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# Teen Reach: Outcomes From a Randomized, Controlled Trial of a Tobacco Reduction Program for Teens Seen in Primary Medical Care

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**ABSTRACT.** *Objective.* To test the long-term efficacy of brief counseling plus a computer-based tobacco intervention for teens being seen for routine medical care.

*Methods.* Both smoking and nonsmoking teens, 14 to 17 years of age, who were being seen for routine visits were eligible for this 2-arm controlled trial. Staff members approached teens in waiting rooms of 7 large pediatric and family practice departments within a group-practice health maintenance organization. Of 3747 teens invited at  $\geq 1$  visits, 2526 (67%) consented and were randomized to tobacco intervention or brief dietary advice. The tobacco intervention was individually tailored on the basis of smoking status and stage of change. It included a 30-second clinician advice message, a 10-minute interactive computer program, a 5-minute motivational interview, and up to two 10-minute telephone or in-person booster sessions. The control intervention was a 5-minute motivational intervention to promote increased consumption of fruits and vegetables. Follow-up smoking status was assessed after 1 and 2 years.

*Results.* Abstinence rates after 2 years were significantly higher for the tobacco intervention arm, relative to the control group, in the combined sample of baseline smokers and nonsmokers (odds ratio [OR]: 1.23; 95% confidence interval [CI]: 1.03–1.47). Treatment effects were particularly strong among baseline self-described smokers (OR: 2.42; 95% CI: 1.40–4.16) but were not significant for baseline nonsmokers (OR: 1.25; 95% CI: 0.97–1.61) or for those who had “experimented” in the past month at baseline (OR: 0.95; 95% CI: 0.45–1.98).

*Conclusions.* Brief, computer-assisted, tobacco intervention during routine medical care increased the smoking cessation rate among self-described smokers but was less effective in preventing smoking onset. *Pediatrics* 2005;115:981–989; tobacco, adolescents, intervention, cessation, primary care.

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ABBREVIATIONS. OR, odds ratio; CI, confidence interval; GEE, generalized estimating equations; PTC, Pathways to Change.

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Tobacco use remains the number 1 cause of preventable morbidity and death in the United States, each year resulting in >430 000 deaths,<sup>1</sup> >5 million years of potential life lost,<sup>2</sup> and \$50 billion of direct medical expenditures related to smoking alone.<sup>3</sup> Among adults who have ever smoked daily, 82% first tried cigarettes and 53% smoked daily before age 18 years.<sup>4</sup> According to recent estimates, almost one half of current adolescent smokers who continue to smoke regularly will die from a smoking-related disease.<sup>5</sup>

After several decades of decline, rates of smoking in the past month increased in the early 1990s for grades 9 through 12 and peaked in 1997 at 37% for grade 12. Smoking rates have since declined but remain unacceptably high at ~27% for 12th-graders.<sup>6</sup> Rates of adolescent smoking are higher among whites (40%) than among either Hispanics (34%) or blacks (23%).<sup>5</sup> Male and female adolescents have similar smoking rates, except among blacks (only 17% of high school girls smoke cigarettes, compared with 28% of boys).<sup>5</sup> For most adolescent subgroups, rates of tobacco use must be at least halved to meet Healthy People 2010 targets.<sup>5</sup>

Tobacco use can be reduced among youths by preventing (or delaying) initiation and promoting cessation. The large volume of research on smoking prevention in schools and communities has been summarized in several government reports<sup>4,7</sup> and meta-analyses.<sup>8</sup> Although many interventions based on social influence or life skills training show significant short-term results, the effects dissipate over time. A comprehensive, long-term study by Peterson et al<sup>9</sup> showed no effects for a multiyear, school-based, prevention program, which provides sobering evidence of the limitations of school-based programs alone. A recent smoking prevention intervention among families enrolled in 2 managed care organizations similarly found no effect on smoking susceptibility or experimentation among preteens.<sup>10</sup> Comprehensive programs that include both school-based and community components show more durable effects.<sup>11,12</sup> The clinical care setting is a potentially important, unexplored contributor to youth tobacco use prevention and cessation efforts.

In contrast to prevention programs, few adolescent cessation programs have been evaluated rigorously.<sup>13</sup> School-based cessation programs, even when preceded by extensive formative research,<sup>14</sup> typically recruit few smokers in that setting, experience high

attrition rates, and produce low cessation rates.<sup>4</sup> Very few studies have recruited adolescents in medical settings or used state-of-the-art approaches, such as computer-based expert systems.<sup>15</sup> To date, these studies have been limited by nonexperimental designs and/or short-term outcomes.

The Teen Reach (Research Approaches to Cancer in a Health Maintenance Organization) program was a randomized, controlled trial of the long-term efficacy of brief clinician advice, the Pathways to Change (PTC) interactive computer program,<sup>15,16</sup> and brief motivational counseling to reduce the prevalence of smoking among teens seen for routine medical care. This population-based, individually tailored intervention capitalized on the teachable moment present at the primary care physician visit and the attractiveness to teens of a multimedia, computer-based, interactive program. Other attributes of this strategy included (1) a focus on the whole population of adolescents (whether smoking at entry or not), (2) a stage-based, theory-driven intervention, (3) the ease and practicality of the intervention for clinicians, and (4) the relatively low cost of delivering the intervention to teens during routine medical care.

## METHODS

### Setting

Participants were adolescent members of Kaiser Permanente Northwest, a health maintenance organization in the Portland, Oregon, and Vancouver, Washington, metropolitan areas that serves ~450 000 individuals. Pediatrics and family practice departments at 7 Kaiser Permanente Northwest medical centers participated in the study during a 23-month recruitment period, from October 1997 through August 1999.

### Participants

Figure 1 shows the flow of participants through the study. Study staff members scanned electronic appointment records to identify age-eligible teens with appointments at participating medical centers. Staff members invited adolescent primary care patients waiting to see their physician or allied health care provider to participate in a study of "healthy lifestyles and changes in health habits." Eligibility criteria included age 14 through 17 years, willingness to stay after the visit for ~15 minutes, and no intention to leave the geographic area within 1 year. No incentives were offered. Subjects who agreed to participate signed consent forms and completed short, self-administered questionnaires. We assigned participants randomly to either a tobacco prevention/cessation intervention or a brief dietary intervention (both described below). Hollis et al<sup>17</sup> provided additional details about recruitment and characteristics of the study sample.

### Randomization

Random assignment to the smoking intervention group or diet intervention group was blocked over time and stratified according to medical center and 30-day cigarette smoking status (smoked or did not smoke) at study enrollment. Study staff members not involved in recruitment or randomization printed the stratified allocation assignments on index cards and concealed the cards in envelopes. Recruitment/intervention staff members opened the envelopes after gaining teens' written consent to participate in the study and determining the teens' smoking status from questionnaire responses. The Kaiser Permanente Northwest institutional review board approved and monitored this study.

### Tobacco Intervention

We designed the tobacco intervention to reduce the prevalence of cigarette smoking by preventing smoking uptake among non-smokers and increasing cessation among smokers. The intervention included 3 primary elements at the enrollment visit. (1) Staff members provided a written prompt (ie, a suggested 30–60-second advice message) to primary care clinicians to encourage teens to quit smoking or to not start. Clinicians were also asked to encourage the patient to talk briefly with a health counselor (study

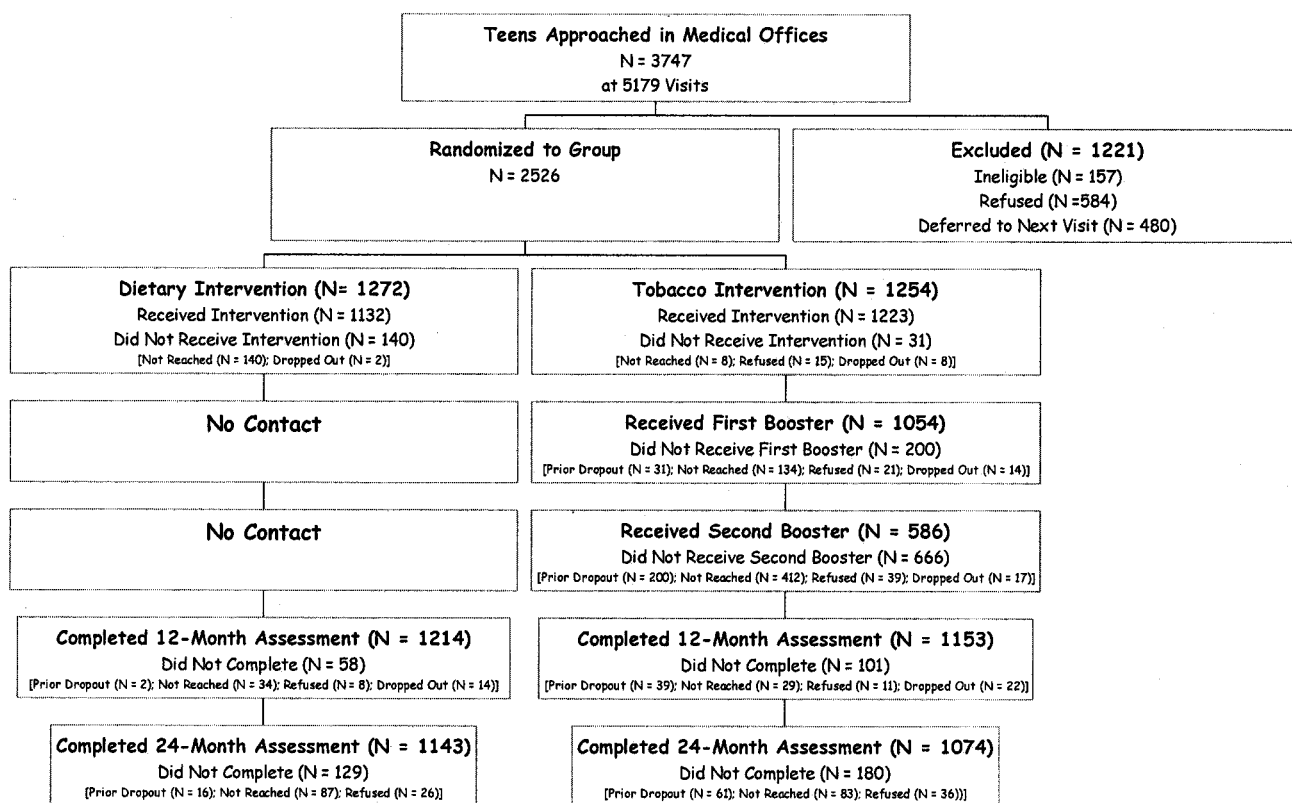


Fig 1. Flow of participants through the study.

staff member) immediately after the visit. (2) Teens had a 10- to 12-minute session on a computer with the PTC expert system, which was developed by Prochaska, Velicer, and colleagues<sup>16,18,19</sup> for use with adolescent nonsmokers and smokers. This multimedia interactive version of the print-based system has been successful in trials with adult smokers.<sup>20-23</sup> The PTC program assessed the stage of readiness to begin smoking (for nonsmokers) or the stage of change to quit smoking (for smokers) and then delivered highly individualized advice and encouragement tailored to the teen's reported readiness stage. The program included brief (5-10-second), stage-relevant, teen testimonial movies and graphics designed specifically to appeal to teens. (3) Teens had 3 to 5 minutes of post-PTC motivational counseling with bachelor's or master's degree-level health counselors trained in motivational interviewing techniques.<sup>24</sup> Handouts included a synopsis of the stage-relevant advice or encouragement generated by the PTC program, topic-specific information sheets generated by the computer program as requested by the participant, and small quit kits (eg, cinnamon sticks and Pez candy dispensers) to encourage nonsmoking.

In addition, we conducted 2 individual booster sessions with the PTC and health counselor during the next 11 months. Whenever possible, counselors met with teens at future visits within the intervention contact window to deliver the intended follow-up interventions. In practice, counselors conducted most follow-up intervention sessions via telephone, reading the text of the computer queries and advice messages to the teen and mailing the printed reports generated by the PTC program. Counselors made up to 25 contact attempts at a variety of day, evening, and weekend times, left up to 5 telephone messages, and sent up to 2 letters requesting callbacks.

### Diet Intervention

Teens allocated to the diet intervention served as attention control subjects. Health counselors provided 3 to 5 minutes of motivational counseling to promote increased consumption of fruits and vegetables. The recommendations followed the National Cancer Institute Five-a-Day campaign. Counselors provided teens with 2 nutritional information brochures and a small snack-packet of fruit leather. This intervention did not include a computer component. We assumed that some teens would also receive brief tobacco advice as a part of usual care, but we did not prompt clinicians.

### Intervention Training and Quality Assurance

Counselors used motivational interviewing techniques<sup>24</sup> during the structured counseling sessions for both the tobacco and diet interventions. The lead health behavior interventionist, a master's degree-level counselor with substantial experience in adolescent health behavior changes, provided the initial counselor training and monitored quality and consistency over time. Interventionists conducted solo sessions only after completing training certification. In the field, interventionists documented components of intervention delivery, including whether they notified the clinician to deliver the brief advice message for the tobacco intervention group. These data were monitored to evaluate the quality of intervention delivery.

To assess the frequency of clinician tobacco cessation advice, research staff members asked participants in both study groups whether their clinician discussed any of the following topics during the visit: nutrition, sun exposure, tobacco use, and exercise. These questions were completed immediately after the consultation with the clinician and, for treatment subjects, just before receiving other intervention components (eg, the computer program).

### Follow-up Assessments

A combination of mailed questionnaires and telephone interviews (for those who did not respond to the mailing) provided outcome data after follow-up periods of 1 and 2 years. One month before each annual anniversary of the teen's enrollment, research staff members mailed a questionnaire and a cover letter to the teen. Two weeks later, we mailed a second questionnaire if the first had not been returned. Two weeks after the second mailing, if necessary, study staff members attempted contact via telephone.

Blinded study personnel conducted all follow-up assessments. To enroll more participants, we extended the recruitment period beyond our original plans and thus reduced the calendar time available for the 2-year assessment. The second annual follow-up period was therefore truncated by 2 to 3 weeks for the last 140 participants enrolled in the study. The mean follow-up period from study enrollment was 12.4 months (SD: 0.84) for the first assessment and 24.4 months (SD: 0.80) for the second assessment. Follow-up assessments were completed by the end of September 2001.

## Measures

### Outcomes

The primary outcome of the study was the proportion of teens who reported no smoking in the 30 days before the 1- and 2-year follow-up assessments. We hypothesized that abstinence rates would be higher in the tobacco treatment group, compared with the diet control group. Our projected sample size of 2538 assumed a usual care smoking prevalence at follow-up evaluations of ~30% (actual value: 31.4%),  $\alpha$  of .05, 0.85 power, a 2-tailed test for the difference in proportions, and a 20% reduction in smoking prevalence in the treatment group. We also used self-reported 30-day use of cigarettes, cigars, pipes, and chewing tobacco at follow-up evaluations to assess abstinence from all forms of tobacco.

### Covariates

Table 1 lists additional sociodemographic, tobacco use, and health-habit measures. We briefly summarize these measures here; Hollis et al<sup>17</sup> described them in more detail. We based the depression screen on the 3 items recommended by Rost et al.<sup>25</sup> Stage of acquisition for smoking and stage of smoking cessation were based on the algorithms described by Pallonen et al.<sup>26</sup> Susceptibility to smoking in the next year was based on the algorithm described by Pierce et al.<sup>27,28</sup>

An index of 6 questions derived from the National Cancer Institute Five-a-Day campaign and used previously in dietary research<sup>29,30</sup> provided measures of consumption of servings of fruits, vegetables, and combined fruits and vegetables. French fries were excluded from this measure. A square root transformation was applied to improve normality, and we excluded the overall index scores if >2 items were missing.

### Analyses

We compared characteristics of the study groups at baseline by examining percentage distributions of categorical variables and means of continuous variables. We used a generalized estimating equations (GEE) approach for repeated categorical measures to assess the effects of the tobacco intervention across the 2 follow-up years. In these models, treatment group-time interactions provided the tests of hypothesized treatment effects. The primary test of the tobacco intervention's efficacy was the overall difference in rates of abstinence from smoking at follow-up evaluations. Secondary questions of interest, however, were whether the tobacco intervention reduced smoking onset among baseline nonsmokers, promoted cessation among baseline smokers, or both. Consequently, we examined GEE models for cigarette nonsmokers and smokers (30-day use) at baseline and for subcategories within these groups on the basis of a question about self-described smoking status. Most analyses were conducted with SAS software,<sup>31</sup> although we used the Solas software package<sup>32</sup> for the multiple-imputation procedure described below.

### Missing Data Imputation

Because of the current debate regarding how to handle missing data in tobacco trials, we examined study outcomes by using 6 alternative methods for handling missing smoking outcome data.<sup>33,34</sup> The first method used the available raw data (ie, "complete cases"), with no adjustments and no imputation for missing data. The second approach, propensity analysis, adjusted the intervention effect at each follow-up time for differences in participants' predicted propensity for being lost to follow-up monitoring. The propensity model was based on baseline age, gender, race/ethnicity, smoking status, stage of change, friends' smoking, smokers in the home, educational aspirations, BMI, exercise patterns, and

**TABLE 1.** Baseline Characteristics According to Study Group

Characteristics	Study Group				Total	
	Treatment		Control		No.	%
	No.	%	No.	%		
No.	1254		1270		2524*	
Female	738	58.9	758	59.6	1496	59.2
Age						
14 y	345	27.5	329	25.9	674	26.7
15 y	316	25.2	334	26.3	650	25.7
16 y	321	25.6	316	24.8	637	25.2
17 y	272	21.7	293	23.0	565	22.4
Ethnicity						
Black	60	4.8	58	4.6	118	4.7
Asian/Pacific Islander	47	3.8	46	3.6	93	3.7
Hispanic/Latino	56	4.5	62	4.9	118	4.7
Native American/Alaskan Native	24	1.9	29	2.3	53	2.1
White	989	79.6	973	76.9	1962	78.2
Other	67	5.4	97	7.7	164	6.5
Highest level of schooling planned						
Less than high school graduate	16	1.3	13	1.0	29	1.2
High school	81	6.5	101	8.0	182	7.2
2-y college or technical school	211	16.9	199	15.7	410	16.3
4-y college or more	938	75.3	951	75.2	1889	75.3
Exercises for ≥30 min						
Once a week or less	305	24.4	312	24.6	617	24.5
More than once a week	947	75.6	958	75.4	1905	75.5
BMI (tertiles)						
Lower (<20.7)	390	31.1	400	31.5	790	31.3
Middle (20.7–23.7)	384	30.6	400	31.5	784	31.0
Higher (>23.7)	412	32.9	391	30.7	803	31.8
Unknown (missing height or weight)	68	5.4	81	6.4	149	5.9
Tried to lose weight in past year?	572	45.7	596	46.9	1168	46.3
How many friends smoke cigarettes?						
Few or none	743	59.4	737	58.1	1480	58.7
Up to approximately one half	266	21.3	288	22.7	554	22.0
More than one half	243	19.4	244	19.2	487	19.3
No. of smokers in home						
None	803	64.2	771	60.8	1574	62.5
≥1	448	35.8	498	39.3	946	37.6
Positive screen for depressive disorder	606	48.5	689	54.3	1295	51.4
Smoking acquisition stage						
Acquisition precontemplation	886	91.7	883	90.7	1769	91.2
Acquisition contemplation	48	4.9	49	5.0	97	5.0
Acquisition preparation	32	3.3	42	4.3	97	3.8
Smoking cessation stage						
Cessation precontemplation	52	18.5	53	18.7	105	18.6
Cessation contemplation	58	20.6	64	22.5	122	21.6
Cessation preparation	60	21.4	57	20.1	117	20.7
Cessation action	82	29.2	76	26.8	158	28.0
Cessation maintenance	29	10.3	34	12.0	63	11.1
Susceptible to smoke in 1 y	491	39.2	519	40.8	1010	40.0

All comparisons were nonsignificant at  $P < .05$  except for depression screen results ( $P < .01$ ).

\* Subtotals vary slightly because of missing data, and 2 deceased subjects in the diet condition were excluded.

depression. The third approach, the pattern-mixture method, adjusted the intervention effect for differences in the pattern of missing data (ie, no missing data, missing at either year 1 or year 2, or missing at both year 1 and year 2).

The last 3 methods imputed missing outcome data in various ways. Method 4 assigned the baseline value when follow-up smoking status was missing. Method 4 was equivalent to the traditional “intent-to-treat” procedure for baseline smokers, but baseline nonsmokers with missing outcomes were assumed to still be nonsmokers. Method 5, a single-imputation regression approach, used a combination of baseline variables (ie, same as for the propensity analysis) to predict and impute missing outcomes. Finally, a multiple-imputation regression approach used these same baseline predictor variables but created and then averaged 5 imputed values for each missing case. Multiple imputation provides a more accurate estimate of the variance for the intervention effect than does single imputation. Conclusions were largely consistent among the various missing-data procedures, and we there-

fore relied on the multiple-imputation procedure for our primary presentation of the main outcomes.

## RESULTS

### Recruitment and Patient Characteristics

Figure 1 shows that 67% of teens (2526 of 3747 teens) approached ≥1 times in medical office waiting rooms consented to the study and were randomized. Table 1 presents baseline characteristics, smoking influences among family and friends, status on a depression screen, smoking status, stage of readiness for smoking acquisition or cessation, and smoking susceptibility. The tobacco and diet study arms were similar with respect to all items, with the exception of a small but significant difference in the proportions

of subjects who screened positive for depressive symptoms.

### Intervention Process Measures

Table 2 shows that a high percentage of clinicians in the tobacco arm received a written prompt to deliver brief tobacco advice. Immediately after the clinical encounter, patients in the tobacco arm were somewhat more likely than those in the diet arm to report that their clinician discussed the tobacco issue, although only 41% recalled such advice. As expected, reports of discussions of other lifestyle topics were similar in the 2 treatment groups.

Almost all participants (97.5%) in the tobacco arm received the baseline computer- and counselor-delivered intervention components (mean length: 15.9 minutes), most received at least 1 computer-assisted booster session (in person or via telephone), and approximately one half completed 2 booster sessions. Most (89%) in the diet arm received brief dietary counseling (mean length: 6.7 minutes) to increase consumption of fruits and vegetables. An index of the counselors' ratings of the participants' talkativeness, friendliness, interest, and cooperativeness showed similar levels of rapport in the tobacco and diet groups (15.2 vs 15.3;  $P = .34$ ).

### Loss to Follow-up Monitoring

Both annual assessments achieved high response rates, with 2367 of 2526 subjects (93.7%) completing the 1-year follow-up assessment (963 by mail and 1404 by telephone) and 2218 of 2526 (87.8%) completing the 2-year follow-up assessment (743 by mail and 1474 by telephone). Figure 1 shows the reasons for nonresponse at each assessment. Loss to follow-up monitoring at 2 years was significantly greater ( $P < .001$ ) in the tobacco arm (181 of 1254 subjects, 14.3%), compared with the diet arm (128 of 1272 subjects, 10.1%), primarily because those in the tobacco arm had more contact with staff members and thus more opportunities to decline participation.

### Diet Treatment Outcomes

Self-reported servings of fruits and vegetables combined did not differ for subjects in the diet control group and the tobacco arms at baseline (3.66 vs 3.63,  $P > .78$ ), 1 year (3.59 vs 3.62,  $P > .77$ ), or 2 years (3.61 vs 3.60,  $P > .92$ ). Similarly, no treatment effects were seen for intake of fruits alone at 1 year (0.99 vs 1.02,  $P > .40$ ) or 2 years (0.97 vs 0.95,  $P > .80$ ) or intake of vegetables alone at 1 year (1.50 vs 1.49,  $P > .92$ ) or 2 years (1.50 vs 1.46,  $P > .48$ ).

### Tobacco Treatment Outcomes

Table 3 shows the proportions of participants who were smoke-free for  $\geq 30$  days at the 1- and 2-year assessments, with planned contrasts from a GEE analysis for treatment effects at each follow-up time, relative to baseline. We imputed missing values by using a baseline regression model with multiple imputations. The tobacco intervention, relative to the diet arm, increased significantly the proportion of all participants (ie, both smokers and nonsmokers at baseline) who were smoke-free for 30 days at the 1-year assessment. This modest treatment effect diminished somewhat by the time of the 2-year assessment but remained statistically significant. Treatment effects did not vary according to (ie, interact with) facility. A similar pattern of results applied when the outcome was defined as no tobacco use (including pipes, cigars, and smokeless tobacco) (data not shown).

Among the nonsmokers at baseline (77%), the tobacco intervention significantly reduced smoking onset at the 1-year assessment, but this prevention effect was no longer significant by year 2. Among all those who had smoked  $\geq 1$  cigarettes in the past 30 days at baseline (ie, experimenters, smokers, and recent quitters), the tobacco intervention produced significant effects at both the 1- and 2-year assessments, although the intervention had no effect on the small subgroup ( $n = 140$ ) of self-described experimenters at baseline. In contrast, the tobacco intervention had a strong cessation effect among those who

**TABLE 2.** Process Indicators of Intervention Delivery According to Study Group

Indicator/Measure	Study Group				P
	Treatment (n = 1254)		Control (n = 1272)		
	No.	%	No.	%	
Clinician prompted to give tobacco message	1012	80.8	NA	NA	NA
Teen recalls clinician discussion of*					
Tobacco	443	40.9	325	28.8	<.0001
Nutrition	210	19.4	208	18.5	NS
Ultraviolet radiation	56	5.2	45	4.0	NS
Exercise	326	30.1	332	29.5	NS
Teen completed intervention att†					
Baseline	1223	97.5	1132	89.0	
Booster 1	1054	84.0	NA	NA	
Booster 2	586	46.7	NA	NA	

NA indicates not applicable; NS, not significant.

\* Denominators exclude 170 missing data in the tobacco intervention group and 145 missing data in the diet intervention group.

† Values exclude 52 missing data among those who received the baseline tobacco intervention and 64 missing data among those who received the baseline diet intervention.

**TABLE 3.** Percent Smoke-Free and GEE ORs and CIs at 1 and 2 Years, According to Study Group and Baseline Smoking Status

Baseline Smoking Status	No.	Year 1 Assessment			Year 2 Assessment		
		Treatment, %	Control, %	OR (95% CI)	Treatment, %	Control, %	OR (95% CI)
All participants	2524*	77.2	72.8	1.27 (1.08–1.51)	72.8	68.6	1.23 (1.03–1.47)
Nonsmokers	1935*	90.8	87.9	1.37 (1.01–1.85)	85.8	83.1	1.25 (0.97–1.61)
Smoked in past 30 d	589†	32.5	23.1	1.55 (1.05–2.31)	29.7	20.9	1.55 (1.02–2.36)
Experimenters	140	46.4	50.0	0.80 (0.40–1.60)	49.7	48.7	0.95 (0.45–1.98)
Smokers	448‡	28.4	13.8	2.45 (1.43–4.20)	23.9	11.4	2.42 (1.40–4.16)

Smoke-free was defined as no cigarettes in the past 30 days, with multiple imputation for missing values at follow-up visits.

\* Excludes 2 subjects who died before the first follow-up assessment.

† Includes both self-described experimenters and smokers and 1 teen who had smoked within 30 days but did not provide self-description data.

‡ Includes those who smoked in the past 30 days and who described themselves as either smokers or former smokers at baseline.

considered themselves to be smokers at baseline (odds ratio [OR]: 2.4; 95% confidence interval [CI]: 1.40–4.16). Conclusions were similar when the outcome was defined as no tobacco in the past 30 days.

In separate posthoc analyses of baseline self-described smokers, the tobacco intervention produced a statistically significant effect among nonwhites (OR: 4.10; 95% CI: 1.01–16.71), despite the small sample size and large CI. The OR was nearly double that seen for whites (OR: 2.16; 95% CI: 1.14–4.08), although the CIs for whites and nonwhites overlapped. In process analyses for all participants in the tobacco treatment arm only, quit rates were higher among those who completed 1 (OR: 2.65; 95% CI: 1.89–3.73) or 2 (OR: 4.03; 95% CI: 2.87–5.65) booster calls, compared with those who completed none. The same was true for baseline nonsmokers who received 1 (OR: 2.72; 95% CI: 1.35–5.47) or 2 (OR: 2.89; 95% CI: 1.48–5.60) booster calls but not for the smaller group of baseline regular smokers (OR: 2.00; 95% CI: 0.83–4.90; and OR: 1.88; 95% CI: 0.73–4.83; respectively). Table 4 shows the ORs and CIs for treatment effects at the 2-year follow-up assessment with 6 alternate methods for handling missing data.<sup>33,34</sup> Results and conclusions were generally similar across methods. For baseline nonsmokers, the regression-based imputation yielded somewhat lower ORs than did imputing the baseline value (ie, assuming that baseline nonsmokers with missing data were still not smoking). For self-described smokers at baseline, the traditional intent-to-treat approach of imputing the baseline value (ie, imputing smoking for missing

values) yielded smaller but still strongly significant differences in 30-day abstinence rates between the diet and tobacco arms at 2 years (OR: 1.86; 95% CI: 1.07–3.23).

## DISCUSSION

In recruiting for this randomized trial of brief tobacco intervention for teens during routine medical care visits, we found that 67% of smoking and non-smoking adolescents 14 to 17 years of age were willing to extend their visits to receive counseling about tobacco or diet. The tobacco intervention included clinician advice combined with an interactive, computer-based, expert system and brief counseling and was designed to capitalize on both the teachable moment created by the clinical encounter and the appeal of interactive, computer-based technology. Other key attributes of this strategy were a focus on the whole population of adolescents (whether smoking at entry or not) and a highly tailored, theory-driven intervention.

Among the entire sample of baseline smokers and nonsmokers, the computer-assisted tobacco intervention produced a significant, albeit modest, reduction in self-reported smoking prevalence at both the 1- and 2-year follow-up assessments. Intervention effects for self-described smokers at baseline were considerably stronger, however, and these effects were largely maintained over 2 years of follow-up monitoring. The 2-year quit rate of 24% among self-defined smokers was high for a relatively brief intervention. This result was, however, within the 22% to

**TABLE 4.** Comparison of Effects of 6 Missing-Data Procedures on Intervention Results for Abstinence at 2 Years

Baseline Smoking Status	No.	OR (95% CI)					
		No Imputation			Imputation		
		No Adjustment	Propensity Model	Pattern Mixture	Baseline Value	Single Imputation	Multiple Imputation
All participants	2524*	1.26 (1.06–1.50)	1.43 (1.12–1.82)†	1.24 (1.03–1.48)	1.17 (1.00–1.36)	1.16 (0.98–1.36)	1.23 (1.03–1.47)
Nonsmokers	1935*	1.25 (0.96–1.63)	1.28 (0.98–1.68)	1.25 (0.96–1.64)	1.30 (0.99–1.69)	1.15 (0.91–1.46)	1.25 (0.97–1.61)
Smoked in past 30 d	589‡	1.67 (1.11–2.52)	1.76 (1.15–2.70)	1.68 (1.11–2.53)	1.29 (0.86–1.93)	1.68 (1.12–2.52)	1.55 (1.02–2.36)
Experimenters	140	1.05 (0.52–2.16)	1.03 (0.50–2.12)	1.05 (0.51–2.16)	0.85 (0.43–1.67)	1.16 (0.57–2.34)	0.95 (0.45–1.98)
Smokers	448§	2.43 (1.39–4.28)	2.55 (1.42–4.60)	2.45 (1.40–4.29)	1.86 (1.07–3.23)	2.43 (1.39–4.22)	2.42 (1.40–4.16)

\* Excludes 2 subjects who died before the first follow-up assessment.

† Based on a 1- and 2-year repeated-measures GEE model including baseline smoking status as a covariate.

‡ Includes both self-described experimenters and smokers and 1 teen who had smoked within 30 days but did not provide self-description data.

§ Includes those who smoked in the past 30 days and who described themselves as either smokers or former smokers at baseline.

25% cessation rate range reported for 4 adult smoking-cessation studies that used a print-based version of the multimedia expert system intervention used in this study.<sup>20-23</sup> If this approach was implemented broadly and achieved similarly high recruitment and quit rates, then the expected impact on cessation at the population level would be striking.

Quit rates were relatively high (ie, 21% at 2 years) among control subjects who reported at least 1 cigarette in the past 30 days at baseline. This subgroup, however, included self-described experimenters, of whom almost one half (48%) in the control group reported abstinence 2 years later. Among self-described baseline smokers in the control group, the abstinence rate was much lower (11%). Clearly, the smoking patterns of many experimenters are in flux, which might argue for longer (eg, 2-year) follow-up intervals than are common in studies of adults (eg, 6-12 months).

As has been true for school-based, smoking prevention programs,<sup>9</sup> our intervention was less effective in preventing smoking onset among baseline nonsmokers. Treatment effects were significant, although modest, at 1 year and became nonsignificant at the 2-year follow-up assessment. Similarly, no effects were seen among the small group of self-described recent experimenters who did not view themselves as smokers at entry. Why might tobacco prevention programs have so little effect on preventing onset among nonsmokers and those who are early in the tobacco uptake process? One possibility is that those who are still in the experimentation or social smoking phase fail to appreciate just how addicting tobacco really is. Previously, we reported<sup>17</sup> that most of these experimenters at baseline (76.3%) had no intention to smoke in the future. Indeed, many intend to smoke just at parties, to smoke only for a while, or to quit well before any serious health effects would befall them. Unfortunately, many do become addicted and remain long-term smokers. Increasing awareness about the actual frequency of addiction and long-term smoking may be useful.

We found no evidence that our control condition, a 3- to 5-minute motivational intervention, increased intake of fruits and vegetables. The tobacco intervention, however, was well received by patients. In addition to the high recruitment rate, we found that 98% of those randomized to the tobacco arm used the computer program and received brief counseling. Although clinicians were prompted to advise treatment participants but not control subjects, treatment participants were only modestly more likely than control subjects (41% vs 28%) to report that their clinician discussed tobacco during the visit. It is possible that teens under-reported clinicians' tobacco advice, although teens' reports were given immediately after the visit and just before use of the computer program. Most participants (84%) completed 1 follow-up support call, and nearly one half completed 2 calls after extensive efforts to reach them. Other posthoc correlational analyses showed that those in the treatment arm who completed booster calls were more likely to be abstinent. This finding could reflect a true "dose-response effect" or perhaps

could indicate simply that new and continuing smokers were less willing to take the calls. Although some teens were difficult to reach, it should be recalled that they were not volunteers who came to us for help with smoking. They were both smoking and nonsmoking patients with a wide range of interest in the tobacco issue who received a very brief intervention as a part of a routine visit.

Although the overall follow-up rates at 1 year (94%) and 2 years (88%) were high, loss to follow-up monitoring was somewhat greater in the treatment arm, compared with the control arm (14% vs 10%). We applied a variety of recommended methods to account for or impute missing data.<sup>33,34</sup> We found that the various methods had relatively little effect on the outcomes or conclusions about treatment effects. For baseline smokers, the traditional approach of imputing the baseline value (ie, assuming that smokers with missing values were still smoking) yielded a lower, although still clearly significant, OR. For nonsmokers at baseline, multiple imputation was more conservative than substituting the baseline value and assuming that they were still not smoking. An even more conservative approach would be to assume that all baseline nonsmokers with missing follow-up values had started smoking. This assumption is hard to justify, however, given that 83% to 86% of baseline nonsmokers with follow-up data were still abstinent. We view the multiple imputation method as the more reasonable and sophisticated approach for handling missing data for a population that includes both smokers and nonsmokers at baseline. It is reassuring that the various missing-data procedures had minimal impact on the overall study conclusions.

A limitation here is that our study sample was largely white (78%). Power was insufficient for specific race or ethnicity subgroup comparisons, but treatment effects for nonwhites were significant and at least as strong as those seen for whites. Another limitation is that our end points were based on self-reported smoking status, which might understate or bias actual smoking rates. Ideally, we would have confirmed biochemically the smoking status at both follow-up points, but current biochemical verification procedures are not well suited for detecting the light and/or occasional smoking patterns typical among adolescents. Because our aim was to conduct a real-life and highly externally valid study, we judged that limiting participation to only those adolescent patients willing to consent to come back for future face-to-face follow-up visits to provide saliva samples would not be feasible and would likely reduce substantially the participation rate and generalizability. The Society for Research on Nicotine and Tobacco Subcommittee on Biochemical Confirmation<sup>35</sup> also concluded that, in large-population, low-intensity, intervention trials, biochemical confirmation is often neither feasible nor desirable. Although self-report may inflate quit rates, the committee determined that the magnitude of such inflation is small and "rarely is differential across intervention conditions."<sup>35</sup> Verification is warranted for teens and/or adults where there is an incentive to deceive,

such as in diversion programs or when outcomes are shared with parents or other authority figures. This study had minimal incentives to deceive, because all participants were assured that their data would not be shared with either their parents or their clinician. In this relatively low-intensity, low-demand setting, we expect that misreporting would be modest, similar across groups, and unlikely to have accounted for the large treatment effects seen 2 years after treatment. The baseline age-specific prevalence of reported smoking in this population was also similar to that seen in anonymous statewide surveys, which suggests that most patients were willing to report honestly. However, reporting bias cannot be ruled out completely as a possible explanation for the findings.

The clinical context of our study and the individualized attention from trained counselors might have contributed to the strong effects on quitting among the youth smokers. A European study<sup>36</sup> used an earlier version of the same computer program in a classroom setting, with no adjunct counseling or follow-up support, and found no prevention or cessation effects. That study suffered from having non-equivalent groups at baseline and a relatively short follow-up period. A follow-up report found that lack of engagement in the intervention was a predictor of subsequent smoking.<sup>37</sup> One possibility is that individual patients in a clinical setting might be more likely to engage in the intervention than students in a classroom, although we could not assess this directly.

Although our intervention protocol was designed as a prototype for a practical, office-based strategy, research staff members delivered all aspects of the intervention other than the clinician's brief advice. In real-world practice, office staff members would need to assess smoking status, introduce the teen to the computer program, provide brief motivational counseling, and complete follow-up support. Highly motivated clinicians and support staff members could reasonably offer a similar intervention, but these components would likely prove challenging to integrate into most practice settings. Realistically, health care delivery systems will likely need additional research evidence and a more easily managed approach before they invest significant resources. Future research should explore ways to take advantage of the power and opportunity of clinical encounters while minimizing the time and training demands on clinicians. For example, clinical staff members could provide the first 3 A's (ie, ask, advise, and assess interest) and then refer interested teens for centralized, multisession, proactive, telephone counseling, combined with an interactive website that teens could access conveniently and repeatedly from home. Although they are potentially more practical, the efficacy of more centralized approaches needs to be determined, and we are currently testing 1 such model. We recommend currently that clinicians follow the US Public Health Service recommendations<sup>38</sup> for adolescents and routinely ask about smoking, offer brief advice, assess smokers' interest in quit-

ting, and provide brief assistance and follow-up monitoring as appropriate.

## CONCLUSIONS

This study is the first large randomized trial to test a brief computer-assisted tobacco prevention and cessation intervention for adolescents in a medical setting. The high acceptance rate, combined with the strong effects on cessation among both white and nonwhite adolescents, shows that a relatively brief tobacco intervention during routine office visits can help teen smokers quit.

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## REFERENCES

1. McGinnis JM, Foege WH. Actual causes of death in the United States. *JAMA*. 1993;270:2207-2212
2. Centers for Disease Control and Prevention. Smoking-attributable mortality and years of potential life lost: United States, 1984. *MMWR Morb Mortal Wkly Rep*. 1997;46:444-451
3. Centers for Disease Control and Prevention. Medical-care expenditures attributable to cigarette smoking: United States, 1993. *MMWR Morb Mortal Wkly Rep*. 1994;43:469-472
4. US Department of Health and Human Services. *Preventing Tobacco Use Among Young People: A Report of the Surgeon General*. Atlanta, GA: US Department of Health and Human Services; 1994
5. US Department of Health and Human Services. *Healthy People 2010*. Washington, DC: US Department of Health and Human Services; 2000
6. Johnston LD, O'Malley PM, Bachman JG. *The Monitoring the Future National Survey Results on Adolescent Drug Use: Overview of Key Findings, 2002*. Bethesda, MD: National Institute on Drug Abuse; 2003
7. Lynch BS, Bonnie RS. *Growing Up Tobacco Free: Preventing Nicotine Addiction in Children and Youths*. Washington, DC: National Academy Press; 1994
8. Bruvold WH. A meta-analysis of adolescent smoking prevention programs. *Am J Public Health*. 1993;83:872-880
9. Peterson AV Jr, Kealey KA, Mann SL, Marek PM, Sarason IG. Hutchinson Smoking Prevention Project: long-term randomized trial in school-based tobacco use prevention: results on smoking. *J Natl Cancer Inst*. 2000;92:1979-1991
10. Curry SJ, Hollis J, Bush T, et al. A randomized trial of a family-based smoking prevention intervention in managed care. *Prev Med*. 2003;37:617-626
11. Perry CL, Kelder SH, Murray DM, Klepp KI. Community-wide smoking prevention: long-term outcomes of the Minnesota Heart Health Program and the Class of 1989 Study. *Am J Public Health*. 1992;82:1210-1216
12. Biglan A, Ary DV, Smolkowski K, Duncan T, Black C. A randomized controlled trial of a community intervention to prevent adolescent tobacco use. *Tob Control*. 2000;9:24-32
13. Sussman S, Lichtman K, Ritt A, Pallonen UE. Effects of thirty-four adolescent tobacco use cessation and prevention trials on regular users of tobacco products. *Subst Use Misuse*. 1999;34:1469-1503
14. Sussman S, Dent CW, Stacy AW, et al. Project towards no tobacco use: one-year behavior outcomes. *Am J Public Health*. 1993;83:1245-1250
15. Pallonen UE, Velicer WF, Prochaska JO, et al. Computer-based smoking cessation interventions in adolescents: description, feasibility, and six-month follow-up findings. *Subst Use Misuse*. 1998;33:935-965

16. Velicer WF, Prochaska JO. An expert system intervention for smoking cessation. *Patient Educ Couns*. 1999;36:119–129
17. Hollis JF, Polen MR, Lichtenstein E, Whitlock EP. Tobacco use patterns and attitudes among teens being seen for routine primary care. *Am J Health Promot*. 2003;17:231–239
18. Redding CA, Prochaska JO, Pallonen UE, et al. Transtheoretical individualized multimedia expert systems targeting adolescents' health behaviors. *Cogn Behav Pract*. 1999;6:144–153
19. Velicer WF, Prochaska JO, Bellis JM, et al. An expert system intervention for smoking cessation. *Addict Behav*. 1993;18:269–290
20. Prochaska JO, DiClemente CC, Velicer WF, Rossi JS. Standardized, individualized, interactive, and personalized self-help programs for smoking cessation. *Health Psychol*. 1993;12:399–405
21. Velicer WF, Prochaska JO, Fava JL, Laforge RG, Rossi JS. Interactive versus non-interactive interventions and dose-response relationships for stage-matched smoking cessation programs in a managed care setting. *Health Psychol*. 1999;18:21–28
22. Prochaska JO, Velicer WF, Fava JL, et al. Counselor and stimulus control enhancements of a stage-matched expert system intervention for smokers in a managed care setting. *Prev Med*. 2001;32:23–32
23. Prochaska JO, Velicer WF, Fava JL, Rossi JS, Tsoh JY. Evaluating a population-based recruitment approach and a stage-based expert system intervention for smoking cessation. *Addict Behav*. 2001;26:583–602
24. Miller W, Rollnick S. *Motivational Interviewing*. New York, NY: Guilford Press; 1991
25. Rost K, Burnam MA, Smith GR. Development of screeners for depressive disorders and substance disorder history. *Med Care*. 1993;31:189–200
26. Pallonen UE, Prochaska JO, Velicer WF, Prokhorov AV, Smith NF. Stages of acquisition and cessation for adolescent smoking: an empirical integration. *Addict Behav*. 1998;23:303–324
27. Pierce JP, Farkas AJ, Evans N, Gilpin E. An improved surveillance measure for adolescent smoking? *Tob Control*. 1995;4(suppl 1):S47–S56
28. Pierce JP, Choi WS, Gilpin EA, Farkas AJ, Merritt RK. Validation of susceptibility as a predictor of which adolescents take up smoking in the United States. *Health Psychol*. 1996;15:355–361
29. Buller DB, Morrill C, Taren D, et al. Randomized trial testing the effect of peer education at increasing fruit and vegetable intake. *J Natl Cancer Inst*. 1999;91:1491–1500
30. Buller DB, Buller MK, Larkey L, et al. Implementing a 5-a-day peer health educator program for public sector labor and trades employees. *Health Educ Behav*. 2000;27:232–240
31. SAS Institute. *SAS/STAT User's Guide, Version 8*. Cary, NC: SAS Institute; 2000
32. Statistical Solutions. *Solas v. 3.0*. Cork, Ireland: Statistical Solutions; 2001
33. Hall SM, Delucchi KL, Velicer WF, et al. Statistical analysis of randomized trials in tobacco treatment: longitudinal designs with dichotomous outcome. *Nicotine Tob Res*. 2001;3:193–202
34. Schafer JL, Graham JW. Missing data: our view of the state of the art. *Psychol Methods*. 2002;7:147–177
35. SRNT Subcommittee on Biochemical Verification. Biochemical verification of tobacco use and cessation. *Nicotine Tob Res*. 2002;4:149–159
36. Aveyard P, Cheng KK, Almond J, et al. Cluster randomised controlled trial of expert system based on the transtheoretical ("stages of change") model for smoking prevention and cessation in schools. *BMJ*. 1999;319:948–953
37. Aveyard P, Markham WA, Almond J, Lancashire E, Cheng KK. The risk of smoking in relation to engagement with a school-based smoking intervention. *Soc Sci Med*. 2003;56:869–882
38. Fiore MC, Bailey WC, Cohen SJ, et al. *Treating Tobacco Use and Dependence: Clinical Practice Guideline*. Rockville, MD: US Department of Health and Human Services; 2000

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## Teen Reach: Outcomes From a Randomized, Controlled Trial of a Tobacco Reduction Program for Teens Seen in Primary Medical Care

Jack F. Hollis, Michael R. Polen, Evelyn P. Whitlock, Edward Lichtenstein, John P. Mullooly, Wayne F. Velicer and Colleen A. Redding

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