group. Community intervention trial for smoking cessation (COMMIT): I. Cohort results from a four-year community intervention. *Am J Public Health.* 1995;85(2):183–192.
30. Greenwald P, Sondik EJ. *Cancer Control Objectives for the Nation: 1985–2000.* Washington, DC: Division of Cancer Prevention and Control, National Cancer Institute; 1986:1–93. NCI Monographs 2.
31. O'Malley PM, Johnston LD, Bachman JG. Adolescent substance use: epidemiology and implications for public policy. *Pediatr Clin North Am.* 1995;42(2):241–260.
32. Burns D, Pierce JP. Tobacco use in California 1990–1991. Sacramento, Calif: California Dept of Health Services; 1992.
33. Hosmer DW, Lemeshow S. *Applied Logistic Regression.* New York, NY: John Wiley & Sons; 1989:14–16.