Chapter 2

Recruitment and Training of Practicing Physicians, Dentists, And Their Office Staffs

CONTENTS

Recruitment and Training of Practicing Physicians, Dentists, And Their Office Staffs

Editor: Stuart J. Cohen

INTRODUCTION This chapter contains a description of a series of research studies that involved the recruitment and training of practicing physicians, dentists, and their office staffs. The first section, by Drs. Lindsay and Wilson, describes the educational programs used to train community-based family physicians in Ontario, Canada, to help their patients stop smoking. Using the results of their experience with the first group of trainees, the investigators developed a more advanced and clinically effective 4-hour training program to assist a new cohort of community-based family physicians in helping their patients stop smoking. Of note in these investigations were the direct comparison of the performance and effectiveness of trained and untrained physicians, and an effort to assess the benefit of rescheduling patients for followup visits related to smoking.

In the second paper, Dr. Kottke and his colleagues describe the programs and results from a series of investigations in the Doctors Helping Smokers project, which involved more than 150 primary care physicians in Minnesota. The project emphasized the system for recruiting physicians and the establishment of a clinic environment system involving all office staff in the smoking cessation program. The clinical settings involved in the Doctors Helping Smokers project ranged from small private practices to large medical clinics. For the latter settings, the intensity of project support averaged 6 site visits, 24 telephone calls, and 6 mailings to help initiate the clinic smoking cessation program and sustain it for 18 months or longer.

In the chapter's third section, Drs. Wadland, Hughes, and Secker-Walker review the recruitment of smokers from a five-physician family practice in rural Vermont and from a six-physician academic general internal medicine practice. Their project attempted to assess the additional impact resulting from a prescription for nicotine gum on patients' efforts and success in quitting smoking and in their confidence in their physicians' advice. Of interest in the project was a 2- to 3-hour training program to help physicians in delivering smoking cessation advice and instruction in the proper use of nicotine gum.

The fourth paper, by Dr. Cummings and associates, describes the various studies and surveys involved in the Quit for Life project. The Quit for Life group conducted two randomized controlled trials to see if their program to train physicians in counseling patients about smoking cessation and to augment the training with involvement of their office staffs would result in

greater smoking cessation among the patients of physicians in the training program than among the patients of physicians who did not participate. The cohorts of physicians consisted of 81 internists from the Kaiser Permanente Medical Group of Northern California and 44 private-practice internists and family practitioners. Three 1-hour training sessions were held; they included videotapes to demonstrate smoking cessation counseling, role-playing, and positive feedback. The correct use of nicotine gum and the benefit of followup visits were emphasized. Of note in the discussion are the problems of recruiting private-practice physicians to participate and of obtaining office staff support for implementing an office-based cessation program.

The fifth paper, by Drs. Cohen and Stookey and Ms. Kelly, describes parallel studies involving two cohorts of primary care physicians and two cohorts of private-practice dentists from Indiana. The first cohort of physicians involved residents in internal medicine and faculty general internists and their patients from the outpatient medicine clinic of a city/county teaching hospital. The second group of physicians were general internists and family physicians drawn from five sites of a large, freestanding HMO. Both cohorts of dentists were limited to private general dental practitioners and periodontists who primarily treated adult patients on a regular basis. The goal of the project was to develop, validate, and evaluate practical methods to help clinicians be more effective in helping their patients stop smoking. Of special interest was the impact of chart reminders and/or nicotine gum on the counseling provided by clinicians and on their patients' smoking cessation.

The final section describes the Tobacco Reduction and Cancer Control (TRACC) program developed by Dr. Hollis and his colleagues in Oregon and involving the clinical facilities of Kaiser Permanente. TRACC used a team approach to counseling smokers in a variety of situations and settings, including nurse-assisted smoking counseling for outpatient settings, smoking interventions for hospital patients, smokeless tobacco intervention for dental patients, and smoking cessation among adolescents. Some unique features of the TRACC program were the use of a videotape to teach smokers steps for quitting successfully and establishment of a centralized system to identify smokers and their quit dates so that supportive followup calls could be made by trained phone callers.

Collectively, the studies described here indicate that within the context of a 4-hour workshop, physicians and other health providers can be trained to be more effective in counseling their patients who smoke. Moreover, smoking cessation efforts in these projects appeared more likely to be successful when office systems were in place that involved the office staffs in the programs. Components of a successful office support system appear to include

- A way to readily identify patients who smoke and to highlight that information for the clinician;

- A method of triage so that the patients who are most ready to make an effort to stop smoking get more intensive counseling; and
- A followup procedure to support patients in their efforts to quit smoking.

Effects of Training Family Physicians in a Comprehensive Smoking Cessation Intervention[1]

Elizabeth A. Lindsay and Douglas M. Wilson

INTRODUCTION The McMaster/Waterloo[2] family practice studies were carried out between 1984 and 1989. The phase I study measured the impact on patient smoking cessation of a continuing education event with supporting educational materials and an office cueing system. Through the phase I studies, we learned that the physicians who were not provided training but were given a reminder system in their offices appeared to offer advice as effectively as trained physicians, because as many patients of untrained physicians expressed their intention to stop smoking: 82.2 percent of patients in the untrained group and 77.4 percent of patients in the trained group stated that they intended to quit after the physicians addressed the issue with them. It is noteworthy that the patients in this study did not have to make a commitment to stop smoking. Motivation to stop smoking was not part of the eligibility criteria.

Untrained physicians did not perform key elements of the intervention taught to trained physicians, such as setting stop-smoking dates, providing take-home material, and offering followup support; patients of untrained physicians reported being much less successful with smoking cessation at 2 months (6.6 percent) than those of trained physicians (16.5 percent). The 1-year cessation rates in the trained group were lower than the reported 2-month results but maintained statistical significance over the control condition. Following this successful outcome, the goal of the phase II study was to assess specific components of the experimental intervention tested in phase I. Because of the time and financial implications of offering long-term followup, we chose to compare the impact of short-term intervention (two visits) with a longer program offered by physicians.

In all of this work, the educational programs and resource materials enabled the physicians to intervene confidently in a systematic manner with their smoking patients. We found that physicians perceived the intervention to be helpful to them, that their compliance in delivering the specific elements of

[1] This research was supported by NIH grant no. CA-38334, by a Canadian National Research and Development Program Scholar Award to J.A. Best, and by Ontario Ministry of Health Research grant no. 01922.

[2] McMaster University, Hamilton, Ontario, and University of Waterloo, Waterloo, Ontario.

the intervention was at least 80 percent for each of the key elements, and that patients appreciated and responded well to their physicians' offer to help. Among the patients in the phase II study—who all had expressed an interest in stopping smoking—the 1-year, validated cessation rates averaged 13 to 14 percent. The long-term followup did not increase cessation significantly over the two-visit followup. However, we have strong evidence that many of the patients who were not intended to receive long-term followup actually did receive it through a natural sequence of followup appointments for other conditions.

This introduction is intended for program planners and educators who are responsible for providing education for physicians, residents, or the staffs who work with them. Recommendations for providing effective training in smoking cessation are presented here. The recommendations are grounded in the research described in this chapter and others in this monograph, but they also reflect our experience as workshop leaders in 20 states and 4 provinces in the United States and Canada.

Integration Into Practice

A review of recent physician intervention research projects leads us to conclude that making a measurable difference in the number of patients who have stopped smoking at the end of 1 year requires (1) an office system that will remind physicians to address the smoking issue and (2) the capacity to deliver an efficacious cessation intervention. A physician must be highly committed to the smoking issue to invest the time and energy required to set up a practice with a reminder system and to develop skills in effective counseling about smoking cessation. An educational planner must understand that the level of commitment to this issue, as well as knowledge and skills, will vary widely in a community of physicians; therefore, the objectives and format of educational sessions should vary as well.

Because there is a wide range of commitment and interest in smoking cessation among physicians and their office staffs, it is important that physicians know what they need to do to obtain different levels of impact. They may decide to limit their involvement in this issue to brief advice to stop smoking to all smoking patients, and others may decide to offer visits to patients that will focus on smoking cessation. Other physicians may choose to offer a long-term program that includes followup visits. For physicians to make choices about their level of involvement, they need to know the increases in cessation they can expect with increasing levels of intervention. We find that, among trained physicians, the level of involvement is an individual decision and depends on many factors. Educational planners can facilitate these decisions by what they include in their training sessions.

Clear Objectives

To help physicians be more effective, it will be important to set realistic objectives for specific educational programs. There will be a number of factors to consider as objectives are set; for example, time availability is a strong determinant of what can be accomplished. We find that several hours are needed to teach physicians how to set up their offices and how to deliver

an efficacious intervention. In addition, to ensure that an office cueing system is set up, a personal visit to physicians' offices is often necessary. This comprehensive approach may be impractical in many continuing medical education situations. (See Chapter 5 for examples of how this can be accomplished.) Therefore, it is clear why it is important to teach physicians these skills while they are still in training.

Learning needs of the audience should be put together with time availability to determine what the objectives will be for a specific educational event. It will be important to consider the learners' level of motivation, their present skill level, and what is the most important material to be covered. For example, 30 minutes with a highly motivated physician might best be spent on helping the physician to be clear about what to do with a 10-minute office visit with a patient. In an hour with an audience that has gathered for a purpose unrelated to smoking cessation, the content might focus more on motivation for why smoking cessation is a good use of physician time. This type of audience will also need to hear a summary of an approach with practical tips that will demonstrate how to intervene effectively.

Features of The Program The content of an educational presentation should cover the following elements: (1) motivational material, including scientific evidence, that will increase physicians' commitment to integrating effective smoking cessation interventions into their practice; (2) background material that will increase participants' understanding of smoking behavior, addiction, and behavior change; (3) the content and skills for delivering an effective intervention with patients; (4) knowledge and resources for creating a smoke-free office and an office system that cues and supports the intervention with patients; and (5) a description of the variety of roles that are possible for the physician as an influential figure in the community.

Areas of Emphasis Physicians want to know what they should do with the brief time available to them. It is important to give specific structure to the patient visits and clearly defined content to cover. Our research to date has demonstrated that physicians are generally good at offering advice to stop smoking and indicating why patients should stop. Therefore, in our workshops we often move quickly through that aspect of an intervention and focus more on less familiar aspects of the intervention, such as the importance of setting a stop-smoking date, providing guidance for proper use of nicotine gum, advising patients on how to deal with withdrawal symptoms, and issues related to followup, such as weight gain and dealing with relapse.

How to deal with followup is confusing to some physicians. Our suggestion is to offer followup to any patient who is attempting to stop smoking. This can take the form of further visits or phone calls, the offer of which indicates continuing support that is perceived as important by patients. The research findings on the effect of this offer are mixed. We know that only some patients will attend followup visits and that those patients are more highly motivated than those who do not attend. We also

know that followup sometimes is provided as part of future visits that are unrelated to smoking cessation. We believe that it is important for physicians and their health care teams to know how to deal with followup issues and to provide an opportunity for those patients who want this help to be able to obtain it easily.

Educational Methods We have found a combination of demonstration and practice with supportive print resources leads to high physician compliance with our approach to smoking intervention. It is this combination that requires more time than is available in a 1-hour presentation.

Physicians who have participated in this educational model rated the event highly in evaluations and often mentioned specifically the importance of having an opportunity to practice the intervention and use the support materials at the training session. Because the physicians have chosen to attend a workshop, they are probably not representative of the general population of physicians; however, their comments provide direction for the ideal model.

Flow of the Session For both 1-hour and longer sessions, it is important to involve participants and ask them to speak from their own experience. We have found it particularly helpful to ask physicians, very early in the session, what they have found to be obstacles to providing effective smoking cessation advice to their patients. We note these issues on a flipchart and assure participants that we will try to address all of the issues during the session.

There is an increasing use of technology at continuing medical education events that engages participants by asking key questions about the content to be covered in the session. Through the use of touchpads and computerized compilation of responses, answers are displayed on the screen within 30 seconds. This technique actively involves participants in the session and enables presenters to know the knowledge levels and practices of the audience.

The flow of the session should reflect the motivation and knowledge level of participants. Generally, we move from general background to the specific detail of what to do. The flow is also congruent with the sequence of the intervention. It is sensible to discuss how to address the smoking issue with patients, what to do with a followup visit, and then focus on specific difficult issues. Unfortunately, the introductory material sometimes takes longer than is intended and there is insufficient time for the important followup issues. This latter material is what physicians often need to know, and we suggest organizers take steps to ensure that time is carefully monitored.

A Range of Learning Opportunities Given the wide range of motivation to learn about smoking cessation, it is appropriate to offer different levels of learning opportunities to meet the needs and the practical considerations in most medical communities. (Chapter 5 demonstrates how this is being accomplished in the Community Intervention Trial for Smoking Cessation [COMMIT].)

The effort spent in marketing educational events will be an important determinant of attendance. We have learned, through a survey of physicians in 11 communities across the United States and Canada, that physicians believe they are addressing cessation with most smoking patients and that they feel adequately prepared to address the issue. If this is generally the case, it is probable that physicians will not see the need to attend a continuing medical education session on smoking cessation. We also know that they overreport the frequency of their interventions and that most do not include the ingredients we have found to be important for successful cessation. It will be important to help physicians assess accurately what they need to know about delivering an efficacious intervention and realize that they can make a significant impact by applying the intervention consistently.

The scheduling and the setting for CME events will be important determinants of who and how many will attend. In our research projects, when full attendance of participating physicians was critical, we offered several choices for attendance and chose the time for events after asking for "most convenient times" from potential participants. These choices should be determined by an analysis of your local customs and needs. It is always important to provide a comfortable learning environment and appropriate refreshments, and we have found that CME credits and financial incentives also can affect attendance.

Who Should Teach The leaders at educational sessions must have a depth of knowledge about smoking cessation so they can describe simply and clearly what physicians need to do in their brief time with patients. We have found that a team of a family physician and a behavioral scientist works very well, but the professional background of the leaders may be less important than their ability to deliver clear instructions, respond well to learner concerns, and help physicians see that smoking cessation is an effective use of their time.

Health Care Teams Smoking cessation interventions may be greatly enhanced by involvement of a receptionist, an office nurse, or other team member. In some cases, reimbursement considerations as well as interest and skills of a team member make this a feasible model.

It will rarely be enough to simply tell physicians how they can integrate their team in the smoking cessation initiatives. Other staff members need to attend training or receive training in their office environment. Any office system must be simple and nonintrusive to the regular work of the practice, and there must be a perceived payoff for putting the system in place. It may, therefore, be important to include a mechanism for keeping track of successful stop-smoking attempts to demonstrate the effect of their efforts.

PHASE I PROJECT (1984-1987)

McMaster/ Waterloo Project

The goals of the McMaster/Waterloo Family Practice Smoking Cessation Project were as follows: (1) to develop a smoking cessation intervention that could be delivered by community physicians within the context of regular office practice; (2) to design and deliver a continuing education session that increased the motivation, knowledge, and skills of the study physicians; (3) to create the print and audiovisual materials that would enable the effective delivery of the training session and the patient intervention; (4) to test the intervention package by means of a randomized controlled trial in which the physician was the unit of randomization; (5) to carry out both process and outcome evaluations to increase our understanding of physician compliance with the recommended changes in practices, the smoking cessation process, and the impact on patient behavior; and (6) to assess the role of the offer of further followup after two visits (phase II project).

Physician and Patient Recruitment

Eighty-three community family physicians and 1,942 smoking patients participated in this trial. We had invited 460 family physicians practicing within a 40-mile radius of McMaster University to participate. Their names were obtained from an Ontario Medical Association listing that includes the majority of family physicians in the area. One hundred two physicians responded positively, but 12 withdrew or, because of distance, were set aside for future studies, prior to randomization. The remaining 90 physicians, who represented 75 practices, were randomly allocated, by practice, to the three treatment groups; 7 physicians withdrew from the study after randomization. Comparison of characteristics of the physician dropouts and the study physicians (70 practices) revealed no significant differences that we feel would bias the composition of the experimental groups.

Patients entered the study when they visited their physician for a routine office appointment. We tried to recruit the most representative sample of smoking patients by asking all smokers to participate. Receptionists in all three groups recruited the study participants according to a standard protocol that started at the beginning of each family practice session by asking all patients if they were smokers. Receptionists asked each eligible smoker (not pregnant or breastfeeding, over age 16, and smoking at least one cigarette each day) to participate until a maximum of two smokers each day agreed to complete the questionnaire. The consent letter provided with the questionnaire asked patients to agree to be followed and emphasized that they were *not* agreeing to try to stop smoking.

The experimental variation in condition began when the patient went in to see the physician. In condition 1 (usual care), the physicians were not to know which of their patients had agreed to participate in the study. If it was part of their usual practice to address the smoking issue with patients, they did so. We gave no instructions to patients about whether they should mention their agreement to participate to their physician, and we had no way of assessing whether they did.

In condition 2 (cued only), the physicians were cued by a project document indicating the patient's agreement to participate. These physicians were instructed to advise the patient to quit smoking and offer nicotine gum as an aid to quitting. There were no further instructions given to these physicians.

In condition 3 (trained and cued), physicians had attended a training session to develop the knowledge and skills for delivering the intervention. A project flowsheet cued these physicians as to which patients were in the study and also helped them to remember the ingredients of the intervention. In addition, self-help materials were provided for distribution to patients.

Materials and Training Techniques

The continuing medical education protocol was set up to enhance learning through attention to a comfortable setting and provision of time for the group to visit informally before the session began. Introduction material provided a context in which the intervention for smoking cessation could be seen as a worthwhile and appropriate activity for physicians. The protocol included (1) premailed background material that included several recent reprints from medical journals, (2) a 3- to 4-hour training session, and (3) materials that guided and reminded physicians of the maneuver taught in the training session.

Training Program

Training Session

The purposes of the session were to increase (1) knowledge and understanding of the contents of the intervention, with particular emphasis on the rationale for and proper prescribing of nicotine gum; (2) skills for challenging smokers about quitting, negotiating a decision about quitting, and setting a quit date, as well as offering supportive followup visits; and (3) a positive attitude toward the importance of the physician's role in smoking cessation and toward implementing the intervention. The session began with an overview of the research project, including a brief discussion of the smoking cessation process, the literature on physician-delivered interventions, and a description of proper use of nicotine gum.

The experimental intervention included three types of visits. To teach the content and skills for these visits, the training session followed a loop-like format, in keeping with learning principles that support the need for information, demonstration, and practice. First, we described the protocol through slides and verbal instructions; then a physician-patient interaction was demonstrated on videotape, and participants experienced guided practice with surrogate patients. Through this sequence of description, demonstration, and practice, participants learned the procedures for *a challenge visit*, *a quit-date visit*, and *supportive followup visits*.

Intervention Taught

The full intervention, including six potential contacts, would be carried out over a 2-month period.

The first visit. When a patient agreed to participate, the receptionist attached project materials to the patient chart. The materials reminded the physician that the patient was a smoker and guided the discussion about smoking cessation. After the regularly scheduled office visit, the physician

spent an additional 5 to 7 minutes with the patient, discussing the importance of stopping smoking and the advantages of quitting in terms of the individual's personal health and current symptoms related to smoking. The following were key parts of this discussion: (1) gathering a smoking history, such as the number of years of smoking and the quantity smoked each day, and (2) getting a sense of the patient's willingness to try quitting. It was also important to challenge the patient to make a clear decision about quitting and to set a date to stop smoking within the next month, when the patient would come back to see the physician.

During the initial visit, the physician informed the person about nicotine-bearing chewing gum as an aid to quitting and provided the patient with self-help materials. Before leaving the office, the patient set up an appointment for a quit-date visit and, if feasible, appointments for the four followup visits. The patient also received a document that resembled a contract, indicating his or her decision to try to stop smoking and dates of future appointments. Physicians did not receive reimbursement for this first visit, but the Ontario Health Insurance Plan reimbursed them for subsequent visits.

Quit-date visit. At the 10-minute quit-date visit, the physician reinforced and supported the patient's reasons for wanting to stop smoking, and the patient was to stop at that visit. For those patients who chose to use the gum, the physician explained its proper use while the patient tried a piece. Patients paid for the nicotine gum. In the training for this visit, we emphasized the importance of encouragement and building the patient's confidence. See Figure 1 for the patient chart that guided the content for this visit.

Supportive followup visits. The content of these four brief followup visits over the next 2 months varied, depending on the stage of the cessation process and the personal issues brought by the patient to each visit. Physicians assessed this stage by simply asking how the patient was doing with the smoking cessation program. A flowsheet for each patient provided guidelines for monitoring and supporting techniques. We encouraged physicians to listen carefully to the issues raised by the patient and to offer advice that was personal and supportive.

Print and audiovisual materials. For the purposes of training, we developed a slide presentation and demonstration videotapes. For the office maneuver, we developed a flowsheet for patient visits, a patient contract, and patient self-help "Tip Sheets." The patient materials were adapted from one-page summaries that were developed by the Stanford Cardiovascular Risk Reduction project for use with refrigerator magnets.

Results

Definition of Outcomes

The primary definition of successful cessation was self-reported sustained abstinence for 3 months prior to biochemically validated cessation after 1 year. However, we also included self-reported attempts to stop smoking and self-reported 2-month cessation.

Figure 1
Patient chart, quit-date visit and followup

PATIENT FLOW SHEET

Patient Name: _____

Major reasons for quitting: Health; Other

Cigarette symptoms, e.g., cough

	Quit Day	Post Quit Day	Post Quit Day	1 Month	2 Month
DATE:					
General well-being					
Average daily use of cigarettes over the past week					
Commitment to quitting (low, medium, high)					
Confidence to succeed (low, medium, high)					
Concerns about quitting					
Any strategies for getting ready?					
Average daily use of Nicorette over the past week					
Any side effects of Nicorette — Do you like the gum?					
Any withdrawal symptoms after stopping cigarettes?					
How often do you feel like smoking? How strong is this craving? (low, medium, high)					
Does the gum help you cope with this craving?					
Have you noticed any weight gain? Is this a problem? Need information?					
Do you spend a lot of time around other smokers?					
Are you feeling support from others at home or at work?					

Patient Response

Patients' intentions to stop smoking with or without gum were recorded at the time of the initial visit. Of those who stated an intention to try to quit (approximately 80 percent), a significantly higher proportion of patients in the trained and cued group (71 percent) than in the cued-only group (61 percent) chose to stop smoking and to use nicotine gum. Gum use for greater than 2 weeks was less than 25 percent for both groups (Wilson et al., 1988). (See Tables 1 and 2.) Approximately 65 percent of patients in the trained and cued group returned for at least one followup visit. The 1-year cessation rate increased with the number of followup visits attended (Wilson et al., 1988).

On the 2-month questionnaire, 38.1 percent of the usual-care patients, 62.8 percent of the cued-only group, and 76.7 percent of the trained and cued group reported attempting to stop smoking for at least 24 hours. Successful cessation was reported by 3.8 percent in usual care, 6.6 percent of the cued-only group, and 16.5 percent of the trained and cued group (Table 3). Our primary definition of successful cessation was self-reported sustained abstinence for 3 months prior to biochemically validated cessation after 1 year. Validated 3-month sustained cessation rates at 1-year followup, adjusted for covariates, were 4.4 percent for usual care, 6.1 percent for the cued-only group, and 8.8 percent in the trained and cued group (Table 3).

The criterion for validation of smoking cessation was a saliva cotinine value of 0.057 μmol/L or lower, or a saliva thiocyanate level of 1,724 μmol/L or lower if the patient was still chewing nicotine gum. Approximately 92 percent of patients who reported they were not smoking were validated. Those not reached were classified as smokers. Of the patients who reported themselves as ex-smokers for at least 1 week and submitted to cotinine validation, 25 percent did not qualify as nonsmokers according to the validation criteria. Another 8 percent of those who reported themselves as nonsmokers would not submit to validation and thus were classified as smokers (Lindsay et al., 1989).

Physician Practices

Counseling performance was measured by means of exit telephone interviews with a random 15 percent of patients and rated audiotapes of physician counseling with simulated patients. Physicians in the trained group were more likely than untrained physicians to use procedures they were trained to include, such as offering advice, inviting patients back for followup, setting stop-smoking dates, and providing take-home materials (Lindsay et al., 1989; Wilson et al., 1988).

Physicians who were cued to offer nicotine gum (both cued-only and trained and cued) offered nicotine gum at nearly the same frequency, whereas the usual-care physicians offered gum much less frequently (Wilson et al., 1988). Cueing and training each had highly significant effects on counseling performance, as demonstrated by the significant variations in performance between experimental conditions. Performance, as measured by exit interview scores, was associated with all short-term outcomes; however, in our first analysis of performance, the rated simulation performance scores were not.

Table 1
Patient's recall of office visit with physician[a]

	Percentage of Yes Responses				
	Usual Care (n=90)	Cued Only (n=94)	Trained and Cued (n=96)	Chi-Square[b]	p
Did Doctor Say Anything About Patient's Smoking?	31.1%	70.2%	85.4%	61.96	< 0.001
Suggested Quitting	24.4	64.0	84.4	59.72	< 0.001
Offered Help	12.2	61.7	84.5	106.93	< 0.001
Suggested Gum Method	8.9	58.5	62.5	38.15	< 0.001
Set Quit Date	2.2	11.7	54.2	80.84	< 0.001
Doctor Wants To See Again	4.4	22.3	83.3	137.22	< 0.001
Gave Reading Materials	2.0	17.0	80.2	144.07	< 0.001

[a] *Gathered through open-ended questions asked within 3 days.*
[b] *Chi-square based on differences among the three groups.*

Table 2
Stated intention to try to stop smoking in untrained (gum-only) and trained (gum-plus) groups and patient attendance at followup visits (gum-plus)

	Total n	Do Not Want To Quit n (%)	Try To Stop Without Gum n (%)	Try To Stop With Gum n (%)	Attended at Least One Followup Visit[a,b] n (%)	Attended Four or Five Followup Visits[b] n (%)	Unsure or No Data n (%)
Gum Only	726	108 (14.9)	171 (23.6)	425 (58.7)	ND	ND	21 (2.9)
Gum Plus	606	74 (12.1)	86 (14.2)	383 (63.2)	390 (64.3)	129 (21.3)	63 (10.4)

[a] *Includes those attending a quit-date visit.*
[b] *ND, no data available.*

Table 3
Smoking cessation attempts and proportion of ex-smokers in each of the treatment groups, as indicated in patient charts and 2-month questionnaire

	Total n	Physician Discussed Smoking With Patients[a]	Patient Intends To Quit[a]	Tried To Quit for 24 Hours[b]	Not Smoking at 2 Months (Self-Report)[b]	Adjusted Sustained 3-Month Cessation Rates at 1 Year (Validated)[b,c]
Usual Care	601	ND	ND	36.4%	3.8%	4.4%
Gum Only	726	98.0%	82.2%	60.7	6.6	6.1
Gum Plus	606	90.8	77.4	71.9	16.5	8.8

[a] *ND, no data available.*
[b] $p < 0.05$.
[c] *Analysis of covariance adjusted for differences at baseline.*

No performance indicator that we measured through exit interviews or simulated visits predicted long-term outcomes (J.A. Best and colleagues, unpublished data).

We were not satisfied with our first analysis of the audiotaped simulated visits, so a cooperating investigator conducted an innovative analytic procedure adapted from judging of technical and artistic merit in figure skating (Burgess, 1989). This analysis of 35 audiotapes of untrained and trained physicians to assess content and style of the delivery of a smoking intervention once again demonstrated a highly significant effect of physician training on the content of the intervention and on 2-month cessation rates. The analysis also revealed one measure of style, degree of empathy, and predicted enhanced 2-month cessation (Burgess, 1989).

Conclusions The research demonstrated that physicians will attend a half-day continuing education workshop to enhance their skills in smoking intervention. We found that the physicians integrated the maneuver into their practices but often needed the research staff to ensure that the project smoking cessation materials were used appropriately. When the materials were used with patient charts, physicians performed the intervention according to their training. Untrained physicians who were cued by project materials to address cessation with smoking patients performed several aspects of the intervention with the same frequency as trained physicians. Patients agreed to try to stop smoking as frequently in both groups, and similar numbers chose to use nicotine gum to try to stop smoking. Significantly fewer patients of physicians in the untrained groups reported trying to quit smoking for 24 hours. The trained group helped patients set a stop-smoking date, provided take-home materials,

and offered followup support much more frequently than the untrained physicians. The trained, gum-plus group had much higher 2-month cessation rates than the other two groups, but the difference, although retaining statistical significance, was much smaller at the end of 1 year.

The influence of a physician intervention decreases with time. This is an expected finding, as the patient's daily social environment and other factors are likely to increase in relative influence as time passes after the physician intervention. We need to develop complementary interventions that will improve maintenance of the early effects of physician interventions.

Side Studies

Patients of Trained Physicians

We conducted a series of interviews over 1 year with patients whose physicians invited them to try to stop smoking (Willms et al., 1990 and 1991). The physicians in this study were trained in the same way as those in the main trial, but they were selected from a different community, distant from the main trial center. The interviews were designed to assess, from the patients' point of view, which were the most important components of the intervention. The interviews were transcribed and interpreted through application of a systematic approach for qualitative research methods (including ethnographic methods).

This research indicated that the most significant component of the physicians' intervention was the kind of support given. We describe the results of this study with the terms "interventionistic" and "personalistic." Although both aspects were important, patients emphasized the importance of the personalistic components. These activities include aspects of the physicians' work that are nurturing, egalitarian, and mutually communicative. It appears from this work that it is important for physicians to speak with biomedical authority, because our evidence suggests that patients expect a certain amount of that content and because there is need for emphasis on creating more organization- and clinic-based supports (Willms et al., 1991).

Nicotine Gum As an Adjunct

Another side study of the main trial assessed the intervention package tested in the main trial with and without the offer of nicotine gum (Gilbert et al., 1989). A separate sample of 12 community physicians selected previously for the main trial and set aside because of distance from the main center attended a 4-hour training session during which the maneuver was demonstrated and practiced. We taught physicians how to deliver the intervention both with and without the offer of nicotine gum. Receptionists were instructed to recruit the first two smokers visiting the practice each day. Patients (n=223) were randomized to receive the same intervention, but either including the offer of nicotine gum or without the offer of nicotine gum.

One-year smoking cessation was validated by cotinine saliva analysis. The validated 3-month sustained abstinence rates at 1 year were 8.1 and 9.8 percent in the gum and no-gum groups, respectively. The 95-percent confidence interval for this difference was -9.3 to 6.4 percent.

There was no evidence from this study that smoking cessation rates were enhanced by the offer of 2-mg nicotine-bearing gum, when added to a comprehensive intervention offered to all smokers in primary care. Insufficient power may be partially responsible for our findings; however, the trend in the findings does not support the additional usefulness of nicotine-bearing gum. It is also of interest that the other side study (described above)—which also tracked cessation rates for those offered and not offered gum—showed that cessation rates were higher but not statistically significant in the no-gum group.

PHASE II PROJECT (1987-1989)

Developing a More Effective Intervention

Physicians in the phase I study found that the time they needed for talking to patients, when added to a regular visit, was quite disruptive to their practices. Therefore, we shortened the first visit to include only the following:

Structuring The Visits

- An offer to patients to be part of the McMaster Family Smoking Cessation Program;
- Questions to patients about their interest in stopping smoking and the completion of a questionnaire;
- A clear statement of concern and support from the physician; and
- A request to come back and talk further about stopping.

Physicians offered patients an opportunity to come back for a separate visit to discuss their approach to cessation. At this second visit, a random selection of half of the patients were invited to come back for further followup.

Consideration of what is known about the cessation process can guide the selection of times that appear to be most appropriate to provide further physician support visits. These considerations led to the following recommendations for timing of the four followup visits:

- Close to the quit date (encouragement to get off to a good start, ensure proper use of gum, if appropriate);
- Seven to ten days after stopping (provide help with withdrawal symptoms);
- One month after stopping (patient may be able to give other lifestyle issues attention); and
- Two to three months after stopping (most relapses occur in first 3 months; the patient is learning to be a nonsmoker and is adapting to the nonsmoking culture).

The need for these visits and their timing are individually determined. Therefore, as with many aspects of the Family Practice Smoking Cessation Program, physicians offered opportunities for followup but let individual patient needs determine timing and content.

First return visit. If patients returned to discuss their smoking, physicians took a history of their smoking behavior, including information about previous attempts to stop smoking and what was helpful or not helpful in those attempts. Other key questions as well as a take-home questionnaire helped patients think about the reasons they smoked and why they wanted to stop. The ethnographic work in the first study suggested that patients appreciated a personal approach from their physicians that communicated a clear interest in individual concerns and advice that was relevant to their experience (Willms et al., 1991).

Assistance offered by the physician. The revised intervention recommended that physicians suggest several strategies for getting ready to stop smoking, including setting a stop-smoking date. The self-help materials available for each patient provided many tips on how to prepare, such as anticipating the discomfort of withdrawal symptoms. During the first week or two after cessation, an inability to handle withdrawal symptoms often undermines a smoker's good intentions. Guidelines recommended that physicians ask patients about previous experience with withdrawal and plan for how to deal with potential problems. This was in keeping with another finding from the ethnographic work, which indicated that patients expected and appreciated physicians focusing on the physiological aspects of the cessation process, especially regarding feeling better and becoming "healthier." The offer of nicotine gum with instructions for proper use was a part of this intervention, but because of the limitations of the evidence of its effectiveness in the previous study, physicians were advised to offer gum to smokers who seemed to be physically addicted to nicotine or who had previously made several unsuccessful attempts to stop smoking.

Office system for cueing and monitoring the intervention. A systematic approach to cueing and monitoring smokers was built into the Family Practice Smoking Cessation Program. The physician's office staff flagged all smokers' charts and appended flowsheets to guide the intervention in patient charts for the physician's attention.

Development of Training Session And Resources

Our previous study demonstrated that the training workshop provided to physicians led to changes in practice and ultimately led to higher smoking cessation rates among patients (Wilson et al., 1988). Review of continuing education intervention research indicates that physicians rarely change clinical practices through simple acquisition of knowledge (Fowler et al., 1989).

Through the first Family Practice Smoking Cessation Program, we learned that physicians without special training appeared to perform some of the elements of the intervention equally as well as the trained physicians (Lindsay et al., 1989). We found that physicians in both groups were almost equally successful at motivating patients to try to stop smoking and that they were equally persuasive about the use of nicotine gum. There were large differences

in performance in the areas of setting stop-smoking dates, offering followup, and providing self-help materials to patients; and we also detected small differences in physician style in talking to patients (Burgess, 1989).

Less than half of the patients in the phase I study took advantage of the physicians' offer of followup visits. Little training time was spent on the followup visits, and physicians reported feeling least prepared for the followup element of the intervention. Because the focus of the present study was on the effect of followup and because of these weaknesses in the first study, a higher proportion (approximately 50 percent) of the content of the training was dedicated to content and process of the followup visits.

The training session followed the loop format used successfully in our prior work, which provided information, demonstration, and practice with feedback. By repeating this sequence for at least two types of visits, workshop participants had an opportunity to develop their skills in applying the intervention.

Teaching about style as well as content. Patients told us that physician style was important in their approach to smoking cessation. However, we were unable to quantify the characteristics of more successful approaches in the first study. The work of Ockene and colleagues (1990), in which a patient-centered intervention is taught to residents, emphasized the importance of asking questions and providing feedback to patients about their feelings. There is evidence in other areas of patient care that believing one is understood and receiving feedback about how the physician perceives the patient's feelings are related to both satisfaction and compliance by patients. The training included discussion of these style issues as well as a video demonstration of recommended interpersonal skills. These issues were reinforced through study materials provided for use during the patient visits.

Focus on key followup issues. The guidelines for the four followup visits were based on the cessation process and consideration of the amount of time physicians were likely to spend in these visits. Three key content issues and five style issues were the focus for followup visit training. Patients' interests and needs guided the content. The guidelines provided suggestions for how physicians could support patients in planning for and adapting to their new lifestyle as nonsmokers. The training session provided information on weight control, preventing and coping with relapse, and one method of relaxation to cope with stressful situations.

Study Design And Participants

This study tested the impact on smoking cessation of the offer and provision of several followup visits compared with attendance at one followup visit among patients who wanted to stop smoking.

Forty-one community family physicians agreed to participate in the study. They were recruited from the Hamilton, Ontario, area and were eligible if they agreed to attend the training session and provide administrative assistance

through their office staff. Undoubtedly, these physicians were more interested than the average physician in providing smoking cessation assistance to their patients.

All of the physicians participated in a 4-hour training session designed to develop their ability to deliver two cessation interventions: one that included followup continuing for several months and one that did not. Six hundred forty-seven smoking patients participated and were randomly allocated to one of the two conditions.

Implementation Patients entered the study when they visited their physician for a regular office visit. The intention in this study was to attract people who were interested in stopping smoking. To qualify, patients had to smoke at least one cigarette every day (or most days), be 16 years of age or older, and not be pregnant or breastfeeding. Receptionists provided a copy of the consent form and the questionnaire to patients. Signs were posted in the offices to inform patients about the availability of the program.

Physicians spoke to consenting patients about their interest in stopping smoking. If patients expressed an interest in stopping, physicians invited them to return for a more in-depth discussion and development of a plan. When patients returned, receptionists provided physicians with the next in a sequence of numbered envelopes along with the patient chart. The materials for the two interventions were printed in different colors and were prepacked in envelopes that were placed in a random sequence determined by a computerized program and were numbered accordingly.

At the return visit, all patients were to receive the same intervention up to the point of the offer of further followup visits. In one group, the physicians completed their intervention at this visit. In the other group, the physicians offered to see patients four times over a 2- to 3-month period.

Process Measures And Baseline Characteristics Pretest questionnaires were completed to provide physician and patient characteristics. Interviews with patients, within 2 weeks of the quit-date visit and at 6 months after, provided information about patient perceptions about the visits with their physician and about their experience with attempting to stop smoking. The primary outcome in this study was sustained 1-year validated cessation rates, although we also provided 6-month self-reported data.

Results

Patient Reports of Physician Behavior

All physicians participating in the study attended the training session. Through exit interviews, patients reported what physicians included in the smoking cessation visit and their perceptions of its usefulness. At least 75 percent of the patients rated their physicians as very helpful, encouraging, and understanding. Patients who received the offer of followup rated their physicians as more helpful and encouraging than the ratings by patients who did not receive this offer (Gilbert et al., 1992). More than 90 percent of the time, physicians included advice about health risks, helped patients set a quit date, gave patients a stop-

smoking contract, offered the use of nicotine gum, and provided self-help materials and reasons for the patient to stop smoking (Gilbert et al., 1992).

More than 80 percent of patients said their physicians discussed weight control, withdrawal symptoms, the role of planning and exercise, the importance of social support, and the role of spouses, as well as giving some attention to stress management. These first return visits averaged 16.5 minutes.

Patients' Perceptions — At the 6-month interview, we asked patients what aspects of the stop-smoking program had been the most helpful. At 6 months, physician advice and support were rated as the most helpful elements by patients in both groups; setting a quit date, having printed materials, and using nicotine gum were also rated highly. The usefulness of the contract and followup were rated lower.

Smoking Cessation — Although there were significant differences in self-reported cessation between the two experimental groups at 2 months and at 1 year, when the rates were validated at 1 year the differences lost statistical significance. We found considerable crossover had occurred between the two groups; that is, the group that was not to receive long-term followup often actually did receive it when they returned to their physician for other problems, and the long-term followup group often did not return for their followup visits. This blurring of the difference between the two groups makes interpretation of results difficult.

Elements of Successful Cessation — We also looked at the relationship between what elements of the intervention patients considered helpful or not helpful and whether they succeeded in stopping smoking. At the 6-month interview, patients rated the degree of helpfulness of various parts of the intervention. Physician advice and support were rated as the most helpful ingredients and followup visits as the least helpful. However, when we look at cessation rates at 6 months, we find that the patients who found the quit date, contract, and followup most helpful were also those with the highest cessation rates. This raises the question: Do patients who are highly motivated to stop smoking take advantage of all aspects of the program and therefore rate the components higher, or do the program components actually lead to higher cessation rates?

Approximately one-quarter of the patients at the 6-month interview rated nicotine gum as helpful. When asked at 1 year to describe their use of nicotine gum, slightly more than one-quarter of the patients (28 percent) reported using the gum for longer than 2 weeks. The cessation rate at 6 months for patients who rated the gum important was 27.3 percent.

Discussion — The purpose of this study was to determine the importance of long-term followup in relation to successful smoking cessation, to gather process data regarding the feasibility of incorporating this maneuver into regular office routines, and to determine the perceived relative importance of other ingredients of the intervention.

Cessation Rates

The cessation rates in this study compare favorably with those in other studies. The 13- to 14-percent 1-year validated rate is similar to the rates for more motivated patients in our previous study and is in the same range as the results of other studies that have tested maneuvers of similar intensity. It is important for physicians to know that if they offer a smoking-specific visit to smoking patients, approximately 60 percent of those patients who have expressed an interest in stopping smoking will return, and the one visit will produce cessation rates in this range. It also appears that those patients who return for further visits are more successful in stopping smoking than those who do not return. Although we have not demonstrated the effectiveness of followup, the higher cessation rates will mean both physicians and patients may perceive this time as useful.

Structure of The Visits

We found that physicians who attended the 4-hour training session set up their offices to accommodate the intervention, used the resource materials, and complied with the intervention. The brief introduction visit did not disrupt practice and the return visit focused on smoking, allowing physicians to take a smoking history, set quit dates, give instructions for gum use, and address other questions raised by patients. Although these visits were demonstrated in the training to be 8 to 10 minutes long, physicians estimated that they averaged 16.5 minutes. The visits were paid for by the provincial health insurance.

It appears that physicians offered patients long-term followup as indicated in the randomization process, but only 69 percent of those randomly offered followup attended more than one further visit. We discovered through chart audits that long-term followup happens naturally as patients return for future visits for other reasons (Gilbert et al., 1992). This natural followup within the no-followup group may explain why we found no differences in 1-year cessation rates. We should point out that the average duration of a scheduled followup visit was slightly more than 12 minutes. It is very unlikely that discussion about smoking on unscheduled followup was this long. However, we conclude that setting up smoking-specific followup visits after one smoking-focused visit may not be necessary for most people, as long as physicians are keeping good records and remember to check on progress at these other visits.

Personalized Advice And Support

Project records and patient interviews indicate that physicians followed the recommended protocol and were perceived to be encouraging, understanding, and helpful. Patients reported that physician advice and support were the most important aspects of the intervention. This evidence validates the survey data that have indicated that patients do appreciate and value their physicians' interest in their smoking. Our data also indicate a high level of patient satisfaction with this particular maneuver; that is, patients gave high ratings of importance to their physicians' support in their cessation attempts.

Quit Date, Contracts, Gum — Our data demonstrate that most patients did set a stop-smoking date, but the effectiveness of the strategy was not tested in this study. In retrospect, only 140 indicated that the quit date was helpful, but 33 percent of those who found it helpful were successful at 6 months. As to the use of the contract and the nicotine gum, it appears that some individuals find each of these techniques helpful. This trial did not attempt to study those who selected these elements of the intervention.

Followup Visits — This study focused on the impact of physicians offering longer term followup, and we did search for differences between those who attended followup and those who did not. There is an overlap of the characteristics of those most likely to stop smoking and those who attended followup that confounds our ability to understand whether there are, in fact, differences. The primary overlapping characteristic is that those who are lighter smokers attended followup and also were more likely to be successful. This finding may be a little surprising, because one might expect the more addicted smoker to seek more medical assistance. Older, more educated patients with fewer friends who smoke tended to take advantage of followup visits. We might speculate that the more isolated smoker might seek ongoing support from his or her family physician.

Conclusion — Physicians who attended training and used the program resources integrated the intervention into their practice fully when patients expressed an interest in participating. We do not know whether study physicians applied the intervention to patients not in the study or continued to use the resources after the study ended. Provision of a visit dedicated to smoking cessation produced substantial cessation rates, and the offer of subsequent smoking-specific followup visits did not increase those rates significantly.

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Doctors Helping Smokers: Development of a Clinic-Based Smoking Intervention System[3]

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BACKGROUND: DOCTORS HELPING SMOKERS

As with the other NCI-sponsored physician and dentist intervention trials, the goal of Doctors Helping Smokers was to determine how physicians might promote smoking cessation effectively among their patients. A decade before the Doctors Helping Smokers proposal was written, Russell and coworkers (1979) had already documented that a physician could make a small but significant impact on smoking cessation rates simply by advising patients to quit smoking and giving them a smoking cessation brochure. Additionally, the Multiple Risk Factor Intervention Trial had demonstrated impressive efficacy with its smoking intervention (Multiple Risk Factor Intervention Trial Research Group, 1982), and the Minnesota Heart Health Program had developed state-of-the-art self-help materials that could also be used in a one-to-one counseling session.

Because the first author had received a National Heart, Lung, and Blood Institute Preventive Cardiology Academic Award in 1981, we had already begun to work with primary care physicians at the time that we were preparing the Doctors Helping Smokers grant application. By analyzing the organizational context of angioplasty, the treatment of hypertension, advice to quit smoking, and advice to eat a low-fat diet, we identified nine factors that we believed must be considered in the implementation of any program (Kottke et al., 1987) (Table 4). This experience led us to formulate the problem of developing physician-based smoking interventions as a systems problem rather than a problem of selecting a single best solution from among a field of candidates (Kottke et al., 1990a).

We also recognized that any intervention must satisfy two conditions if it is to be effective—it must be efficacious (change patient outcomes when it is applied) and it must be acceptable to both the professional delivering the intervention and the patient who is the target of the intervention. We elected to focus Doctors Helping Smokers on the task of developing a solution to the problem that physicians tended not to use smoking interventions that were already available and of documented efficacy.

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Table 4
Checklist for implementation of systematic smoking intervention protocols in medical practice

Knowledge of Relevance	Have we assured that the physician understands that his or her patients will benefit from a cue to stop smoking?
Skills	Have we given the physician the skills to advise the patient to stop smoking and help the patient develop problem-solving and maintenance skills?
Adequate Return	Have we designed a program that will either pay for itself or effectively serve as a practice-builder for the physician?
Organization	Have we designed an organization that will cue the physician to ask the patient to address smoking and to support the physician when he or she receives a request for help?
Perceived Effectiveness	Have we demonstrated to the physician that asking the patient to stop smoking increases the probability that the patient eventually will quit?
Perceived Patient Demand	Have we demonstrated to the physician that his or her patients want advice and help to stop smoking?
Perceived Legitimacy	Have we demonstrated to the physician that asking patients to stop smoking is a legitimate professional behavior?
Confidence	Have we given the physician the confidence to ask patients to stop smoking?
Commitment	Have we imparted to the physician the commitment to ask patients to quit smoking?

The proposal's original hypothesis was that physicians who attended a 6-hour training workshop and were supplied with the self-help booklet developed by the Minnesota Heart Health Program would so appreciate the negative health effects of smoking and be so convinced of the efficacy of their intervention that they would increase markedly the rates at which they gave advice to quit smoking. It was also hypothesized that this increase in physician activity would, in turn, lead to increases in patient smoking cessation rates.

As a test of recruitment strategies, physicians were recruited through one of three variations in a direct mail program. This recruitment program demonstrated that none of these direct mail interventions could recruit physicians at a rate that would have much impact on the patient or physician population. Regardless of the content of the particular mailing to a physician, only 10 percent of physicians responded, and 7 percent or fewer were willing and able to participate in the trial (Kottke et al., 1990c). Other investigators in this field have reported the same experience (Cummings et al., 1989a; McPhee et al., 1989; Wilson et al., 1988).

Rounds I and II of Doctors Helping Smokers asked the participating physicians to identify every smoker in their practices and ask them to quit smoking (Kottke et al., 1989). As part of the evaluation of our intervention,

patients of those physicians were interviewed by telephone soon after their clinic visits and again a year later. Several findings emerged from this study:

- Even physicians who had promised to ask every smoker to quit smoking were unable to accomplish this task in more than 60 to 70 percent of cases.
- The proportion of patients who would agree to quit smoking when asked by a physician (approximately 30 percent) was far smaller than the proportion who would try to quit smoking during the subsequent year (approximately 50 percent).
- Quit attempts were frequently followed by rapid relapse. One-quarter of the patients who reported that they had quit smoking for at least 24 hours relapsed within 2 days, half relapsed within a week, and 65 percent relapsed within a month. If a patient was able to remain abstinent for 180 days, the probability of relapse within the next 180 days was low.
- Two factors had to be favorable if a smoker was going to quit smoking: the desire to quit smoking (in this case measured by the patient's response, on a 1 to 10 scale, to the question "How much do you want to quit smoking?") *and* the ability to deal with dependency on cigarettes (in this case measured by the length of time, after first rising, that the patient smoked his or her first cigarette). The desire to quit smoking was a necessary precursor of a quit attempt and was stimulated when the patient's spouse, significant others, or physician expressed a desire for the patient to quit smoking. However, even when the patient had a high desire to quit smoking, the probability of sustained abstinence was low if the patient smoked soon after first rising in the morning (Venters et al., 1990).
- The major source of disagreement between the physician and many patients was not whether patients should quit smoking but, rather, exactly how and when.
- Physicians disliked exhorting patients to quit smoking and would justify with multiple reasons why they did not perform that task. Conversely, physicians enjoyed assisting patients who wanted to follow their recommendations.
- Ongoing support from a physician reduced the probability that a patient who had stopped smoking would relapse.

A META-ANALYSIS OF CONTROLLED TRIALS

To better understand the source of apparent contradictions in the smoking cessation trial literature, Kottke organized a meta-analysis of 39 controlled trials that might possibly be delivered in a physician's office (Kottke et al., 1988). The same general pattern was observed for studies that reported their results after 6 months of followup and studies that reported their results after 12 months of followup. The fact

that the intervention effects were uniformly stronger after 6 months of followup than after 12 months indicated that intervention effects decayed over time. No single intervention strategy was particularly more effective than all others. Success was associated with the following:

- Patient exposure to more than one intervention modality;
- Length of time that the subject was in contact with the program;
- Number of times that the subject was in contact with the program;
- Use of both physicians and nonphysicians; and
- Use of both group and face-to-face programs.

It was predicted from multivariate modeling that a program featuring two intervention modalities with six reinforcing sessions over a period of 1 year would produce a 43-percent success rate. This analysis demonstrated that the smoking cessation process has more characteristics of behavioral shaping (Skinner, 1959) than of health beliefs (Becker and Maiman, 1975).

NOKOMIS CLINIC INTERVENTION PROGRAM

During round I, we came to appreciate that physicians wanted to know precisely how to organize their practices to systematically provide smoking cessation advice; hypothetical situations did not convince most physicians that they should attempt an innovation in their own practices. We therefore used the storefront clinic directed by one of us to develop, test, and document whether our team-based smoking interventions produced success. This project demonstrated the following:

- Most smokers were willing to discuss smoking cessation, but only a few smokers could be recruited into formal programs.
- Just as a successful research program requires both testable hypotheses and a system to test them, the delivery of clinical smoking interventions required a system to deliver the intervention (Table 5).
- A clinical smoking intervention program could be described as containing five necessary components—identification of all smokers through a screening and labeling program, reminders to the physician, a brief message to quit smoking delivered by the physician, self-help materials, and followup (Table 6).
- The smoking intervention clinic environment program could be defined as consisting of seven necessary elements—policy establishment, coordination, an implementation plan, orientation and training, resources, audit, and maintenance (Table 7).
- When these conditions were implemented, almost 90 percent of smokers could be identified and almost the same proportion could be given a smoking cessation message at every encounter.

Table 5
Parallel components of supporting environments for testing the efficacy of interventions and delivering efficacious interventions as clinical programs

Research Environment	Clinical Environment
• Subject identification	• Identification of patients who smoke
• Standardized intervention	• Cessation message and application of patient-specific aids from a menu of efficacious interventions
• Data entry form	• Progress record
• Observation for effect of intervention	• Followup with patients
• Removal of environmental confounders	• Smoke-free clinic
• Official agreement to sponsor research	• Clinic endorsement
• Research personnel recruitment	• Necessary supporting staff
• Principal investigator	• Physician in charge
• Research assistants	• Clinical assistants/nurses
• Project coordinator	• Staff member in charge
• Manipulation protocol	• Physician role defined
• Manual of operations for research assistants	• Staff role defined
• Orientation and training	• Orientation and training
• Funding	• Cost-benefit adequacy
• Evaluation	• Evaluation
• Feedback	• Feedback
• Morale maintenance	• Spirit-building within team of providers

Table 6
Basic elements of patient-provider interaction for effective intervention

Screening and Labeling	• Routinely identifies at least all adult patients as to use or non-use of tobacco.
	• Labels charts for user or non-user status.
	• Re-screens users at each office visit for current usage.
Physician Reminders	• Reminds physicians at each visit of user status and current usage.
	• Reminds physicians of previous tobacco-related encounter attitudes and plans.
Physician Message	• Physician message during each visit that is brief, clear, supportive, and specific (negotiates specific plans, assistance, and followup).
Assistance	• Self-help guides, education, and counseling available to those who want or need them.
Followup	• Supportive communication (re-visit, phone call, or mail) near a promised quit date and after quitting.
	• Review of previous plans at all visits.

Table 7
Supporting elements needed to ensure application of the intervention

Policy Establishment	Clinic management clearly and specifically states the goal and timeframe of action. It names the individuals with authority to carry out the plan.
Coordination	Both a physician coordinator and a staff coordinator are identified to implement the policy. In large clinics, a committee or task force is desirable to support the coordinators.
Implementation Plan	A written plan is devised that identifies how each intervention element is to be performed, including the role definitions, job descriptions, financial aspects scheduling, and a timetable for startup.
Orientation and Training	Every physician and staff person affected by the plan is informed of it, given an opportunity to feel involved, and trained in the tasks that will be required of them.
Resources	All the materials needed are devised or obtained and distributed. Referral arrangements are identified (as needed).
Audit	Establishes a way to periodically assess both the end results and the process for both the overall clinic and for individual physicians and staff members.
Maintenance	Keeps the system going and improves its performance through a combination of feedback and audit information, spirit-building information and events, and repeat orientations and training as needed for both old and new clinic members.

- Not only was the program acceptable to smokers, but also they appreciated the assistance. Fewer than 5 percent of the smokers reported feeling that it was not appropriate for the clinic to ask its patients to stop smoking. Almost 80 percent reported that the program seemed to be about right, about 10 percent said it was too much, and 10 percent said it was too little. Three-quarters agreed that they were more satisfied with their overall care at the clinic because of the stop-smoking efforts there; one-quarter said that they would recommend the Nokomis Clinic to others because of those efforts.

Whereas the interventions used in round I and round II failed to produce sustained smoking cessation, the Nokomis Clinic project intervention system produced 1-year cessation rates of about 20 percent (Solberg et al., 1990). This project demonstrated that through development of a supportive environment and involvement of the entire clinic work unit in the smoking intervention effort, an effective and efficacious intervention effort could be incorporated into a busy family practice clinic, and it could be sustained there for more than 4 years.

When fully incorporated into an office practice, the smoking intervention system developed at the Nokomis Clinic would have the following features:

- Each adult patient would be categorized as a smoker or a nonsmoker and each medical record would be labeled accordingly.
- At every visit, each smoker would be asked about current tobacco use and be asked by the physician to quit smoking.
- The clinic would implement an intervention program that could respond to the particular needs of the individual smoker.
- A smoking cessation progress record would be kept for each smoker and used as a reminder to raise the topic as well as a simple way for physicians to review past actions and to arrange future assistance and followup.
- Self-help materials would be readily provided to interested smokers.
- The clinic would implement a process to assure that the progress of each smoker be followed and that quitters be reinforced for abstinence immediately after quit dates or as they visited the clinic for other reasons.

This smoking intervention system became the basis of the American Academy of Family Physicians Smoking Intervention Kit (AAFP Stop Smoking Program, 1987a and 1987b), and it provided much of the philosophical background for the National Cancer Institute publication, *How To Help Your Patients Stop Smoking* (Glynn and Manley, 1990). It also became the intervention program suggested to the clinics in the round III trial.

DOCTORS HELPING SMOKERS, ROUND III

For round III, Doctors Helping Smokers collaborated with Blue Cross/Blue Shield of Minnesota through its managed care plans, Blue Plus and HMO Midwest. Blue Cross/Blue Shield contracts with independent primary care practices in Minnesota through Blue Plus, and in Wisconsin through HMO Midwest, to provide health services to the individuals covered by these plans. In none of these medical practices do managed care patients make up more than 15 percent of all patients seen by the practice.

The target clinics of the round III intervention were all 11 Minnesota clinic organizations that provided service to enrollees living outside the Minneapolis-St. Paul metropolitan area but within a 2-hour drive of Minneapolis-St. Paul. At the beginning of the study, 126 primary care physicians were practicing in these clinics in 31 sites. Two sites closed during the period of the study.

The clinics in the control group were 10 clinic organizations in western Wisconsin that held contracts to provide services to individuals covered by the managed care contracts of Blue Cross/Blue Shield of Minnesota. These clinic

organizations were somewhat smaller than the intervention group clinics; they averaged 7.7 primary care physicians per clinic and 1.5 sites per clinic.

The Patients When enrolling in Blue Plus or HMO Midwest, each enrollee is required to name a clinic that will be responsible for his or her primary care. (Because many individuals work in Minnesota while living in Wisconsin, it is not unusual for an individual covered by Blue Plus to name a Wisconsin clinic for primary care.) Blue Cross/Blue Shield has the names, addresses, and insurance claims of these enrollees and could survey them without the involvement of the physicians in either the intervention group or the control group clinics. This group of enrollees was used to evaluate the round III intervention.

In contrast to other programs that have tested smoking interventions in clinics (Cummings et al., 1989a; McPhee et al., 1989; Russell et al., 1979; Wilson et al., 1988), participating physicians consisted of an entire population, not volunteers from a population, and at no time did Doctors Helping Smokers provide salary support for any clinic employee, place a study employee in a clinic for the purpose of providing patient care, or have a Doctors Helping Smokers employee routinely monitor physician and staff activity.

Physician Recruitment The failure of rounds I and II to attract more than a small minority of physicians to give smoking cessation advice led us to develop a markedly different recruitment strategy for round III of Doctors Helping Smokers. While rounds I and II used direct mail contact with the individual physician, as described above, round III was based on developing a relationship with entire clinic groups over a period of time. Table 8 summarizes the differences between the recruitment strategies for the first two rounds and for round III of Doctors Helping Smokers. A letter was the initial contact for both, but the sponsoring organizations for round I did not have day-to-day interaction with the clinics as did the sponsors of round III. The initial response required of the physician in round I was the mailing of a postcard; aside from a reminder letter or two, Doctors Helping Smokers had no plausible explanation for attempting further contact with the physician if this card was not mailed. The letter in round III only advised the physician of the nature of an upcoming telephone call.

The second contact in both rounds I and II was a telephone call. However, the purpose of the telephone call in round I was to confirm that the physician was willing and able to participate in the randomized trial. In round III, the purpose of the telephone call was to ask the physician to name a date when the Doctors Helping Smokers team could visit the clinic to explain the study. The physician had to agree only to stay at the clinic over the lunch hour to meet with the Doctors Helping Smokers investigators.

The first face-to-face contact (third of all contacts) in round I occurred only if the physician attended the workshop. The first face-to-face contact (third of all contacts) with round III physicians was in their own clinics; they had to

Table 8
Summary of recruitment process for Doctors Helping Smokers

	Rounds I and II	Round III
Initial Contact	Mail	Mail
Organizational Relationship	No day-to-day contact about clinical matters	Day-to-day contact about clinical matters
Initial Response Required of Physician	Mail postcard	No response required
Second Contact	Telephone	Telephone
Second Response Required of Physician	Agree to come to workshop and participate in trial	Agree to stay at clinic to have lunch with Doctors Helping Smokers team
Third Contact	Face-to-face at nonclinic site if in workshop group; mail contact otherwise	Face-to-face in physician's own clinic
Third Response Required of Physician	Carry out trial in own office	Agree to ongoing negotiation of specific activities with Doctors Helping Smokers team

agree only to continue discussions with the Doctors Helping Smokers team about potential intervention strategies they might be willing to adopt for their clinical practices.

Using a philosophy similar to what later was called "the social learning model of consultation" (Brown and Schulte, 1987), which was based on Bandura's social learning theory (Bandura, 1977), we used the following recruitment process in round III: One of the Doctors Helping Smokers investigators contacted the medical director of each intervention group clinic with an introductory letter. The letter explained the study without asking for any commitment. We followed the letter with a telephone call to the medical director to arrange a site visit. The purpose of this visit was primarily informational but included four goals:

- To personally introduce the Doctors Helping Smokers investigators and the Doctors Helping Smokers agenda to the clinic physicians and administrators;
- To describe the commitment of Blue Plus to clinic-based smoking cessation interventions;
- To reach a consensus that smoking should be treated to the extent that it would not disrupt other clinic operations; and

- To ensure that the effort would be a true collaborative effort,
  - — The physicians in each clinic would agree to consider implementing the Doctors Helping Smokers program, but individual physicians or the entire group would be free to start or stop at any time without a requirement to justify the action to Doctors Helping Smokers.
  - — The clinic personnel would be seen as contributing depth of knowledge about the personnel, organization, and patient preferences at that particular clinic: Doctors Helping Smokers would be seen as contributing breadth of knowledge and special expertise about smoking intervention techniques and activities based on experience at multiple sites.
  - — Doctors Helping Smokers would provide a recommended approach and provide intervention and training materials, training programs, audits, feedback, and consultation at the desire of the clinic.
  - — Doctors Helping Smokers would advocate only interventions of documented feasibility.

To avoid having the physicians hold back for fear of being trapped into undesired or nonproductive commitments, the Doctors Helping Smokers team explicitly told each clinic that they did not need to even start the project unless they wished to and that they would be free to stop at any time.

Complimentary workshops, in which physicians, nurses, administrators, and other clinic personnel received instruction and exchanged experiences with each other, were provided three times a year at Blue Plus headquarters. The workshops were usually organized into three components. First, a national expert (e.g., Ronald Davis, M.D.; Stuart Cohen, Ed.D.; Thomas Glynn, Ph.D.) was brought in to discuss smoking intervention from a national perspective; this gave the attendee a sense of interacting in an important, high-level, national process. Second, the Doctors Helping Smokers investigators would discuss their new procedures and findings; this allowed the investigators to transfer information to attendees and give them a sense that they were essential participants in the local program. Finally, the individual attendees would present their own activities; this created a sense of commitment and competence in the attendees and allowed them to learn from each other's experiences.

Newsletters were mailed bimonthly to all key personnel at the clinics, and the two nurse-educators employed by Doctors Helping Smokers telephoned or visited each clinic site at regular intervals to provide help with problem-solving, to assess program progress, and to provide feedback and reinforcement. The newsletters provided information about the project to those who were not currently involved and provided information and a sense of belonging to office personnel who had become active in Doctors Helping Smokers. The site visits were essential for recruitment of the clinic personnel and to reinforce their

commitment to the project. The site visits served particularly to signify to the clinic personnel that they were important to the project as individuals and that the project staff valued their contribution highly.

The Patient Intervention Program

The clinics could adopt any patient intervention program that they wished. However, we strongly advocated the above-described program developed at Nokomis Clinic. Rather than trying to recruit smokers into formal cessation programs, the patient intervention program designed for Doctors Helping Smokers was based on consistent and repeated advice to the smoker to quit smoking. The entire clinic was involved, and the clinic's task was defined as working with patients who wanted help rather than trying to convince resistant patients to quit smoking.

The Clinic Environment Program

The goal of the clinic environment program was to provide the physicians and medical staff with an environment that made it easier to give the advice than not to give it. It was also the intent of the program to reinforce clinic staff members when they gave smoking cessation advice. In designing the system, the investigators looked to the organization of surgical operating rooms, coronary care units, hypertension treatment programs, and other successful interdisciplinary medical systems as models to be emulated.

In the specific case of a clinical smoking intervention program, we postulated that a supportive environment would have to include 14 elements (Solberg et al., 1990):

- A smoke-free clinic;
- Formal clinic endorsement of the program;
- Staff support;
- Physician support;
- A physician coordinator;
- A staff coordinator;
- Definition of the physician's role and responsibility;
- Definition of staff roles and responsibilities;
- An orientation program;
- Cost-benefit adequacy;
- Program evaluation;
- A system to feed results back to the physicians and staff;
- A spirit-building program; and
- A program to market and advertise the program.

The purpose of a *smoke-free clinic* was to avoid giving the patient conflicting messages about the importance of being a nonsmoker. A clinic was considered smoke-free if patients, physicians, and employees were prohibited from smoking in all clinic buildings and on clinic grounds.

We believed that *clinic endorsement* of the program was essential if the clinic was to be committed to the program. Clinic endorsement was considered present if the clinic management had developed systems and procedures to incorporate smoking interventions into the daily clinic routine and had announced the formation of a smoking intervention program.

Staff support was considered present if staff members encouraged each other to perform the program well; if there was no negativity or sabotage by staff members; if nurses, medical records personnel, and receptionists were all involved and supportive of the program; and if personnel wore symbols (pins and T-shirts) associated with the program.

Physician support was considered present if the physicians were positive about the program and encouraged each other to participate in the program; if no physicians were negative about the program or sabotaged the program; if physicians exhibited leadership to their employees; and if physicians wore symbols of the program.

Many observers of innovation and product development have observed that new products languish if they don't have a "product champion," and all successful medical programs—for example, operating rooms, coronary care units, and emergency rooms—have both a physician coordinator and a staff coordinator. The *physician coordinator* was expected to be the "product champion" for the smoking intervention program. The physician coordinator was expected to meet with the staff on a regular basis, discuss the program at the physicians' meetings, and take supportive action when required. The *staff coordinator* was expected to champion the product among the employees and to bring the employees' problems to the attention of the physician coordinator.

The *physician role* was to give a brief smoking cessation message, to ask the patient if he or she were willing to set a quit date, to give the patient self-help materials, to reinforce those who had quit smoking, and to document the encounter on the smoker progress record. The *staff role* included identifying smokers, documenting the patient's history of tobacco use, and carrying out the activities identified by the Nokomis Clinic project.

The physicians and staff could not be expected to participate in the program if they did not understand what was expected of them. Therefore, the purpose of the *orientation program* was to train the physicians and staff who worked in the clinic at the beginning of the project and train new physicians and staff as they were hired by the clinic. The orientation program was also expected to follow up with physicians and staff as required by special circumstances.

Programs that do not have *adequate cost-benefit ratios* can be expected to disappear in times that the clinic is in a crisis. Therefore, it was a goal to have the smoking program benefit the clinic financially and benefit the staff emotionally. Benefits had to exceed costs in terms of fiscal return, production of health to the patient, and emotional reward to the staff. Cost-benefit adequacy also was considered to require a method to recover the program costs, definition of service charges, billing and receipt of payments, and administrator satisfaction that the program was not an undue financial burden on the clinic.

Preventive medicine programs like the smoking intervention program tend to give only negative feedback. Smokers who are resistant to the smoking cessation message create a stronger impression than those who quit smoking because they were given advice to quit. Therefore a formal *program evaluation*, *feedback system*, and *spirit-building program* were considered necessary to demonstrate that the program was being carried out and that it was successful. Program evaluation required the development of a plan to evaluate whether the patients were being identified as smokers or nonsmokers, whether the charts were being labeled, whether patients were being given a smoking cessation message, whether patient progress was being documented, whether patients were quitting smoking, and whether patients were getting positive reinforcement for quitting. It was expected that both individual and group performance of these tasks was to be evaluated.

The *feedback* component of the program was expected to present program results to the clinic management, physicians, and staff groups at regular intervals. It was also expected that feedback be provided to individual physicians and staff.

The goal of the *spirit-building* component of the intervention was to reinforce the positive aspects of the intervention for the clinic as a group and for individuals in the clinic. The spirit-building component was also expected to create incentives for participating in the program.

Physicians respond to patient demand for services, so it would be ideal if patients would ask for smoking cessation assistance. If the program is to be sought by the patients, it must be advertised and marketed to the patient community. The *marketing and advertising* component of the program was expected to generate demand for the program among the patient population and community. Also, it was expected to prime the smoker so that he or she expected to be asked about smoking when coming to the clinic for other reasons.

Round III Results

Clinic Recruitment

All medical directors in the 11 intervention clinics agreed to an initial meeting with a Doctors Helping Smokers/Blue Plus physician and the nurse-educator. The presence of the nurse-educator at this meeting reinforced our intentions to use a team approach, and it introduced her as the individual who would be making the site visits. At some

of the initial meetings, only the medical director represented the clinic. At some of the clinics, a few additional physicians joined the medical director, and at others, nearly the entire medical staff was present. Although only 6 of the 126 primary care physicians (5 percent) attended the first workshop and only 13 physicians (10 percent of the total) attended any workshop, all 11 clinic groups were represented by at least some clinic personnel at the first training workshop. The members of the Doctors Helping Smokers intervention team made 177 site visits, 759 telephone calls, and 175 mailings to the intervention clinics between May 1, 1987, and October 31, 1988. This was an average of 5.7 site visits, 24.0 telephone calls, and 5.6 mailings per practice site.

Approximately 6 months after the initial contact with the clinics participating in round III, an audit of the Doctors Helping Smokers patient encounter records demonstrated that 68 percent of the primary care physicians were completing the Doctors Helping Smokers records for at least some of their patients. On the survey that was mailed at the same time that the medical records were audited, more than 90 percent reported that they had heard of a systematic program in their clinic to identify and help patients who smoked (Kottke et al., 1990c) (Table 9). None expressed a belief that their clinic should not be involved with such a program, and 69 percent reported using the program with their patients who smoked. One-third of the physicians reported that the program had helped them deal with the problem of smoking among their patients. Fewer than 10 percent of the physicians reported that they had been very much involved with developing the program.

Eighteen months after initial contact, physicians in 25 of the 31 sites were participating in the implementation of a smoking intervention system similar to, or exactly the same as, the Doctors Helping Smokers program. All 11 clinic systems were represented by at least one active site. Although 2 sites had closed, physicians in 24 of the remaining 29 sites were participating in the implementation of a smoking intervention system similar to, or exactly the same as, the Doctors Helping Smokers program. Five sites never started any component of the Doctors Helping Smokers program.

One of the investigators conducted site visits during February, March, and April 1989 to assess the level of implementation at each of the other 24 sites. Although the rates of implementation varied for the different components of the patient intervention program, between 40 and 50 percent of the 29 clinic sites showed very little evidence of implementing the program (Kottke et al., 1992). About one-quarter of the 29 sites systematically identified smokers and noted the smoking intervention encounter at every visit. Fewer than 20 percent of the 29 sites kept complete smoker progress records, but almost half of the sites had implemented a cessation intervention plan and a patient followup plan. Three-quarters of the 29 sites made self-help materials available for their patients.

Table 9
Self-reported participation in round III[a]

Physician has heard of Doctors Helping Smokers.		
Yes = 79 percent	No = 5 percent	Uncertain = 2 percent
Physician believes clinic should be involved with Doctors Helping Smokers.		
Very much = 53 percent	Quite a bit = 21 percent	Somewhat = 10 percent
Not at all = 0 percent	Not answered = 2 percent	
Physician uses the program with patients who smoke.		
Now and in past = 59 percent	Past only = 2 percent	Never = 25 percent
The extent to which physician identifies patients who smoke and offers them help to stop smoking:		
All patients = 26 percent	Most patients = 46 percent	
Some patients = 13 percent	No patients = 1 percent	
Program has helped physician to deal with patients who smoke.		
Yes = 30 percent	Uncertain = 28 percent	No = 5 percent
No experience = 24 percent		
Physician reports being involved in development of program.		
Very much = 8 percent	Quite a bit = 8 percent	Somewhat = 36 percent
Not at all = 34 percent		

[a] *105 of the 122 primary care physicians returned the survey. The response to each variable plus the 14-percent nonresponse rate totals 100 percent.*

Clinic Environment Program

Between one-quarter and one-third of the 29 clinic sites showed little or no evidence of adopting the clinic environment program. About 15 percent of the 29 sites adopted all aspects of the clinic environment program. Adoption of individual components varied from a high of 80 percent for a smoke-free clinic to a low of 14 percent for formal endorsement of the program, evaluation of the program, adoption of a spirit-building program, and development of a marketing program.

The reasons for not adopting the clinic environment program differ for each site, and the investigators have not yet been able to develop a mathematical model that explains the reasons for adoption or nonadoption by each of the sites. We believe that four major factors contributed to the problem of nonadoption: (1) the instability of the regional medical environment at the time of the study, (2) the investigators' inability to visit the clinics more frequently to provide them with help and reinforcement, (3) the investigators' inability to reimburse clinics for even the modest extra effort required by each of the physicians, and (4) the generally held attitude that giving smoking cessation advice is optional in clinical practice.

Patient Experience

Although only 10 percent of physicians ever attended a workshop, the inclusion of office staff as part of the intervention team and the use of site visits created avenues of communication with the clinics that could be used to foster adoption of the Doctors Helping Smokers intervention. Therefore, round III changed the experience of patients who attended the intervention group clinics during the intervention period (Kottke et al., 1992). For those who had visited their clinic in the 6 months prior to the preintervention survey, the proportion reporting that tobacco use had been brought up by the physician or clinic staff was equally low (about 22 percent) for both cohorts (Table 10). The two cohorts did, however, report significantly different experiences during the intervention. The mean proportion of patients who reported on the postintervention survey that someone asked them if they smoked was about 14 percentage points higher for the intervention clinics than for the control clinics ($p < 0.05$). The mean proportion of patients who reported on the *preintervention survey* that *no one* had asked if they smoked at their last clinic visit, and subsequently reported on the *postintervention survey* that *someone* had asked if they smoked when they last visited the clinic, was also higher for intervention group clinics in comparison to control group clinics ($p < 0.05$).

The mean proportion who reported on the postintervention survey that they had been asked if they smoked when they last visited the clinic, and who reported on the preintervention survey that no one had asked if they smoked, was about 8 percentage points higher for the intervention cohort than for the control cohort ($p < 0.05$). The mean proportion of patients who reported on the postintervention survey that their doctor had advised them to stop smoking was about 14 percentage points higher for intervention group clinics than for control group clinics ($p < 0.05$).

The difference in the mean proportion reporting that the smoking cessation advice was helpful when given was about 50 percent higher for the intervention group cohort than for the control group cohort, and the rate at which specific help was offered was nearly twice as high for respondents in the intervention group cohort than for respondents in the control group cohort. Because of the small sample sizes, these differences only approached statistical significance ($p < 0.10$).

In comparison to patients of control group clinics, patients of intervention group clinics who were not smoking at their last visit were more than twice as likely to report that *someone* had commended or complimented them at their last visit for not smoking and were almost three times as likely to report that *their doctor* had commended or complimented them at their last visit for not smoking (both $p < 0.05$). About twice as many of the members of the intervention cohort reported that they felt helped by the clinic or doctor in some way to remain an ex-smoker. Because of the small sample sizes, the difference in this rate for the two cohorts was not statistically significant.

Table 10
Activities of the control and intervention clinics, as reported by regular smokers[a]

	Control[b]	Intervention[b]	
(Number of Clinics Analyzed)	(8)	(10)	
Prior to the Intervention			
Tobacco use was brought up by a physician or staff at any visit in the 6 months prior to intervention.	22.9%±11.2	21.9%±9.6	0.84
At the Last Clinic Visit During the Intervention Period			
Someone asked whether the patient used tobacco.	26.0±12.2	39.8±12.3	< 0.05
Patient was asked if he/she used tobacco when he/she hadn't been asked before the intervention.	20.4±6.9	28.7±8.5	< 0.05
The doctor advised the patient to quit smoking if he/she was still smoking at the last clinic visit.	26.4±14.6	40.5±12.1	< 0.05
The patient considered advice helpful if given.	16.4±9.0	23.9±8.0	< 0.10
The patient was offered specific help if he/she expressed interest in quitting.	13.4±11.1	22.8±11.5	< 0.10
If the Patient Was Not Smoking at Last Clinic Visit			
Someone commended or complimented the patient for not smoking.	11.3±11.8	28.2±19.9	< 0.05
The doctor commended or complimented the patient for not smoking.	9.5±11.4	25.9±19.8	< 0.05
The patient felt helped in some way to remain an ex-smoker.	6.6±9.8	13.0±16.9	0.33

[a] *Regular smokers were those who smoked one or more cigarettes every day for the 7 days prior to the preintervention survey.*
[b] *Column entries are percentages of patients responding affirmatively.*

LESSONS LEARNED Through an iterative cycle of hypothesis formulation, program development, hypothesis testing, and hypothesis reformulation as suggested by Argyris et al. (1985), Doctors Helping Smokers was able to develop a clinic-based intervention that increased the rate at which smoking patients received advice to quit when they sought care from a group of nonvolunteer medical clinics. We feel that the following observations are the most important lessons to be learned from this study.

Requirements for Recruitment

The success of recruitment in round III is predicted by the literature on the relationship between social contacts and successful recruitment. Green (1970) found that perceived expectations of the subject's friends is an important modifier of behavior, and Rogers (1983) noted that innovations are most likely to diffuse when individuals are alike in personal and social characteristics. Gerlach and Hine (1970) found in their studies of Black Power and Pentecostal organizations that recruitment predictably takes place through preexisting, significant social relationships of positive affect; mass media are rarely the source of recruitment. In their studies, the type of relationship (brother, spouse, parent, fellow church member, neighbor, patron, peer) was a less important predictor of recruitment than either the *frequency of interaction* between recruiter and potential member or the *affect of the relationship* (positive or negative) with the potential convert. Recruitment was always achieved by those with whom the relationship had been very positive; negative relationships, even between kin supposedly important to each other, did not result in recruitment.

Positive, Ongoing Relationship

Face-to-Face Interaction

Factsheets, letters, brochures, articles, and other mass media only provide information (Gerlach and Hine, 1970). Rogers (1983) has found that without regard to the type of innovation, only 5 to 10 percent of individuals will respond to information in the absence of peer group support. The responders represent members of two groups: information seekers, who wish to find out more about the activities being promoted, and individuals who are already active and are seeking reinforcement. The implication is that mailed materials can provide support for the already active or information for those not active, but any differences among mailed materials will result only in minor differences in recruitment rates.

Repeated Contacts

The Doctors Helping Smokers experience is consistent with Rogers' observation that adoption of innovation requires ongoing contact between the change agents and the adopter. Rogers (1983) noted that the requirement of more than 20 contacts per year between an early adopter and a change agent is not atypical if an innovation is to be diffused. Without a similar level of investment, apparently one cannot expect adoption even if recruitment is initially successful. The 177 site visits, 759 telephone calls, and 175 mailings from Doctors Helping Smokers to the clinic sites between May 1, 1987, and October 31, 1988, were inadequate to produce full adoption.

Entire Work Unit

Although similar proportions of physicians attended workshops in all three rounds, round III resulted in recruitment of 10 times as many physicians because the recruitment effort was directed toward the entire clinic and took place in the clinic. Doctors Helping Smokers is not the only trial where it was observed that recruiting whole work units was far more successful than recruiting individual physicians (Cummings et al., 1989a).

An effective program involves recruiting the entire unit, because peers and employees who are not part of a new program will be working against it if they do not understand how it contributes to the mission of the clinic. The surgeon

Charles H. Mayo, the sociologist Eliot Freidson, and others have all appreciated the impact that the organizational base of the medicine work unit has on the ability to complete a desired task (Freidson, 1970; Mayo, 1988; McDonald et al., 1984).

Behavior Shaping

A model that assumes that patient behavior is primarily motivated by attempts to avoid disease makes patient behavior appear irrational. The vast majority of smokers acknowledge that smoking is a health hazard, that quitting smoking would benefit their health, and that they would like to quit smoking. Even so, they claim that they are unable to stop smoking for extended periods of time.

The data from the meta-analysis (Kottke et al., 1988) and from Doctors Helping Smokers (Kottke et al., 1989, 1990c, and 1992) demonstrate that smoking and smoking cessation behavior is rational if it is viewed as a process of behavior shaping (Skinner, 1959) or social learning (Bandura, 1977). Patients give priority to achieving goals that are more immediate than the maintenance of physical health into the far future. The smoker may feel that smoking increases the probability of attaining these short-term goals. It is up to the smoking intervention program to help the patient learn ways to achieve short-term goals without smoking and to come to believe that smoking interferes with the attainment of short-term goals.

Desire and Ability To Quit

Our experience with transdermal nicotine patches is consistent with the observation that a way of countering the factors of habit and addiction and a way of maintaining a high desire to quit smoking must be present if a smoker is to remain abstinent. Almost 80 percent of patients on the active patch, compared with 40 percent on the placebo, quit smoking while on the patch, but the long-term success of the two groups was identical (Hurt et al., 1990). The nicotine patch offered the smokers a way to deal with the addiction but could not maintain their desire to abstain from smoking. The desire to quit smoking, independent of habituation or addiction, is a product of the social environment and must be continuously reinforced by the social environment and support system.

Physician and Staff Behavior

If viewed from a "rational" perspective, failure to adopt a smoking intervention of documented efficacy is an enigma: Addressing matters that affect a patient's health is a physician's responsibility. Physicians believe that smoking is among the most harmful of the behaviors that their patients can practice (Orleans et al., 1985; Wechsler et al., 1983), and more than half of American smokers try to quit each year. Why, then, is it so remarkably difficult to get physicians to give smoking cessation interventions to their patients (Cummings et al., 1989a; Kottke et al., 1990c; McPhee et al., 1989; Wilson et al., 1988)? Why do patients continue to report that their physicians still do not routinely give them advice to stop (Anda et al., 1987)? And, why do physicians not adopt smoking cessation interventions that have been documented to be both efficacious and cost-effective (Cohen et al., 1989;

Cummings et al., 1989b; Kottke et al., 1989; Ockene et al., 1991; Strecher et al., 1991)? From the perspective of the health belief model (Becker and Maiman, 1975), physician behavior is as irrational as patient behavior.

However, physicians are not typically irrational and, viewed from another perspective, their behavior is not mysterious. American medicine is driven primarily by patient expression of demand for service, not unexpressed patient need for service (Kottke et al., 1990b). Viewed in this context, physicians can truly want their patients to quit smoking but fail to act because they expect their patients to follow the convention used for almost all medical encounters: They expect their patients to broach the subject of smoking cessation as a signal that they want and will accept help with the problem.

Although physicians enjoy special status in society (Freidson, 1986), it appears that their behavior is determined by the same factors that determine patient behavior. The physician never has adequate time to complete all possible tasks, and some rewards can be increased only at the cost of other rewards. Time spent talking with patients about smoking means time not spent seeing patients who are presenting undiagnosed symptoms and signs. The physician's diagnosing conditions tends to increase patient satisfaction; trying to convince patients to stop smoking tends to upset and anger patients. Behavior shaping predicts that, given a choice, physicians would tend to choose the behavior that is emotionally reinforcing, making diagnoses, over the behavior that is emotionally punishing, advising people to quit smoking. The observation that physician performance at the task of asking patients if they smoke and advising them to quit tends to decay over time (Ewart et al., 1983) corroborates this explanation.

Mutual Acceptability Of the Encounter

Patient-physician interaction takes the form, almost exclusively, of a patient seeking out a physician and asking for help through the making of a "chief complaint." The physician responds by telling the patient if and how he or she is willing to provide help. It is the exceptional situation in which the physician acts against the will of the patient. These situations are limited to incarceration when the patient is mentally incompetent, notification of contacts when the patient poses an infective threat to the community, and pediatric immunization. In the first, the physician must obtain a court order to act. In the second, the private physician almost always lets the public health officials take over responsibility for care. On the basis of this observation, we can expect that physicians will always try to avoid conflict with the patient and take action only if it is in response to a patient request or is likely to be accepted by the patient.

In the case of advice to quit smoking, if the physician is expected to take action, that action must be defined as *advice* to the patient to quit smoking. There is little reason to believe that physicians will ever adopt the practice of routinely attempting to *convince* their patients to quit smoking. Even if the physician is not considered obligated to convince the patient to stop smoking,

it is appropriate to obligate the physician to carry out six smoking intervention tasks (Kottke et al., 1990b): (1) understand why people smoke and how they quit; (2) identify patients who smoke; (3) advise those patients to quit; (4) enable them to stop smoking by prescribing services or by imparting them with the knowledge, skills, and confidence to stop; (5) help those patients to maintain abstinence by providing positive reinforcement both in the examining room and in the community; and (6) establish, support, and maintain a system to facilitate tasks 2 through 5.

CONCLUSIONS On the basis of the empirical evidence gathered in Doctors Helping Smokers, we have markedly reformulated the way in which we see the smoker, the physician, and the environment in which they interact:

- The smoker, rather than being an individual lacking in knowledge about the harmful effects of smoking who would quit if he or she were aware of these facts, almost always knows about the harmful effects, usually would like to quit, has a 40-percent probability of trying to quit in a given year, but is unlikely to remain abstinent after any single attempt.
- The physician, rather than being an autonomous individual who would try to convince the smoker to quit if he or she were aware of the harmful effects of smoking, is an individual who is highly aware of the harmful effects of smoking but operates under a number of misconceptions about how to help smokers quit, lacks the resources to identify the smokers who want to quit and provide them with help, and experiences intense competition for his or her time and attention.
- The environment, designed to help the physician meet the demands of the patient for acute care, currently offers little support to the physician who would like to help patients stop smoking.

We therefore designed an interdisciplinary clinic-based program that (1) identified all smokers but focused on providing help to the smokers who wanted to quit smoking, were trying to quit smoking, or who had recently quit smoking; (2) conceived of the physician as an individual who is highly dependent on office staff for support and, therefore, involved the entire office staff in the effort to identify smokers, advise them to quit, and provide them with the help they might want or need in the smoking cessation effort; and (3) provided a clinic environment that cued the staff to act and reinforced them when they did act. Through the Doctors Helping Smokers program, we have demonstrated, in a group of nonvolunteer clinics, that at least some clinics can be recruited to adopt the program described above and that this adoption, even at incomplete levels, results in significant increases in the rates at which smokers are identified, advised to quit, and reinforced in their quit attempts.

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Prompting Smoking Cessation In Family Practice

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INTRODUCTION The primary aims of this project were to determine the effect of a prescription for nicotine gum when added to brief physician advice and followup on (1) smoking cessation, (2) quit attempts, (3) intentions to quit, (4) self-efficacy about the ability to quit, and (5) confidence in physician advice. The study design was a randomized clinical trial where adult smokers receiving routine health care from their family physician were assigned to either the group receiving physician advice against smoking and followup (advice alone) or the group receiving physician advice against smoking and followup plus a prescription for nicotine gum (advice plus gum). Subjects were expected to fill the prescription at their own expense. Verification of smoking cessation was done at 6 months by self-report, observer report, and carbon monoxide (CO) monitoring. The intentions to quit, self-efficacy, and confidence in physician advice were measured by brief questions given before and after the physician visit. The secondary aims were to describe and compare the rates of recruitment between two intervention sites. As a pilot project, the study generated information useful for further clinical trials on smoking cessation in primary care medicine. Because of the varied success of nicotine replacement therapy in general medical practice, there is a need to assess alternative pharmacological measures for smoking cessation in the same setting.

RECRUITMENT IN A PRIMARY CARE TRIAL Physicians in two primary care practices in Chittenden County, Vermont, agreed to participate in this pilot project on smoking cessation. The first practice (site 1) was a private family practice with 5 physicians (aged 35 to 62) and about 15,000 patients, including children. The clinic is located in a semirural town near Burlington. At this site, the study was conducted during 34 working days from February through April 1987.

The second practice (site 2) was an academic general internal medicine practice with 6 physicians (aged 32 to 58) and about 16,000 patients, not including children. The practice was located in the University Health Center in Burlington. Site 2 had a history of research efforts related to smoking cessation and adult comprehensive care (Bronson and Omeara, 1986). The study described here was carried out during 53 working days from July through October 1987.

All adult patients entering the practices for routine, nonemergency care, including new and return appointments, received a screening questionnaire to identify health risks (see Appendix A at the end of this chapter). The screening form asked all potential subjects about their age, gender, and general health

risks, including smoking. Because both smokers and nonsmokers completed the screening form, it allowed for gathering of information on both groups without embarrassing smokers by being the only group completing forms. The screening of potential subjects was done either by the practice receptionists at the first site or by trained study coordinators at the first and second sites. All study forms were color-coded to make filing easy for the coordinators.

At the private-practice site, 576 adult patients were screened, of whom 128 (22 percent) were smokers (Figure 2). Among the 128 adult smokers screened, 54 percent consented to enter the study (see consent form, Appendix B). Among those who consented, 11 smokers (9 percent) failed to meet the inclusion criteria, as determined by an entry questionnaire and a medical screening form (Appendixes C and D). The forms were color-coded for easy reference. A total of 58 smokers (45 percent of those eligible) enrolled in the clinical trial.

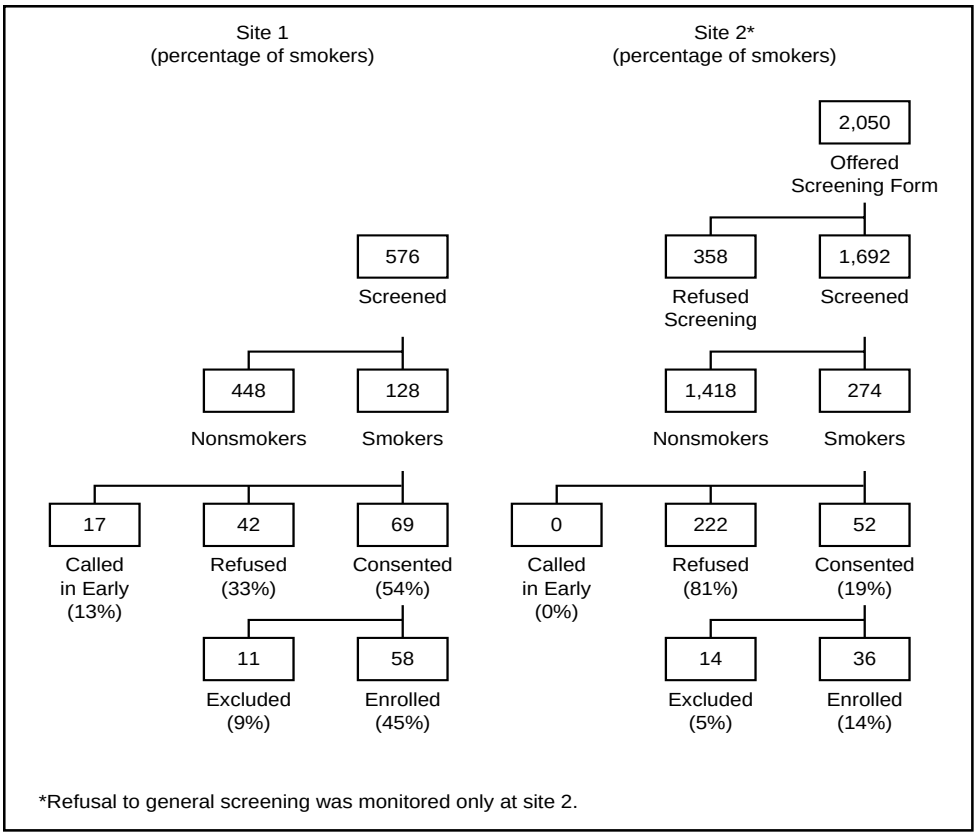
Initially at site 1, the receptionists screened 287 patients over 21 days, or 13.7 patients per day; whereas the study coordinators screened 267 patients over 13 days, or 20.5 patients per day. The receptionists received only a brief orientation to the project. They were instructed to hand out forms to interested smokers and refer them to the coordinators for more instruction. The rate of enrollment was 1.7 patients per day.

At site 2, the screening form was offered to 2,050 adult patients, of whom 358 (17.5 percent) refused to read it, and 1,692 (82.5 percent) completed it. Of those completing the form, 274 (16.2 percent) were smokers. Site 2 had already done a study on smoking cessation (Bronson and Omeara, 1986) that may have affected the overall prevalence of smokers in the practice. Among the smokers screened, 19 percent consented to enter the study. A total of 38 smokers (14 percent of those eligible) enrolled in the trial. The rate of enrollment was 0.7 subjects per day.

It was hypothesized that the impersonal nature of handing out a consent form discouraged enrollment. To test this hypothesis at site 2, 104 interested patients were randomly assigned to have the study coordinators either actively read the informed consent form to them or to have subjects read the consent form on their own. The actively informed group had 51 patients, of whom 27 consented (53 percent). The self-informed group had 53 patients, of whom 25 consented (47 percent). The difference between the two methods of gaining consent was not found to be significant.

The conclusions of tracking recruitment in this clinical trial on smoking cessation in two general medical practices were as follows: (1) the rate of enrollment was 3.3 times as great in the private practice as in the academic practice (45 vs. 14 percent); (2) trained coordinators were better recruiters than practice receptionists; and (3) having the study personnel actively involved in obtaining informed consent did not improve recruitment. This study has been described in more detail by Wadland and colleagues (1990).

Figure 2
Comparative depiction of recruitment to a smoking cessation trial at two sites



** Refusal to general screening was monitored only at site 2.*
Source: Wadland et al., 1990; used with permission of the authors.

TRAINING ON BRIEF ADVICE As part of the current trial, participating physicians attended a 2- to 3-hour workshop training them to (1) elicit a health problem that is a reason for smoking cessation; (2) state the reversibility of the problem; (3) provide a previously tested cessation booklet, "Quit and Win"; (4) give a prescription for nicotine gum and instructions on its proper use; (5) ask for a commitment to quit smoking; (6) ask for a quit date; (7) make an appointment for followup at 1 to 2 weeks after the quit date; and (8) congratulate the patient for trying to quit. The physicians received continuing medical education credit and refreshments for attending the session, which was held in their offices after patient care hours. Prior to the session, they had received a packet of information explaining the study rationale, review articles on nicotine replacement therapy, expected time commitment of the physician and practice personnel, and payment for participation—

$10 per subject receiving physician advice against smoking. The physicians were invited to comment on the study protocol and to make suggestions for applying it in their practices.

Common scenarios were role-played. For example, a patient wants to quit because of frequent coughing and easily sets a quit date. Another patient has no real reason to quit and is not sure of committing to an exact date to quit. A third patient wants to quit but is not sure of the date. A fourth patient really likes smoking and believes it is a personal right. Physicians watched the project directors play out such scenarios, and then they role-played themselves. Finally, the physicians viewed a slide-tape show on nicotine gum and its proper use. There was ample time for questions and answers.

During the course of the study, the office coordinators provided qualified subjects with an envelope containing different instructions to the physicians, based on the randomization schedule. After the physicians dealt with the primary reason for each visit, they reviewed the degree of smoking dependency, provided by the entry questionnaire (Appendix C). The entry form included information on the type of cigarettes smoked, average number of cigarettes per day, and Fagerstrom tolerance questions for assessing the degree of dependency. All subjects received generic advice suggesting reasons to quit and stating the reversibility of symptoms. A generic reminder sheet was used to prompt physicians (see Appendix E).

The physicians then opened a randomization envelope that stated whether the patient was to receive a prescription for nicotine (gum group) or further advice only (no-gum group). Reminder sheets for the gum group (Appendix F) and no-gum group (Appendix G) were provided, depending on the assignment. Subjects in both groups were asked for a commitment to quit and a quit date, and they were offered followup by appointment or phone. To equalize the duration of contacts, patients in the no-gum group, instead of receiving instructions on the gum, were asked about their biggest fear related to quitting and received further coping tips and advice about weight control with smoking cessation. Both groups received about 5 to 10 minutes of physician advice. To verify that they provided advice, the physicians completed a form documenting each patient's quit date (Appendix H). All patients completed an exit questionnaire (Appendix I) verifying the content of the physician advice. All patients answered postadvice questions on intentions to quit, self-efficacy, and confidence in the physician advice. The no-gum group completed a separate exit form to verify the physician advice content (Appendix J). The gum group completed a similar form, verifying that a prescription and instructions for nicotine gum were provided (Appendix K). All subjects were offered a followup visit in 1 to 2 weeks after quitting.

At 1 to 2 weeks after the physician visit, all subjects received by mail a questionnaire (Appendix L) that served as a reminder to subjects and as a log of quit attempts and cessation. At 6 months, subjects received a questionnaire

(Appendix M) asking similar questions to document quit attempts and cessation. All subjects who did not complete the forms were called by telephone. Family observers were asked to verify cessation in those who stated that they had quit. A followup questionnaire on gum use (Appendix N) asked about filling and using the prescription. All subjects stating they had quit at 6 months were invited to receive $25 for verifying cessation with a CO breath test.

SUMMARY OF PILOT TRIAL RESULTS

After recruitment and screening, 94 subjects entered the clinical trial. There were no significant differences between sites with respect to sociodemographic variables, rates of quitting, or quit attempts. Observer verification was always in agreement with subject reporting.

At the 6-month followup, there was information on 43 subjects in relation to smoking cessation. The results are in Table 11. The numbers were small, and there was clearly no significant difference.

The quit attempts were reported by subjects answering the questions in Table 12 at 2 weeks and at 6 months. There was no significant difference between the groups in quit attempts. This may be the result of small numbers, as the mean number of quit attempts was greater in the gum group.

There were no differences in change from before to after the interventions between the gum and no-gum groups with respect to their intentions to quit, self-efficacy about the ability to quit, and confidence in the physician's advice.

Table 11
Cessation at 6-month followup

	Quit	Not Quit
Gum Group	2	20
No-Gum Group	4	17

Table 12
Quit attempts

	Did Patient Make Quit Attempt?		How Many Quit Attempts?	
	Yes	No	Mean	S.D.
Gum Group	21	11	3.35	6.37
No-Gum Group	19	15	1.78	0.94

The gum and no-gum groups were combined in the analysis of preintervention and postintervention changes in intentions to quit and self-efficacy. Concerning prechange and postchange on the intention-to-quit question ("Do you intend to quit?"), 22 subjects reported no change, 3 subjects reported decreased intention to quit, and 40 reported greater intention to quit (Wilcoxon signed-rank test, $p < 0.001$). Concerning prechange and postchange in the self-efficacy question ("Will you succeed if you try?"), 33 subjects reported no change, 4 subjects reported lower self-efficacy, and 24 subjects reported higher self-efficacy (Wilcoxon signed-rank test, $p < 0.001$). These results are encouraging in suggesting that even brief physician advice on smoking cessation will enhance intentions to quit and self-efficacy.

The initial sample size and power calculation to complete the project called for 219 subjects per treatment arm to show a 10-percent difference (10 percent in the no-gum group and 20 percent in the gum group) in quit rate with a power of 80 percent and an α of 5 percent. It was estimated that at least 600 subjects were required for the entire study to allow for refusal and loss to followup. With the recruitment data from this pilot project, a more accurate prediction of the total cost and scope of the project can be made. Using only private practices with 4 to 5 physicians and a population base of 12,000 to 15,000 patients, and assuming 1.5 true subjects enrolled per day, it would take 10 similar practices 40 days, or about 2 months, to accrue 600 subjects.

RECOMMENDATIONS The experience of this project provides an opportunity to share suggestions for other investigators based on what did not work, what worked, and what could be done differently.

The following approaches did not work:

- Using untrained receptionists for recruitment of subjects; and
- Reading the informed consent to subjects (made no difference in recruitment).

The following approaches did work:

- Having trained research coordinators at the practice site and using a generic screening form enhanced recruitment of subjects.
- Color-coding physician and research assistant prompts was helpful.
- Training sessions of physicians at the practice site enhanced study interest.
- Giving feedback to individual physicians seemed to enhance their motivation to continue the study.

The following approaches are suggested for future studies:

- Include the practice personnel in the practice orientation and training sessions about the project.
- Choose sites that have not had prior smoking cessation studies that may have decreased the interest and prevalence of potential subjects.
- Include more sites and longer study periods to enhance sample size.

FUTURE PHARMACOLOGICAL THERAPY

The success of nicotine gum replacement in general medical practice has been marginal at best. Several prior studies (see Table 13) have reported improved quit rates (from 1 to 7 percent better) with the use of nicotine gum versus placebo (Hughes et al., 1989; Fagerstrom, 1988). Studies have been criticized for sample sizes inadequate to detect differences of less than 10 percent. However, a 10-percent difference may be necessary for physicians to sustain an interest in the use of nicotine replacement therapy. Clearly, the effect of nicotine chewing gum is far greater in combination with group therapy in heavily dependent smokers (Tonneson et al., 1988). Many general physicians who tried nicotine replacement therapy with brief advice against smoking are now seeing a number of return smokers who failed nicotine gum therapy. Failed smokers and their physicians are expressing frustration and looking for options. Referring patients to costly behavioral treatment programs is an option, but fewer than 7 percent of those referred actually attend (Hughes et al., 1989). Because more than 70 percent of all smokers see their physician every 2 years, the rationale for a simple, effective pharmacological aid to physician's advice against smoking remains attractive (Pederson, 1984). There is less patient effort and cost and better availability than with psychological treatment.

Physicians should be discouraged from using some pharmacological measures. Silver salts combined with tobacco smoke cause unpleasant metallic tastes and appear ineffective. Sedatives to relieve anxiety have not been effective. Pentobarbital and alcohol do not decrease smoking, and they increase it in abusers of those substances. Diazepam abates the first 24 hours of withdrawal and craving only. Meprobamate shows quit rates similar to no-drug and inferior to placebo treatment. Antidepressants show some promise, but the side-effects profile may be prohibitive. Stimulants such as amphetamines increase smoking. Beta-blockers show no decrease in craving and no long-term quit rates. Narcotic agonists such as naloxone have showed increased smoking and mixed results. Over-the-counter medications such as lobeline have questionable efficacy, in light of poor study designs (Jarvik and Henningfield, 1988).

Though it is not an approved indication for the drug, physicians are using transdermal clonidine in treatment failures with nicotine replacement. Transdermal clonidine is available for the treatment of hypertension and is well tolerated with minimal side effects. There is no need to taper off of

Table 13
Long-term abstinence in randomized trials of nicotine gum with brief advice

			Percentage Abstinent[a]			
			6 months		1 year	
	Setting	n	Nicotine	Control	Nicotine	Control
Nicotine Gum vs. No Gum						
British Thoracic Society (1983)	Pulmonary clinic	777	-	-	10%	9%
Campbell et al. (1987)	General practice	573	-	-	3	1
Fagerstrom (1984)	General practice	145	-	-	25[b,c]	9[e]
Gilbert et al. (1989)	General practice	223	-	-	6	7
Harackiewicz et al. (1988)	University health center	151	-	-	13	15
Page et al. (1986)	General practice	289	12[c,d]	8	-	-
Russell et al. (1983)	General practice	1,354	-	-	9[c]	4[e]
Shaughnessey et al. (1987)	General practice	99	-	-	10	20
Sutton and Hallett (1987)	Worksite	270	-	-	9	2[e]
Sutton and Hallett (1988)	Worksite	161	-	-	9	2
Wilson et al. (1988)	General practice	1,933	-	-	9	4
Nicotine Gum vs. Placebo						
British Thoracic Society (1983)	Pulmonary clinic	802	-	-	10	11
Campbell et al. (1987)	General practice	836	-	-	3	2
Fortmann et al. (1988)	Public health clinic	600	30[b]	22[e]	22[b]	18
Hughes et al. (1989)	General practice	315	29	19	10	7
Jamrozik et al. (1984)	General practice	200	10[b]	8	-	-

[a] *Percentage continuously abstinent and biochemically verified except as noted.*
[b] *Point prevalence rather than continuous abstinence.*
[c] *Biochemically verified in only a subset of claimed abstainers.*
[d] *No biochemical verification.*
[e] *$p < 0.05$ by chi-square test.*

transdermal clonidine as there is with oral clonidine, where abrupt withdrawal can provoke hypertensive rebound. Clonidine, an α_2-antagonist, blocks firing in the locus ceruleus, which is the major controller of sympathetic activity in the brain. It has been used to counter symptoms of withdrawal from alcohol and morphine. Most studies on the use of clonidine in smoking cessation have been limited to oral use, short-term followup, and withdrawal effects (Davison et al., 1988; Franks et al., 1989; Glassman et al., 1984 and 1988; Ornish et al., 1988; Sees and Clark, 1988). There is a growing need for long-term efficacy and safety trials in involving transdermal clonidine as an aid to

smoking cessation in general medical practice. Some creative study designs may consider combinations of pharmacological therapy such as transdermal clonidine with nicotine gum.

Transdermal nicotine replacement may be an attractive alternative for smoking cessation in general medical practice. The transdermal approach improves compliance dramatically and produces more stable blood levels of nicotine than does nicotine chewing gum. Initial reports (McNabb et al., 1982) of short-term success with extensive behavioral therapy are encouraging (Buchkremer et al., 1989; Rose et al., 1985). A preliminary study in general medical practice by Abelin and cowokers (1989) demonstrated 3-month abstinence rates of 36 percent for the nicotine group versus 23 percent for the placebo. There is a definite need to test the long-term efficacy and safety of transdermal nicotine replacement therapy in general medical practice. Mixed study designs using nicotine gum and transdermal nicotine in selective smokers may prove most effective.

Other possible nicotine replacement therapies include nicotine aerosols, inhalers, and nasal sprays; however, social acceptability and potential abuse limit their efficacy. With the advent of transdermal nicotine, future studies on smoking cessation in general medical practice are necessary and the prospect seems promising.

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Smoking Cessation in Primary Care Practice: Summary of Results From the Quit for Life Project

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INTRODUCTION Most American physicians believe that cigarette smoking is an important threat to health and that efforts to encourage smoking patients to quit the habit should have a high priority in the practice of medicine. Physicians are generally aware that cigarette smoking is the single most important avoidable cause of premature death and disability in the United States (US DHEW, 1979). Because some 70 percent of smokers visit a physician each year, patients could be influenced to quit smoking by the physician's counseling or other smoking cessation strategies (Ockene, 1987). Most physicians, however, report that they feel poorly prepared to counsel smoking patients to stop, and only a few say they believe their smoking cessation efforts to be very successful (Cummings et al., 1989d; Ockene et al., 1988; Wechsler et al., 1983).

The literature suggests that physicians can effectively help their patients to quit smoking by routinely asking whether patients smoke, counseling and otherwise motivating patients to quit, helping smokers to commit themselves by establishing a date on which they will stop smoking, getting the patients' further commitment by persuading them to return for a followup office visit, and providing self-help materials and support from the physician's office staff (Orleans, 1985; US DHHS, 1986). Physicians rarely use any of these strategies (Cummings et al., 1989d), however, and the value of training physicians to use these approaches had not previously been tested in a rigorous randomized trial.

We tested the value of these approaches in two groups: (1) internists in a large hospital-based health maintenance organization and (2) internists and family practitioners in private practice. We also conducted surveys of physicians and dentists to describe their current attitudes and practices about smoking cessation, analyzed the cost-effectiveness of counseling about smoking cessation, and, as an underpinning for our research, estimated the best cutoff points for biochemical tests of smoking cessation used in intervention trials. This review summarizes the 10 papers that resulted from the Quit for Life project and offers further observations on the processes used in the studies.

TRIALS

Trial Objectives

The main goal of the trials was to test the value of a combination of commonly advocated strategies for brief physician counseling, using rigorous methods with adequate power to reveal even small effects. addition, we aimed for generalizable results: We sought to create a program that could be adopted by anyone and to test its value in samples of internists in different practice settings.

We developed a standardized continuing education program (Quit for Life) to teach physicians how to counsel smoking patients to quit. The counseling protocol was designed to be concise, to have an impact, and to fit into doctors' busy schedules. We set out to test the hypothesis that physicians who received controlled and standardized training in effective counseling about smoking cessation—in combination with intensified office support and followup counseling—would show higher rates of smoking cessation among their patients than do physicians who do not receive such counseling training combined with heightened staff involvement and patient followup.

Quit for Life Training

We created a standard training program in smoking cessation based on commonly advocated principles of brief counseling. To test the value of the program, we conducted parallel trials, one involving private-practice physicians (internists and family practitioners) and one involving HMO internists. From four medical centers of the HMO, the Kaiser Permanente Medical Group of Northern California, 81 internists were recruited; 40 were randomly assigned to the training program and 41 served in the control group, receiving no counseling training (Cummings et al., 1989a). In the second trial, we recruited private-practice internists and family practitioners, 44 in all; 24 were randomly assigned to the experimental (training) group and 20 to the control group (Cummings et al., 1989b). All physicians in the two experimental groups attended three 1-hour training seminars led by an internist or a psychologist. The seminars demonstrated the five steps that have been advocated as part of brief physician counseling about smoking cessation (Cummings et al., 1989a and b). In the first seminar, the instructor presented a systematic approach to counseling smoking patients to quit. Physicians viewed a videotape illustrating effective counseling approaches and then rehearsed their own counseling techniques through role-playing.

The first Quit for Life seminar focused on five steps in the counseling process:

- Ask all patients whether they smoke.
- Ask all who do whether they are interested in stopping.

For those who say they are interested in quitting, continue with the next three steps:

- Reinforce smokers' motivations to quit. Ask questions about their own reasons for wanting to quit and demonstrate the personal benefits of cessation, rather than making general statements about the consequences of smoking.
- Help those interested in quitting to commit to a specific quit date. Dramatize the quit date as a tangible goal by presenting the patient with a signed physician's prescription form with the patient's name and the quit date written on it.
- Offer a self-help booklet to all smokers, even those who say they are not interested in quitting.

The physicians were urged to practice the five-step counseling approach at once, before the second training seminar.

During training, the physicians practiced these steps in role-plays. The sessions ended with positive feedback from the participants and the instructor for use of the suggested steps during the role-play session.

At the second seminar, 1 or 2 weeks later, the participants discussed their experiences in counseling patients. They related and discussed obstacles faced by patients trying to quit—fear of failure; apprehension about gaining weight; the reactions of spouses, friends, and coworkers who continue to smoke; and the discomfort of withdrawal symptoms. The instructor suggested specific ways to overcome each obstacle discussed. Nicotine gum was recommended as an adjunct to counseling for smokers showing clinical evidence of addiction, and instructions for how to use nicotine gum were reviewed. The instructor also discussed the importance of scheduling followup office visits with the counseled smokers and ways that physicians might respond to problems encountered in followup visits.

The experimental group also attended a third session (a booster) 4 to 12 weeks later, discussing their experiences in counseling smokers. The instructor congratulated those who had tried the suggested approaches and described the medical significance and cost-effectiveness of persistence in counseling smokers to quit, emphasizing the importance of followup office visits.

Recruitment for Two Trials

For the HMO trial, we enrolled nearly 50 percent of the eligible Kaiser Permanente HMO internists with relatively little effort (Cummings et al., 1989a). We first obtained the support of the HMO chiefs of medicine and patient education, enlisted an investigator from each of the Kaiser Permanente groups of internists to help contact colleagues about the study, sent a letter describing the trial to HMO internists, and then made a single presentation to the regular physician staff meeting at each participating hospital. The fact that all HMO physicians practice in one building, where the Quit for Life training was conducted during the time usually devoted to CME, made participation very easy for the Kaiser Permanente physicians.

Recruitment of private-practice physicians for the trial was much more difficult (Cummings et al., 1989b). We enrolled only about 5 percent of eligible private physicians, despite our using more intensive enlistment efforts than those employed with HMO internists. We first enlisted the support of the local medical associations, obtained letters of support from the chief of staff of each major hospital in the region, sent those endorsements in a letter (addressed by hand to prevent its being treated as junk mail) to all primary care physicians in the target region, enclosed a stamped and preaddressed response card and a phone number to call for those interested, conducted a followup mailing, and made presentations to many of the hospitals' staff meetings. In retrospect, we believe it would be more productive to target a smaller, randomly selected group of physicians with personal contacts, perhaps "dear colleague" phone calls from a physician-investigator.

We tried two approaches to recruiting patients for the study. First, we asked the physicians' staff members to help recruit; they were instructed to ask all patients whether they smoke and to invite them to participate in the studies. Patients who agreed were enrolled and then filled out a baseline information questionnaire. Despite intensive efforts to enlist the cooperation of office staffs (see below), recruitment proceeded slowly and unevenly from office to office. We found that it was better to hire research assistants to identify smokers in each office, and most participants were enlisted by research staff. Patients were enrolled until we had accrued from 15 to 30 smokers per physician in 6 weeks.

Data Collection All physicians completed a baseline questionnaire about their training, type of practice, smoking history, and opinions about and practices for counseling smokers. Selected questions were administered a second time to physicians in the experimental group after their training.

Prior to seeing their physicians, participating smokers answered questions about the extent of their commitment to quitting and their level of confidence in their ability to do so. As soon as possible after each patient's visit to the physician, a member of the research staff, who was not aware of the patient's assignment to the experimental (physician training) group or the control group, interviewed each smoker by telephone. The interviewer asked whether smoking had been discussed during the visit, how many minutes had been spent in the discussion, what steps the physician had recommended, what the smoker had agreed to do, and whether the patient had received a self-help booklet or a followup appointment about smoking cessation.

One year after the first telephone interview, smokers were interviewed again by telephone to determine their current smoking habits and how many times they had tried to quit smoking (a single attempt was defined as abstinence for at least 24 hours). Those who said they had not smoked a cigarette during the past 7 days were defined as self-reported nonsmokers; they were offered $25 to have a breath test and give a saliva sample. Investigators analyzed results of patients' self-reported and biochemically validated

abstinence from smoking. All those lost to followup or who refused biochemical testing were counted as smokers.

Conducting the Trials

From the 125 participating physicians, we enrolled 3,004 smokers in the two trials of private-practice physicians and those in an HMO. We interviewed more than 90 percent of the smoking patients after they first received office counseling from their physicians and then interviewed more than 80 percent of those patients again 1 year later. Of those who claimed to have quit smoking, 80 percent completed biochemical tests to confirm that claim, and 10 percent were reclassified as smokers after the testing (Cummings et al., 1989b). Detailed results of these trials have been published (Cummings et al., 1989a and 1989b).

These separate trials had three characteristics in common. First, the smoking cessation counseling and other interventions were designed to be convenient, specific, and standardized. The training was presented in short sessions to fit into physicians' CME schedules. The office materials employed were simple, inexpensive, and easy to use in a physician's office without special training.

Second, the intervention combined many of the elements of other NCI-supported trials—a reminder system and training about counseling involving videotape demonstrations, rehearsals and role-playing, and building upon feedback from the smokers, from other physicians in training, and from the instructor's exercises in reinforcing positive elements of the continuing intervention process.

Third, the trials adhered to rigorous principles of randomized studies. For example, randomization was blinded, all data about cessation outcomes were collected by research assistants who were blinded to the assignment of patients to treatment or control groups, and all data were analyzed by initial assignment (in compliance with the "intention-to-treat" principle).

Office Staff Involvement

We had difficulty in enlisting and maintaining consistent office staff support of physician counseling and other cessation efforts. One member of the research staff spent at least 1 hour in the office of every experimental group physician in the trials. Recruitment in private offices was slow and uneven, with varying levels of cooperation. We also became concerned about biased sampling because at least one physician instructed his staff to enlist only smokers he had counseled who seemed likely to quit smoking.

We had further difficulty enlisting cooperation from the Kaiser Permanente office staff, because staff members frequently rotate from office to office and station to station within the HMO. Staff members who had been trained for the trial were frequently replaced by temporary or "float" personnel. Many HMO staff members expressed the feeling that they were overworked and said they did not regard participation in the trial as "part of [their] job description."

The problem of office staff cooperation was compounded at the HMO by the fact that staff members' loyalties do not focus on a specific physician because they are not employed or supervised by the physicians; they are instead employees of the HMO nursing service and hospital administration. Trying to overcome the lack of cooperation, the research staff offered incentive payments to private and HMO staff members for enrolling smokers and gave periodic gifts of appreciation; but those inducements seemed to make little difference. At the HMO, there was poor compliance by staff in identifying smoking patients, and the prescribed use of stickers to remind physicians of their counseling obligation was ignored consistently by the staff at two-thirds of the nursing stations.

In retrospect, the investigators concluded it would be better to work through the hierarchy of the HMO nursing service from the beginning of the trial and to invite all staff members to participate in the training seminars and in the design of the office staff intervention support system.

To test the hypothesis that a different approach to staff involvement might have a degree of success with staff intervention, we conducted a small controlled trial with Kaiser Permanente after completion of the main trial. This trial included intensive staff involvement in planning and carrying out the intervention as well as designation of followup visits specifically for counseling about smoking. We found that such an approach enhanced the identification of smokers and the use of recommended counseling techniques (Duncan et al., 1991).

Results

In the trial involving physicians in private practice, we found, on the basis of 1-year followup interviews with patients, that physicians in the experimental group who received the special smoking cessation training were more likely to discuss smoking with patients who smoked than were the physicians in the control group (64 vs. 44 percent), spent more time counseling smokers about quitting (7.5 vs. 5.2 minutes), helped more smokers set dates to quit smoking (29 vs. 5 percent of smokers), gave out more self-help booklets (37 vs. 9 percent), and were more likely to make a followup appointment about smoking (19 vs. 11 percent of those counseled) (Cummings et al., 1989b). In the trial involving internists in HMOs, 1-year followup interviews with patients showed that physicians in the experimental group who received the special smoking cessation were more likely to discuss smoking with their patients than were the control group physicians (50 vs. 45 percent), spent more time counseling smokers (5.4 vs. 4.2 minutes), were more likely to write a prescription establishing a quit date (16 vs. 1 percent), and were more likely to schedule followup appointments to discuss smoking (15 vs. 4 percent) (Cummings et al., 1989a).

In two categories studied, however, there was no significant difference in smoking cessation efforts between the physicians who received training and those who did not. Physicians in the experimental group wrote prescriptions for nicotine gum for 10.2 percent of their patients, the control group for

10.4 percent; and 25.6 percent of experimental group physicians suggested a treatment program for their patients, while 25.4 percent of the control group did the same.

Thus, we found that a 3-hour continuing education program about how to counsel smokers, combined with supportive materials for use in the physicians' offices, substantially changed the way physicians counseled patients about smoking. In both trials, with physicians in private practice and those in HMOs, those who received the Quit for Life training counseled patients more often and longer. Physicians in private practice who received the training helped six times as many patients set dates to stop smoking and gave self-help materials to four times as many patients as did physicians in the control group. Among HMO physicians, those who received training helped six times as many patients set quit dates and gave self-help material to three times as many patients as did physicians who did not receive the training.

In both trials, counseling resulted in slightly higher rates of long-term (9-month) abstinence from smoking, but only among patients who specifically expressed a desire to quit. Among counseled patients most interested in quitting, there was a small (2.0 percent) increase in long-term cessation in the private-practice physicians' trial; there was a similar small (1.6 percent) increase in long-term cessation among those most interested in quitting in the HMO trial.

In the overall patient population, however, the trials showed that improved counseling, as reflected in changes in physician behavior, had very little impact on patients' smoking habits. Rates of long-term smoking cessation, confirmed by biochemical tests of patients who report they have quit, were only 1.1 percentage points higher in the HMO experimental group than in the control group (2.6 vs. 1.5 percent), and only 0.7 percentage points higher in the private-practice experimental group (3.2 vs. 2.5 percent). Neither result was statistically significant.

We found that more intensive staff involvement, combined with diligence in scheduling followup counseling appointments ("training-plus") increased the level of physician counseling beyond that seen with the Quit for Life training alone. Those physicians receiving "training-plus" staff support counseled more patients, set more quit dates, and scheduled more followup appointments to deal with smoking cessation than did those who received the training without the coordinated staff support. This pilot study of the effect of staff cooperation and support of physician counseling efforts was too small to determine whether these changes resulted in higher rates of smoking cessation.

The investigators found that convincing patients to set quit dates appears to be an effective technique for encouraging patients to make smoking cessation attempts; patients in the HMO trial who agreed to set quit dates were about four times more likely to attempt to quit for at least 24 hours, even after

results were adjusted to account for evaluations of *desire* to quit, *confidence* in the ability to quit, and *number of cigarettes* smoked per day.

SURVEYS

In addition to the controlled trials, investigators conducted surveys of random samples of internists, dentists, and nurse practitioners to assess and describe their office-practice use of smoking cessation counseling and other interventions. The response rate for the survey of internists was 92 percent—higher than that of any similar previous survey of physicians' smoking cessation practices. We believe the high response rate resulted from the strategy of targeting a random sample of physicians, one small enough for the survey staff to pursue responses aggressively, with hand-addressed letters, multiple telephone calls, and even personal visits (if necessary) from a doctor on the survey team.

The authors found that the internists, dentists, and nurse practitioners surveyed believe that smoking is extremely dangerous to health and that counseling about smoking cessation is important and just as worthwhile as other, more widely practiced preventive procedures, such as mammography. On the other hand, a substantial proportion of physicians *never* use counseling strategies that might help patients to quit smoking. Dentists were even less likely to use counseling strategies such as setting quit dates, providing self-help booklets, or scheduling followup counseling.

In the dentists' survey, only 17 percent of San Francisco Bay area dentists said they frequently discussed smoking cessation with their patients who smoke, in contrast to 58 percent of a similar group of Bay area internists, who said they frequently counsel smokers (Gerbert et al., 1989). Dentists attributed their lack of counseling to inadequate insurance coverage, insufficient time, lack of training, and apprehension that patients might become irritated and leave their dental practices.

Nurse practitioners, however, are more likely than physicians to adopt smoking cessation counseling techniques introduced through CME, investigators found (Zahnd et al., 1990). A study and patient surveys determined that nurse practitioners are more likely than physicians to counsel smokers to quit. Internal medicine nurse practitioners and internists at four HMO centers received training in the Quit for Life program, and their patients were then surveyed about their counseling practices. It was found that nurse practitioners discussed smoking with patients more often than did physicians (64 vs. 50 percent), asked patients more frequently whether they were interested in quitting (49 vs. 40 percent), distributed more smoking cessation literature (37 vs. 25 percent), and made more followup appointments about smoking (36 vs. 19 percent). These results support the view that nurse practitioners, because of greater emphasis on counseling during their professional training, more readily incorporate counseling about cessation into their medical care of smokers than do physicians.

We found in another survey that physicians only infrequently prescribe nicotine gum to their smoking patients, and that a large minority of physicians (20 to 35 percent) are unfamiliar with important features of how the gum should be used as an adjunct to smoking cessation counseling (Cummings et al., 1989c). Thus, there is evidence of a need for physician education about how to use nicotine gum more effectively. The advent of transdermal delivery systems for nicotine may, however, circumvent this gap in physicians' knowledge.

Although more than 90 percent of internists (in HMOs and in private practice) questioned in another survey believe that smoking is extremely dangerous to health, fewer than half believed they were effective at motivating patients to quit smoking, and most felt that counseling about smoking was extremely frustrating because of the minimal success rate relative to the time invested with patients (Cummings et al., 1989d).

A majority of private-practice internists believed that physicians are not adequately reimbursed for counseling about smoking, a sentiment shared by only 28 percent of the HMO internists surveyed. Only a minority of internists in both groups thought that insurance coverage would actually increase the amount of time that they spend counseling smokers. Most internists indicated that insufficient time was an important barrier to helping smokers quit. This may partly explain why, when they do discuss smoking with patients, most internists and other physicians spend fewer than 3 to 5 minutes on counseling. Few internists ever schedule visits with patients primarily to address smoking cessation, perhaps because such visits are not reimbursed by third-party payers. Consistent with previous surveys, we found that HMO internists were much more likely to refer patients to smoking cessation programs. This is probably because such programs are often provided on-site at HMO centers and are at least partially covered by the health plans, which typically provide more preventive care benefits than do traditional health insurance plans.

OTHER ANALYSES In preparation for the trials, we demonstrated that test cutoff points for biochemical validation of smoking cessation used in previous studies were too high (Cummings and Richard, 1988). We devised a method for calculating the optimum cutoff point for these tests to take into account the prevalence of deception among those who claim to have stopped smoking. On the basis of this method, we recommended revised cutoff points for future studies of smoking cessation.

We also analyzed the cost-effectiveness of counseling about smoking cessation, as reflected in longer life expectancy among smokers who succeed in quitting (Cummings et al., 1988). We found that, in terms of cost per years of life saved, counseling about smoking cessation was more cost-effective than treatment of moderate hypertension or hypercholesterolemia. If brief counseling motivated only 1 percent of smokers to quit, the cost per year of life saved was $2,020 for one middle-aged man among the successful 1 percent. We estimated that scheduling a single followup counseling session would also

be quite cost-effective when total population costs of therapy are divided and expressed as costs of counseling the successful 1 percent—$5,051 per year of life saved. By way of comparison, we estimated the cost-effectiveness of treating moderate hypertension at $11,300 per year of life saved.

In additional analyses of data from the Quit for Life trials, we described racial differences in smoking behavior among patients who smoke (Vander Martin et al., 1990). Whites were heavier smokers and more likely to feel addicted to cigarettes. Blacks believed that they were more likely to quit smoking and felt less addicted than whites. Hispanics were lighter smokers, and both Hispanics and Asians rated family pressures as an important reason for wanting to quit smoking.

From our patient questionnaires at baseline and at 1-year followup, we also found that patients' concern about their health was the single most important motivating reason to quit; about three-quarters of those who quit cited a health-related reason. Most commonly, they said that disturbing symptoms and diseases related to their smoking led them to quit. However, most smokers gave more than one reason, often citing social pressures, dislike of the negative aesthetic image, and the feeling of being the victim of addiction.

We also analyzed factors influencing whether patients participating in the two main trials received prescriptions for nicotine gum as a physical adjunct to counseling (S.R. Cummings, unpublished data). Of all the patient factors analyzed, a patient's belief that he or she is addicted to cigarettes appeared to be the most important influence upon physicians to prescribe the gum. In addition, black smokers were less likely to receive a prescription for the gum than were members of other racial groups. Physicians were much more likely to prescribe gum if they were confident of their ability to instruct patients to use it effectively.

DISCUSSION While many physicians say, when questioned, that they are making an effort to counsel smoking patients, a substantial proportion of physicians never use commonly advocated counseling strategies with their smoking patients. Using rigorous randomized trial methodology, we tested the hypothesis that training physicians to use strategies such as quit dates would substantially improve their success in helping smokers quit and remain abstinent. However, the Quit for Life trials confirmed earlier findings about other types of CME: Such programs can substantially change physicians' clinical practices but those changes do not necessarily result in comparable improvements in patient outcomes (Haynes et al., 1984).

Nevertheless, even very small effects from counseling smokers make the effort worthwhile. Primary care providers and those who reimburse medical providers should note that even marginally effective smoking cessation programs are among the most cost-effective interventions in medicine.

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Physician and Dentist Interventions For Smoking Cessation[4]

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BACKGROUND As a result of funding from the National Cancer Institute, parallel studies involving primary care physicians and private-practice dentists were initiated in August 1984. The goal of the projects was to develop, validate, and evaluate practical methods to help physicians and dentists encourage their patients to stop smoking cigarettes and remain nonsmokers. The studies were designed in two stages. The first stage involved efficacy studies to determine which office-based interventions had the greatest impact. For the second stage, effectiveness studies were conducted to determine whether office staff would adopt and incorporate into routine care the interventions that had been successful elsewhere and whether the results from the interventions supported by the office staff would be comparable to the results obtained in practices receiving the support of the research project staff. This paper describes the stage I and II studies involving physicians and the parallel studies with dentists in private practice.

PHYSICIAN INTERVENTIONS

Purpose of Project: Stages I and II

The goal of the stage I project was to develop, validate, and evaluate practical methods to help physicians encourage their patients to stop smoking cigarettes and remain nonsmokers. To determine the most effective intervention method, participating physicians and their patients who smoked cigarettes were randomly assigned to one of the following conditions: (1) control (usual care), (2) nicotine polacrilex available to patients at no charge, (3) a reminder system for following a practical protocol to help patients stop smoking, or (4) both nicotine polacrilex and the reminder system.

The purpose of the stage II trials was to determine the extent to which the "best" smoking cessation intervention identified in stage I was adaptable and generalizable to medical office settings. When stage II began, the stage I trials still had 1 year of data collection remaining; therefore, the "best" intervention method for stage II was determined according to data developed during the first 20 months of stage I. Preliminary analysis of these data determined that for the physicians, all three interventions were equally effective and each was better than the control (Cohen et al., 1989b). However, for the dentists, the nicotine polacrilex intervention either alone or with the reminders was the "best" method (Cohen et al., 1989a). To keep the physician and dentist stage II studies parallel, the method selected as "best" was the nicotine

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polacrilex (group 2 from stage I). In stage II, new cohorts of participating physicians and their panel of patients who smoked were randomly assigned to one of three intervention conditions: (1) control (usual care), (2) nicotine polacrilex program supported by project staff (as in stage I), or (3) nicotine polacrilex program supported by office staff.

Stage I Components

Target Audience And Clinical Setting

The stage I cohort involved 97 residents in internal medicine and 15 faculty general internists who staffed the outpatient general medicine clinic of a city/county teaching hospital. The outpatient clinic was structured so that physicians could provide continuity of care to their patients. A computerized scheduling system increased the likelihood that the same physician-patient dyad would remain together throughout the duration of a physician's residency in the program. The clinic was divided into four different areas or teams, each with its own nurses, clerks, and panel of physicians. To foster the research mission of the clinics and to minimize selection bias, all new patients were randomly assigned to available patient slots across teams, as were new physicians. For the stage I study, the intervention conditions (four groups) were randomly assigned such that each team was assigned to one condition only.

The ambulatory clinics served a predominantly indigent patient population. Patients were eligible for participation in the study if they were between the ages of 18 and 64, reported smoking one or more cigarettes daily, and had an alveolar breath carbon monoxide determination of more than 8 parts per million. Patients were excluded if any of the contraindications for the use of nicotine polacrilex pertained. The sociodemographic characteristics of the 1,420 patients who agreed to participate (the refusal rate was less than 5 percent) were as follows: the mean age was 46.2 (SD 11.6); the mean number of office visits per year was 2.2 (SD 2); 39 percent were white, and 61 percent black; 63 percent were female; the median education level was 10th grade; and the median annual income was $2,500.

Recruitment Procedures

The stage I physicians were all affiliated with the Department of Medicine at Indiana University School of Medicine. The project had the expressed support of the chairman of that department, as well as the section chief of the Division of General Internal Medicine. Consequently, there was considerable pressure to participate in the study, and no one refused. When senior residents left at the end of their program, their panel of patients was retained in the appropriate study condition and assigned to the incoming replacement physician. The replacement physician was oriented into the appropriate study condition and became the physician of record. Rarely did patients change physicians. In the event that a patient was transferred to a physician in a different study condition, the patient was removed from the study but was retained in the data analysis up until the time of removal (e.g., included in 6-month data on smoking status but not in 12-month analysis if the transfer occurred before the 12-month interval).

Specially trained research assistants conducted patient recruitment after an extensive training program in how to approach and interview patients. The research assistants memorized a script that explained to patients the purpose of the study and the fact that people who agreed to participate were agreeing only to have their smoking status assessed; participation did not require an attempt to quit smoking. Each research assistant role-played interviewing and recruiting the other research assistants, who in turn role-played patients who were illiterate, uncooperative, or too ill to be interviewed. Each research assistant spent at least 2 weeks working with his or her assigned clinic teams to learn the entire office system before contacting any patients for recruitment into the study. All patients were screened for eligibility for the study, and they signed an informed consent form that indicated that their smoking habit would be monitored at each regularly scheduled clinic visit regardless of their decision to quit or to continue smoking. Patients were notified that they would be asked to provide a breath sample for carbon monoxide analysis at each regularly scheduled clinic appointment and to answer questions immediately after seeing their physician.

Nature of Training Program

The training program for physicians consisted of two parts: a 1-hour lecture during medical grand rounds and then a special in-clinic followup session to orient each team to its specific study condition. The intent of the first part of the training program was to provide a common educational background on smoking and its management. Because each of the four intervention methods involved different procedures, the physicians received the condition-appropriate orientation at the start of their clinic sessions. The orientation lasted from 10 to 25 minutes, depending on the nature of the intervention. Prior to the grand rounds, all physicians completed a two-page attitude and practice questionnaire about their personal smoking histories, their current smoking management practices for patients, and their current interests and beliefs in effectively helping patients to stop smoking. The 1-hour general lecture presented evidence of the health consequences of smoking, the benefits of quitting, the addictive nature of nicotine, and the effect of nicotine polacrilex on smoking cessation. Also discussed was the available evidence that physicians' advice can be effective in helping counsel patients. Physicians were encouraged to use a four-step counseling protocol developed at the National Heart, Lung, and Blood Institute for counseling smokers: (1) Ask your patients about smoking; (2) deliver a firm quit-smoking message; (3) mutually agree on a quit date; and (4) check your patient's progress at each regularly scheduled visit. Physicians were also given a copy of a National Cancer Institute pamphlet, "Quit for Good," and were informed that copies would be provided to their offices for use with their patients who smoke.

The small group presentations centered on providing specifics for each intervention technique. Physicians in the control group were given a booklet containing the four-step protocol and were encouraged to counsel their

patients who smoke. Neither the physicians nor their staffs were informed as to which of their patients had agreed to participate in the project. Physicians in the other three study conditions (nicotine polacrilex, reminders, both nicotine polacrilex and reminders) received the same instructions as the control group plus additional instruction based on their assigned experimental condition.

For the nicotine polacrilex group, physicians were instructed on the use of fluorescent red stickers to flag the charts of patients who were eligible to receive the nicotine replacement product. Physicians were told that research assistants would place the stickers and remove them after the patient had received the product. The uses, indications, contraindications, and side effects of nicotine polacrilex were discussed in detail. Research assistants dispensed the product at no cost when it was requested by a physician for an eligible patient (i.e., one with an appropriate sticker on the chart and a medication request initialed by the physician). The education of the patient as to the use of the nicotine substitute remained the responsibility of the physician or his or her designee. Physicians were also encouraged to record on the patient's chart when the product had been dispensed.

In the reminder condition, physicians were instructed on the use of two fluorescent chart stickers to help remind them to follow the four-step protocol. A green sticker was used to remind them to ask the patient about smoking, and an orange sticker reminded them to ask the patient to set a quit date. Physicians were informed that a feedback report issued to them bimonthly would provide the names of smoking patients they identified as well as the quit dates they established with their patients.

Physicians in the combined condition (nicotine polacrilex plus reminder) received instruction on the use of all three stickers.

Results

Table 14 shows how physicians behaved under each of the interventions (Cohen et al., 1989b). The impact of the interventions on the smokers is shown in Tables 15 and 16.

Because cigarette smokers often quit smoking and later have relapses, the prevalence of smoking was estimated for two subsequent periods. The prevalence of smoking at 6 months was defined as the smoking status determined at any visit that occurred at least 3 months after the initial appointment but not more than 9 months after it. The second estimate was at 1 year, defined as at least 9 months and 1 day after the initial visit and up to 15 months after the initial visit. If there was more than one visit during a time interval, the smoking status was determined by the status of the last visit during that interval. For patients who had a regularly scheduled appointment during the critical period, their smoking status was confirmed through carbon monoxide assessment, the procedures for which are described elsewhere (Stookey et al., 1987). Patients who did not visit a physician during the 6- or 12-month period were assumed to be smokers. Thus, the results are

Table 14
Reported physician counseling about cigarette smoking

	Percentage of Patients Reporting Actions		
	Asked About Smoking	Advised To Quit	Asked About Setting a Quit Date
Physician Group			
Advice	41%	27%	2%
Gum	84	61	10
Reminder	75	66	33
Both	95	84	58

Table 15
Confirmed success rates at the 6-month visit for each physician intervention[a]

	Percentage, Returnees Only (n=895)	Percentage, All Enrollees (n=1,420)
Physician Group		
Control	1.3%	0.9%
Reminder	7.0	4.2
Gum	7.7	5.0
Both	6.3	3.8

[a] *A generalized linear model was applied separately to returnees only and to all enrollees. The significant p values were 0.005 for the reminder by gum interaction for both analyses.*

Table 16
Confirmed success rates at the 12-month visit for each physician intervention[a]

	Percentage, Returnees Only (n=764)	Percentage, All Enrollees (n=1,420)
Physician Group		
Control	2.7%	1.5%
Reminder	15.0	7.9
Gum	8.8	4.7
Both	9.6	5.2

[a] *A generalized linear model was applied separately to returnees only and to all enrollees. The reminder by gum interaction was significant for returnees only (p=0.002) and for all enrollees (p=0.004).*

reported both for returnees, for whom biochemical validation was possible, and for all enrollees, based on the assumption that a patient was a smoker unless there was biochemical evidence to the contrary.

The range of patients per physician who quit at the 6-month interval was zero to three and at the 12-month interval was zero to four. Thus, smoking cessation by patients was widely distributed across physicians and not clustered into the practices of a few "effective counselors." A generalized linear model was used to analyze the results of the quit-smoking rates. The 6-month results are shown in Table 15. There was a significant negative interaction between nicotine gum use and reminders, both for returnees and for all medical patients. The combination of nicotine gum and reminders did not produce a higher rate of patients who quit smoking than the rate for either condition alone. Pairwise comparisons among the groups (adjusted for multiple tests with the Bonferroni inequality) showed a significant difference ($p < 0.05$) between each of the three intervention groups and the control group for analyses based on patients who had a scheduled return visit and for all patients.

The results at 1 year, shown in Table 16, also produced a significant negative interaction between nicotine gum and reminders. Pairwise comparisons among the groups showed that the three intervention groups were not significantly different from each other; however, each of them was significantly different from the controls for analyses based on returnees and on all patients. (For greater detail, see Cohen et al., 1987 and 1989b, and Stookey et al., 1987.)

Special Resources Or Procedures

For a program of this size, involving 112 physicians, lasting 3 years, and involving more than 1,400 patients, special resources were necessary to achieve sufficient cooperation from the general medicine clinics. Most critical was the use of research assistants who were permanently based in the clinics. Although there were four clinic teams and four research assistants, the responsibilities of the research assistants were divided so that they worked with one team 2 days a week and with another team 3 days a week. This was done so that there was always a backup person familiar with the operational procedures of each team. This rotation also helped dissipate any effect that a particular research assistant might have on patient recruitment or implementation of the study conditions.

For stage I, given the emphasis on training only the physician rather than the office staff, research assistants concentrated their efforts on integrating the program into the regular office routines. This was accomplished in two ways. First, each research assistant spent 2 weeks as an apprentice with his or her designated team, learning all of the office routines and helping with minor chores. For example, the research assistant would occasionally volunteer to assist the check-in clerk or the nurses with clerical duties such as filing charts or helping patients complete registration forms. This work not only relieved the office staff of these tedious tasks but also provided the

research assistant with an opportunity to blend the program functions into the regular office routine. While research assistants were helping to file charts, they were able to find the best occasion to place stickers on the charts of newly recruited patients.

The working relationship that developed among the office staff helped facilitate program implementation. As part of their job responsibilities and throughout the study, when research assistants had free time available, they were expected to help the clinic staff in performing chores that would not interfere with their primary responsibilities. This system of volunteerism helped reduce occasions during which the clinic staff members were overburdened and the research assistants were idle. Conversely, when too many study patients were in the clinic for the research assistant to manage at one time, the office staff would often keep the patients occupied until the research assistant could see them. This system of reciprocity helped to build a supportive relationship between the project and the clinic staff.

Barriers or Problems Overcome

There were few problems to address in the stage I study. In all cases, the research staff learned to adjust to the demands of the clinic setting. For example, the research assistant usually tried to enroll patients before they were seen by the physician. However, whenever an examining room became available, a patient was taken to that room even if the research assistant was in the middle of explaining the study. Some of these procedures were established initially by the clinic directors, but other procedures evolved as more efficient ways of operating became evident.

The training of new office personnel presented some problems. Each year as interns replaced senior residents, about one-third of the physicians were new to the clinic. The training of all new physicians was done by blocking out time in the patient schedule for orientation instructions that lasted from 15 to 30 minutes, depending on the intervention condition. The physicians, in turn, were expected to educate their new staff members on the components of the program, but they often relied on the research assistant to educate new members. Not only were new staff members not trained for their responsibilities in the program, but also many were not informed of the program on accepting the position. Changes in personnel usually slowed the progress of implementing the smoking cessation program. The orientation of new physicians was given by one of the senior research staff members. Followup instruction usually was provided by a research assistant.

One effort to minimize confusion about the nature of the study was the use of a one-half page yellow sheet presenting the goal of the project, the eligibility and exclusion criteria for patients, and a telephone number to call if there were questions. This information was posted on the bulletin board above each physician's desk in the staffing rooms. Despite a careful effort to explain that the research assistants were not smoking counselors, some physicians attempted to refer their patients to the research assistants

for help in quitting. Such requests usually resulted in a re-explanation of the program for the physicians.

Stage II Components

Target Audience And Clinical Setting

The second cohort of physicians consisted of 39 general internists and family physicians who saw adult medicine patients at 5 sites of a freestanding HMO serving central Indiana. At the start of the stage II study, more than 80,000 patients were active enrollees in the 9 sites of the HMO. Each of the five largest HMO sites participating in the project contained two adult medicine clinics. Each adult medicine clinic had its own check-in clerk, nurses, physician assistants, and physicians. Patients were scheduled to see a primary health care provider only within their designated clinic. The interventions were assigned such that at each site two different interventions were conducted, one at each clinic. All combinations of two of the three study conditions were determined and then randomly assigned to each of the five sites of the HMO. This procedure helped offset the fact that there could be differences in the sociodemographic characteristics of the patients, depending on the location of the site they visited for care. For the most part, those patients enrolled in the HMO were from working class or professional class backgrounds.

Recruitment Procedures

Stage II was initiated 1 year before the completion of the 3-year stage I study. The HMO's medical director and director of adult medicine were enthusiastic supporters of the project. Through their efforts, all physicians in adult medicine were notified about the project during a routine monthly staff meeting and asked to share any concerns or reservations about participation in the study. The only concern that physicians voiced was the extent to which their workload would be affected. They were assured that the study was designed to help them clearly identify which of their patients were smokers and that they would then determine the extent to which counseling was appropriate as part of those patients' visits. All physicians were also informed that they were expected to attend a site-specific special orientation meeting. At each of the five sites, the nurse manager was recruited to serve as the project liaison during a special meeting held with the principal investigator of the project and the chief of adult medicine at the HMO. The function of the liaison was to help arrange the logistics of integrating the project into the routines of that site. No additional compensation was offered for that effort.

Unlike the orientation in stage I, stage II orientation emphasized the level of team commitment required of the office staff. Project orientation luncheons were held at each site and included physicians, nurses, other health care providers, receptionists, medical records clerks, and other pertinent support staff. The chief of adult medicine stressed the importance of the project in terms of the benefits to patients at the HMO. He also noted that what staff members were being asked to do should be considered the standard for good care. No one overtly refused to participate in the study.

Nature of Training Program

The educational seminar used a format similar to the stage I training session. Physicians completed an attitude and practice questionnaire at the beginning of the meeting. A general orientation seminar on smoking and its management was followed by the breakup of the group into two smaller groups to discuss the details of the particular intervention.

The first half of the program lasted about 30 minutes and included the same information as the stage I general seminar but emphasized the team approach. The team approach required the involvement of most staff members, in particular the check-in clerk and the nurse manager. In addition, physicians were encouraged to tailor the smoking cessation program to maximize the resources, skills, and interests of the team. At all sites, the site nurse manager was asked to serve as a program coordinator and to be responsible for maintaining the program and providing communication between the office staff and research personnel.

During the general seminar, the emphasis was on specific techniques for physicians to use when counseling their patients who smoke. A videotape, developed at the University of California at San Francisco, was used to show physicians talking with patients about smoking. Shown is an interaction to assess a patient's interest in quitting, establishing a quit date, and receiving educational materials and encouragement. Also shown is an interaction between a physician and a patient who had made a quit attempt and then relapsed before the office visit. One segment depicts a conversation with a patient who is interested in discussing exercise but not smoking. The videotape illustrates a positive, nonthreatening approach to smoking counseling. For example, rather than lecturing patients and emphasizing the health consequences of smoking, the physician role models engage in asking questions such as, "Have you thought about quitting?" and "Are you ready to make another quit-smoking attempt?" The vignettes illustrate how to tailor the counseling for patients who have varying degrees of interest in stopping smoking. Physicians were encouraged to use these skills with their patients who smoke.

At the conclusion of the general seminar, attendees were given a copy of the "Quit for Good" pamphlet. They were informed that copies would be provided at no charge for their patients who smoke.

During the second half of the instructional program, specific techniques pertaining to each intervention condition were outlined and discussed. Persons in the control group were given the same booklet as was given the stage I group, and they were encouraged to follow the step-care protocol for counseling their patients who smoke. Those in the other two interventions received the same instruction as the control group plus additional instruction based on their assigned condition.

Those individuals in the free nicotine polacrilex group supported by research staff were instructed in basically the same manner as their

counterparts in stage I. They were informed that red fluorescent stickers would be placed by research assistants on the charts of patients who were eligible to receive the nicotine replacement product. Physicians were made aware that the stickers would be permanently removed once the product had been prescribed. The uses, indications, contraindications, and side effects of nicotine polacrilex were discussed in detail. This small group instruction took about 20 minutes.

Physicians assigned to the nicotine polacrilex prescription method supported by office staff were instructed on the use, indications, contraindications, side effects, and recordkeeping procedures for nicotine polacrilex in a manner identical to the free-product group described above. However, because the purpose of this trial was to determine the feasibility of having a physician and his or her office staff carry out the step-care protocol of a cessation program with only minimal support from the research team, this group of participants was taught how to perform the procedures needed to support the program on their own. Instead of offices being provided with free nicotine polacrilex to dispense to patients, this group was instructed on how to prescribe the product and instruct patients in its use. Staff members were provided with a one-page handout about use of nicotine polacrilex, which reviewed basic information such as "quit smoking before starting to use the product." Office staff members (usually check-in clerks) were instructed to insert a copy of the handout in the chart of all eligible patients and to review the items with them when nicotine polacrilex was prescribed. Check-in clerks were instructed in the method for placing stickers on the charts of eligible patients. They were informed that the research assistant permanently assigned to their site would provide a list of patients recruited that week who were eligible for a prescription and who should have a sticker placed on their chart. Research assistants periodically checked charts to determine if stickers had been placed. As with the second group, physicians or their designees were encouraged to review the product usage instructions with the patient and to record in the chart when the product had been prescribed. Those physicians and staff members unable to attend the regular orientation meeting were given a personalized presentation before their involvement in the project. This was required for approximately 15 percent of the staff, and 15 to 20 minutes were scheduled before the morning or the afternoon clinic for this small group orientation.

Results

To determine the extent to which the office staff performed the tasks requested of them, the research staff examined the office charts of the patients enrolled in the study. In comparison with the 100 percent of charts that were flagged in the research-support condition, only 43 percent of the charts were flagged in the office-staff condition, and only 31 percent of appropriate charts had nicotine polacrilex instruction sheets attached to them. These results were much lower than anticipated and could be attributed in part to the numerous changes in management and high staff turnover of the HMO during the course of the project.

Not surprisingly, the behavior of the physicians in counseling smokers was affected by the intervention condition. Office exit interviews of patients showed that 44 percent of control group patients, 41 percent of office-staff patients, and 61 percent of research-support patients reported that their physician had talked to them that day about smoking. Also, the percentages of patients who were given or prescribed the nicotine substitute were 15 percent, 22 percent, and 39 percent, respectively, for the control, office-staff, and research-support conditions. Neither the 6- nor 12-month smoking cessation results produced statistically significant differences among the three groups.

Special Resources Or Procedures

In stage II, the emphasis was on working with the entire office staff in a team approach. Developing a rapport with the entire office was a major priority. Research assistants worked at making staff members feel that they were an integral part of the success of the program. In addition, for each HMO site, the nurse manager who already had supervisory responsibility for most of the office staff was designated as the office program coordinator. Communication on specific program details was relayed through the program coordinator. In return, any problems or concerns regarding the in-office mechanisms of the program were communicated to the research staff through the program coordinator. The use of this new position was vital for clarifying the lines of communication and avoiding the misunderstandings that sometimes occurred during stage I. For example, some of the stage I physicians did not want the research assistants to start interviewing patients about study participation until patients had finished their visit with the physicians. Other physicians did not care, so long as their patient flow was not interrupted. A program coordinator would have been helpful in establishing appropriate procedures to reduce potential conflict between the research assistants and clinic staff.

As in stage I, the research assistants were solely responsible for recruiting patients who smoked into the study and obtaining signed informed consent forms. Research assistants were responsible also for conducting all patient exit interviews after patients had been seen by their health care provider and for biochemically verifying the smoking status of those who claimed that they were no longer smoking cigarettes or using other tobacco products.

Barriers or Problems Overcome

Stage II presented some new barriers that had not existed in stage I. Before the study was initiated, the HMO had been locally owned and operated for 13 years. During the 3-year course of the study, the HMO changed management three times. These changes, and the uncertainties they produced, created problems such as low staff morale and subsequent high staff turnover. In this context, the requirements of the study, such as flagging charts of smokers, frequently became viewed as an additional burden and source of frustration.

These changes placed additional demands on the diplomacy of the research assistants. In some cases, research assistants took office staff members to lunch. Also, in an effort to engender rapport and support,

research assistants contributed to all office social events, such as pitch-in lunches. Despite these efforts, the requirements for maintaining an office-based smoking cessation program, such as flagging charts and having an instructional system in effect, were never made part of the job descriptions and responsibilities of the new staff. Had such changes occurred, some of the problems caused by high staff turnover might have been prevented.

What Worked And Why

Much of the success of stage I can be attributed to the support of the directors of the general medicine clinic. They made sure that all new physicians were aware of the project and its importance to the Department of Medicine, making the task of orientation much easier for the research staff.

The fact that much of the logistical support (e.g., putting stickers on charts and attaching nicotine polacrilex instruction sheets to the charts of eligible patients) was performed entirely by the research assistants probably expedited their receptivity by the clinic staff. Another essential ingredient for success was the ability of the research assistants to work without disrupting the routines of the clinic. In time, they became viewed as part of the staff in their teams. When the project concluded, there were requests for them to stay and work as regular staff members on their respective teams.

For stage II, the initial attempt to create a team spirit and orientation appeared to be successful. Having one staff member in each practice serve as the program coordinator expedited communication with the office. Unfortunately, the subsequent frequent changes in management made the continuation of this approach difficult, if not impossible. The coordinators' efforts were shifted toward dealing with morale problems and training new clinic staff members in their routine functions. Thus, little time was left to help resolve problems pertaining to the study. Obviously, medical practices that are in flux are poor candidates for taking on additional projects. However, determining in advance which practices will remain stable is easier said than done. The general principle is that the best predictor of future behavior is past behavior. Thus, for subsequent projects, an examination of staff turnover rates could be helpful in determining which practices to select and which to avoid.

What Did Not Work and Why

Obviously the concentration of the training on the physician in stage I, compared with training the office team in stage II, affected the rate of integration of the program into routine care. Physicians were simply too busy with patient care to concentrate their efforts on all the details of providing orientation to their staffs. The investigators' short-sighted approach to training was, in part, compensated by the continuing presence of the research assistant who often became the primary source for educating the office staff. Thus, for the second study, the investigators opted to provide orientation and training for the entire office staff and not just the physicians.

In stage II, the goal was to foster a team approach. Unfortunately, the unforeseen changes in management of the HMO in large part undermined that effort. The high staff turnover meant that much time was required by the research staff to ensure that new personnel received an orientation to the project. In hindsight, one additional step should be considered: namely, insist that the changes in responsibility required for the smoking cessation program become part of the written job description of all pertinent employees. Had that been done, the study might have fostered the continuity of effort and commitment to tasks required by the project coordinator, the check-in clerks, the nurses, and the physicians.

Another consequence of the changes in management was that the medical director and the director of adult medicine became absorbed with the logistics of changing administrative systems such as billing and reporting responsibilities and were diverted from providing the project with the additional support it needed. At one point, a new medical director was hired, and his first project-related action was to suspend the ongoing project and prevent the research assistants from gathering any information on the patients. About 2 weeks' work was lost. Reinstatement occurred only after one of the senior research staff and the director of adult medicine convinced the new director that patients participating had signed consent forms and that the project had been approved by the Institutional Review Committees of both Indiana University and the HMO.

What Would Be Done Differently Now

Two areas should be emphasized in implementing office-based smoking cessation programs. The first is the fostering of a team approach and a team spirit to implement the program. The second is the creation of conditions so that the program not only is integrated into routine care but also is sustained after the project support system is no longer present. Were the program to be implemented again, the investigators not only would continue to emphasize the team approach but also would concentrate more on having each of the roles involved in the office-based system for smoking cessation become clearly defined and part of the written job roles and responsibilities for appropriate office staff. Furthermore, one of the roles that needed to be assigned was that of instructor for new office staff members about their program responsibilities. Ideally, this instructional role would be the responsibility of the program coordinator.

One task that could have been performed better was the instruction of patients in the use of a nicotine substitute. To increase the likelihood of patients' adherence to the proper use of a nicotine substitute, free, individually packaged samples (from the manufacturer) could be provided to each office for trial use. This would allow the physician or other health professional to field questions concerning the correct usage of the product before the prescription is purchased.

Another task that could have been improved was the use of chart reminders. In both stages I and II, stickers were provided to flag the charts of

patients who were smokers. When a chart did not have a sticker, it was not apparent whether the patient was a nonsmoker or had never been asked about smoking. Ideally, receptionists could be trained to use stickers that identify patients as smokers or nonsmokers. This system immediately distinguishes smokers from nonsmokers and identifies those patients whose smoking status has not yet been determined. This type of reminder system requires commitment on the part of the receptionist and office team, but it is an appropriate measure in determining long-term commitment by the practice to a smoking cessation program.

Because of the investigators' interest in having a sample size sufficient to test the hypotheses under investigation, they enrolled all practices interested in participating. Had this not been a research study, the investigators might have produced better results by establishing a certain number of prerequisites before allowing a practice to participate. Just as the time and effort to counsel smokers will produce maximal results with those most ready to change their behavior, so too the time and effort needed to train practices may be best spent with those most receptive to making changes. In making such a determination, it may be best to avoid offices that have a high level of staff turnover and to assess in advance the extent to which physicians and their office staffs have both the time and interest to establish a smoking cessation program as part of routine care. A preassessment questionnaire might identify those ready for change and those disinclined to change. For example, the physicians might be asked, "Are you willing to use office staff time to put smoking identifiers on all patient charts?" A question to front office staff might be, "Are you willing to put smoking identifiers on all patient charts?"

In working with physicians in future cessation programs, the nature of the training sessions could be modified to produce a more individualized training session. The office could be given a list of very specific job duties to be distributed to all staff members with the understanding that a commitment to each person's responsibilities is necessary to make the program work under a team approach. Specific emphasis would be placed on a team member's accepting the role of "trainer" when new office personnel are hired. This list would go one step beyond telling the office to make it a team commitment by demonstrating how the roles can be distributed. Also, group training in the office could be more effective than a large group session held away from the clinic environment. The general background seminar could still be accomplished through a large group program, but individual intervention techniques might be better demonstrated in smaller site visits to further personalize the program. Although these changes would increase considerably the time demands on the research team, the final payoff of increased team commitment would make the initial investment of time worthwhile.

DENTIST INTERVENTIONS

Purpose of Project: Stages I and II

The goal of the stage I project was to develop, validate, and evaluate practical methods to help dentists encourage their patients to stop smoking cigarettes and remain nonsmokers. To determine the most effective intervention method, participating dentists and their panel of patients who smoked cigarettes were randomly assigned to one of the following conditions: (1) control (usual care), (2) nicotine polacrilex available for patients at no charge, (3) a reminder system for following a practical protocol to help patients stop smoking, or (4) both nicotine polacrilex and the reminder system.

The purpose of the stage II trials was to determine the extent to which the "best" smoking cessation intervention method identified in stage I was adaptable and generalizable to private dental practice settings. When stage II began, the stage I trials still had 1 year of data collection remaining. Thus, the "best" intervention method for stage II was determined on the basis of data developed during the first 20 months of stage I. Preliminary analysis of these data for dentists determined that the nicotine polacrilex intervention alone or with the reminders was the "best" method, and it was, therefore, applied in stage II (Cohen et al., 1989b). In stage II, new cohorts of dentists in private practice and their panel of patients were randomly assigned to one of three intervention techniques: (1) control (usual care), (2) free nicotine polacrilex program supported by the project staff (as in stage I), or (3) prescription nicotine polacrilex program supported by the office staff.

Target Audience: Stages I and II

For both phases of the study, participation was limited to private dental practitioners who primarily treated adult patients on a regular basis. Thus, the participating dentists were general practitioners and periodontists. Excluded were dentists specializing in oral surgery, pedodontics, orthodontics, and removable prosthodontics.

Clinical Setting: Stages I and II

All participating dental offices were in Indianapolis and adjacent suburban areas. Practice size ranged from offices with single practitioners to clinic or group practices. The number of established patients, the number of staff members employed, and the use of a hygienist varied from office to office, as did the use of a recall system and a means for identifying smokers.

To minimize practice size as a potential bias source, offices were stratified on the basis of the number of eligible and interested practitioners at each site. They were then assigned to an intervention condition according to random permutations of four for stage I and random permutations of three for stage II.

Patients were eligible for participation in the study if they were between the ages of 18 and 64, reported smoking one or more cigarettes daily, and had an alveolar breath carbon monoxide determination of more than 8 parts per million. Patients were excluded if any of the contraindications for the use of nicotine polacrilex pertained.

The sociodemographic characteristics of the 1,027 stage I patients who agreed to participate (less than a 10-percent refusal rate) were as follows: the mean age was 37.1 (SD 10.4); the mean number of office visits per year was 1.2 (SD 1.2); 95 percent were white, and 4 percent black; 57 percent were female; the median education level was 1 year of college completed; and the median income was $40,000 annually.

Stage I Components

Recruitment Procedures

Procedures to recruit the dentists for participation in stage I began in August 1984. With names drawn from the American Dental Association's Directory of Practicing Dentists in Indianapolis, more than 350 letters of introduction, briefly explaining the proposed program, were sent to eligible area dentists. Two weeks later, a followup telephone call was made to each eligible dentist; 297 offices were reached by telephone and 92 expressed an initial interest in participating. Next, either the project coordinator or project dentist met with each practicing dentist to further discuss and describe their potential for participation. During this meeting, a brief overview of the project was given, and the role of the dentist in the program was emphasized; 54 dentists agreed to participate and signed up to attend the educational seminar.

The dentists were motivated to participate in the program for a number of reasons. One important factor was the encouragement of the chairman of the Department of Preventive Dentistry, a long-term advocate for a more active role by dentists in smoking cessation. In general, those dentists who had a sincere interest in working with the researchers and in developing a successful cessation program for their offices adapted best to the program components and maintained an organized program throughout the study period.

Patient recruitment was conducted by specially trained research assistants. All patients were screened for eligibility for the study (see "Clinical Setting," above). Patients signed an informed consent form that indicated their smoking habit would be monitored at each regularly scheduled clinic visit, regardless of their decision to quit or to continue smoking. Patients were notified that they would be asked to provide a breath sample for carbon monoxide analysis at each regularly scheduled dental appointment and to answer questions immediately after seeing their dentist.

Nature of Training Program

Except for logistics, the training program for dentists was essentially identical to that provided for physicians. To accommodate the dentists from the practicing community, the lecture seminar was offered on four different dates: two afternoon sessions and two evening sessions. The first half of the program was intended to provide a common educational background on smoking. Because each assigned intervention method involved different procedures, the dentists went to one of four smaller group sessions during the second half of the seminar. Separate presentations were given to each group to review the appropriate procedures for each assigned intervention.

At the beginning of the general lecture, all dentists completed a two-page attitude and practice questionnaire concerning their personal smoking histories, their current smoking management practices for patients, and their current interests and beliefs in effectively helping patients stop smoking. The 1-hour general lecture presented evidence of the medical consequences of smoking, the benefits of quitting, the addictive nature of nicotine, and the effect of nicotine polacrilex on smoking cessation. Also discussed was the available evidence that dentists' advice could be effective in counseling patients. Dentists were encouraged to use a four-step counseling protocol developed at the National Heart, Lung, and Blood Institute for counseling smokers: (1) Ask your patients about smoking; (2) deliver a firm quit-smoking message; (3) mutually agree on a quit date; and (4) check your patients' progress at each regularly scheduled visit. Dentists were also given a copy of an NCI pamphlet, "Quit for Good," and were informed that copies would be provided to their offices for use with their patients who smoke.

The small group presentations centered on providing specifics for each intervention technique. Dentists in the control group were given a booklet containing the four-step protocol and were encouraged to counsel their patients who smoke. Dentists in the other three methods received the same instruction as the advice method plus additional instruction based on their assigned experimental condition. Information and handouts provided to the dentists were physician-based materials because dentist-based materials were not available at that time. The dentists had little resistance to using the materials and were able to adapt the physician-oriented information to their context.

Dentists in the nicotine polacrilex group were instructed on the use of fluorescent red stickers to flag charts of patients who were eligible to receive the nicotine replacement product at no cost. Dentists were told that research assistants would place the stickers and remove them after the patient had received the product. The uses, indications, contraindications, and side effects of nicotine polacrilex were discussed in detail. Offices were provided with product log books to record when nicotine gum was dispensed, and dentists were encouraged to record on the patient's chart when the product was dispensed. It was mandated that the product be stored in a safe, locked place.

In the reminder condition, dentists were instructed on the use of two fluorescent chart stickers to help remind them to follow the step-care protocol. A green sticker was used to remind them to ask the patient about smoking, and an orange sticker indicated that they should ask the patient to set a quit date. Dentists were informed that a feedback report issued to them bimonthly would provide the names of smoking patients they identified as well as the quit dates they had established with their patients. Unfortunately, it seemed that many feedback reports were not read or were ignored by the dentists. It is unlikely that the reports had any great impact on the dentists' behavior.

For the dentists in the combined condition (nicotine polacrilex plus reminder), instruction was given on the use of all three stickers and the dispensing and storing of nicotine polacrilex. For those dentists unable to attend any of the four seminars, a similar in-office presentation was given.

Approximately 1 week before the initiation of the intervention method in each office, a project director and research assistant assigned to that office (research assistants were assigned to an office on the basis of the office location—southwest, southeast, north) visited the office for a 1-hour meeting to review the record-keeping procedures and to answer any questions resulting from the general seminar. Initiation of offices was staggered for logistical purposes, to adequately train and monitor offices and to accommodate those offices that requested a delayed starting date. In-office training procedures began in October 1984, and all offices were initiated by April 1985. Three research assistants were employed to initiate and maintain the offices, allowing for each research assistant to be responsible for 14 to 17 offices throughout the study period. Of the 54 dentists trained, 50 actively participated in the program.

Results

The results of the study have been described in detail elsewhere (Cohen et al., 1987 and 1989b). The dentists' behavior under each intervention is shown in Table 17.

Because cigarette smokers often quit smoking and later relapse, the prevalence of smoking was estimated at two subsequent intervals. The first estimate (6 months) was defined as the smoking status determined at any visit that occurred at least 3 months after the initial appointment but not more than 9 months after it. The second estimate was at 1 year, which was defined as at least 9 months and 1 day after the initial visit and up to 15 months after the initial visit. If there was more than one visit during a time interval, the smoking status was determined by the status at the last visit during that interval. For patients who had a regularly scheduled appointment during

Table 17
Reported dentist counseling about cigarette smoking

	Percentage of Patients Reporting Actions		
	Asked About Smoking	Advised To Quit	Asked About Setting a Quit Date
Dentist Group			
Advice	31%	18%	3%
Gum	72	32	6
Reminder	59	29	14
Both	95	54	31

the critical period, their smoking status was confirmed through carbon monoxide assessment, the procedures for which are described elsewhere (Stookey et al., 1987). Patients who did not visit the dentist during the 6- or 12-month period were assumed to be smokers. Thus, the results are reported both for returnees, for whom biochemical validation was possible, and for all enrolled patients on the basis that a patient was a smoker unless there was biochemical evidence to the contrary.

A generalized linear model was used to analyze the results of the quit-smoking rates. The 6-month results are shown in Table 18. The generalized linear model for all enrollees produced borderline significant main effects for the gum group and for the reminder group. However, the coefficient for the reminder effect was negative. Statistically, this result is caused by the high cessation rates in the gum group coupled with the lower rate in the gum and reminder group. These rates for all returnees may not reflect the effectiveness of the intervention but may, in part, be artifacts of the number of patients who returned during the time window. Whereas those patients who did not return were classified as smokers, the cessation rate in both gum and reminder groups was depressed by a lower 6-month return rate (32.3 percent) than in the other groups (control 43.8 percent, reminder 43.3 percent, and gum 49.5 percent).

The results at 1 year are shown in Table 19. At 1 year, there was a significant effect of the gum for both those patients who returned during that time interval and for all patients. No other effects were significant.

Table 18
Confirmed success rates at the 6-month visit for each dentist intervention

	Percentage Who Quit	
	Returnees Only (n=428)	All Enrollees (n=1,027)
Dentist Group		
Control	7.1%	3.1%
Reminder	7.4	3.2
Gum	18.2	9.0
Both	9.4	3.0
	Generalized Linear Model Significant p Values	
Reminder	> 0.10	0.051
Gum	0.072	0.061

Table 19
Confirmed success rates at the 12-month visit for each dentist intervention

	Percentage Who Quit	
	Returnees Only (n=374)	All Enrollees (n=1,027)
Dentist Group		
Control	7.7%	3.1%
Reminder	8.6	2.8
Gum	16.3	7.7
Both	16.9	4.7
	Generalized Linear Model Significant p Values	
Gum	0.012	0.038

Special Resources Or Procedures

For a program of this size and intensity, special resources were necessary to achieve sufficient cooperation from the dental offices. Maintaining each office's motivation level and commitment to the program required constant attention from the research team.

In stage I, with program emphasis on the dentist rather than on the dental team, research assistants concentrated their efforts on implementing the program components, especially identifying patients who were smokers, and on providing open communication with the dentist. These two objectives proved difficult to achieve without the development of rapport between the research assistant and the office staff. Office staff members were often resistant to an outsider potentially disturbing their daily routine. Many were reluctant initially to include the research assistant as a working part of their program. It became apparent that the research assistants needed to find a way to integrate themselves and the program components into a regular part of the dental offices. This rapport development was crucial to the success of each office program.

The means to develop rapport varied with each office. In some offices, the research assistant would occasionally volunteer to assist the receptionist with clerical duties, such as filing or confirming patient appointments. This work not only relieved the receptionist of these tedious tasks but also provided the research assistant with an opportunity to blend the program functions into the regular office routine. While filing, the research assistant added stickers to the charts of newly recruited patients; while confirming appointments, the assistant obtained patients' smoking status. The working relationship that developed between the receptionist and the research assistant, and

the subsequent routine implementation of the program components by the receptionist, soon led to a well-maintained smoking cessation program.

Personnel in some offices were not comfortable with having the research assistant help with clerical duties. In those offices, the research assistant tried to establish rapport with a specific staff member. Taking the time to make light conversation and to show an interest in the staff member gradually contributed to the development of trust between the two parties.

In other offices, the research assistant found a means to intercede with a solution to a current office problem. For example, one office was preparing to move and was struggling to find time to purchase file boxes to pack patient records. The research assistant surprised the office one afternoon by delivering a case of file boxes. This one simple gesture created a rapport with the office and prompted a newfound interest in the program. For the research assistant, finding a way to develop an essential positive rapport with the office was the most efficient way to assure smooth implementation of the program.

Barriers or Problems Overcome

Implementing a program of this nature led to the identification of a series of barriers or problems that needed to be overcome. Approaches initially anticipated to work often had to be adjusted to meet the demands of a given situation. For example, the logistics of covering offices from such a wide geographic area was anticipated to cause some difficulty with the requirement for research assistants to conduct an exit interview with every smoker to determine their status and the nature of the counseling they received. Initially, this problem was managed through reduction of the number of office sites; only group offices of two or more dentists each were recruited. When initial interest by some group practices decreased, single practitioner offices were then invited to participate. To help offset the increased site locations and provide a more even recruitment and followup schedule, dates for initiation of the program were staggered, and research assistants were assigned to a territory of Indianapolis to reduce travel time between sites as much as possible. Research assistants also carried voice pagers to relay messages from the research institute and eliminate the need for unnecessary travel to offices where a patient had failed to arrive or had canceled an appointment.

Another problem involved the slower than anticipated rate for identifying smokers in each dental practice and then subsequently recruiting them into the study. In stage I, dental offices were expected to identify and recruit 30 to 100 patients (an average of 40 patients per office) in an 8-month period. At 7 months into the program, only 471 of the anticipated 1,000 patients had been recruited in offices involved in the study. For those offices having difficulty in identifying patients who smoked, the research assistant and dentist met to discuss alternative ideas.

Originally, it was presumed most offices would have the smoking status indicated on the patients' charts. For those that did not, office staff members

were expected to ask patients their smoking status over the phone when they confirmed recall appointments. However, in more than half the offices involved, smoking status was not available through the patients' records and the receptionists did not want to risk antagonizing patients by asking their smoking status over the telephone. The following suggestions were given to the dentist as alternatives for obtaining smoking status: (1) update each patient's medical history through the use of a new medical history form that included smoking status; (2) keep a running list of names in the operatory of patients who smoke as they were identified (hygienists had the best means for identifying smokers, through visible tar and nicotine stains at the time of the teeth cleaning); (3) have the dentist or hygienist check the appointment book each week to identify patients they recognized as smokers; and (4) have the research assistant stationed in the waiting room on a given afternoon each week to ask patients their smoking status as they arrived (given as a last choice because of constraints on the research assistant's time).

For those offices having difficulty with adjusting to the routine of a smoking cessation program and with overcoming their hesitancy to address patients about their smoking habit, a meeting was arranged among the dentist, research assistant, and project coordinator. An attempt was made to better tailor the program to each office's specific needs and to provide further ideas on approaching the patient about smoking.

In many cases these procedures, singly or in combination, catalyzed renewed interest in the program and resulted in an increase in the number of patients recruited. For those offices where a rapport was difficult or impossible to achieve, patient recruitment continued to be difficult.

Once the program had been initiated, a system was needed to identify followup appointments and to assess the smoking status of patients at 6 and 12 months after their recruitment date. The use of a 6-month preappointment recall system was presumed to be the means for obtaining followup interviews. The objective was to establish the patient's recall visit at the completion of the initial appointment. However, a wide range of office recall systems was used in the different offices. The following two systems were recommended: (1) the research assistant provided the receptionist with a list of patients due each month and the office staff, in turn, notified the research assistant when a patient scheduled an appointment (this was the weaker of the two systems because it mandated the cooperation of the receptionist in recognizing the participant and notifying the research assistant); and (2) the research assistant checked the appointment book weekly to determine if anyone in the study was scheduled for a recall appointment. The second method was preferred to the first but was not always permitted by the office staff. The second method also did not account for patients scheduling last-minute appointments. The best approach, still, was to develop a good rapport with the office staff to ensure cooperation with recall appointments. If a patient missed a recall appointment and the research assistant was notified about it within 24 hours, a followup interview over the phone was obtained.

The training of new office personnel also presented some problems. In stage I, the dentists were expected to educate their new staff members on the components of the program, but they often relied on the research assistant to do so. Not only were new staff members not trained for their responsibilities in the program, but also many were not informed of the program upon accepting their positions. A well-run recruitment and followup program could quickly be devastated by the arrival of an unwilling new employee. Research assistants took great pains to establish a rapport with new staff members. Treating the new employee to lunch to discuss participation in the program and carefully following progress each week helped to gradually reinstate the program to its original operation. Turnover in participating dental offices was high, and the retraining of new personnel was a continual responsibility of the research assistant.

Stage II Components

As previously stated, stage II was initiated 1 year before the completion of stage I. In August 1986, 354 dentists listed in the American Dental Association Directory and not currently participating in stage I were contacted by mail with a similar letter of introduction. Followup telephone calls found 53 dentists interested in meeting to further discuss the program. During meetings in the dentists' offices, the project coordinator explained the project goals, objectives, and procedures. Unlike the meetings in stage I, the level of team commitment required from the dental office was emphasized. The 42 dentists who agreed to participate were strongly encouraged to bring their staff members to the seminar.

Recruitment Procedures

Nature of Training Program

Dentists and their office staffs participating in the stage II program attended a seminar offered on one of four dates. This educational seminar used a format similar to the stage I training session. A general orientation seminar on the background of smoking opened the meeting and was followed by a breakout into three smaller groups for intervention training. Dentists also completed an attitude and practice questionnaire at the beginning of the meeting. Throughout the seminar, the dentists and office staffs were trained as a unit to emphasize team collaboration and commitment.

The first half of the program included the same information as the stage I general seminar but emphasized the team approach to a successful program. In stage I, it was observed that the hygienist often took the primary role of counselor, with the dentist providing reinforcement counseling and prescribing nicotine polacrilex when indicated. The team approach presented in the stage II seminar emphasized the involvement of staff members, in particular the hygienist, and encouraged the dentist to tailor the smoking cessation program to maximize the resources, skills, and interests of the dental team. The dentists were asked to assign an office coordinator to be responsible for maintaining the program and providing communication between the office and research personnel.

Experience in stage I showed that the mechanics of addressing the patient were a major concern for office personnel. The dentists and staff members were hesitant about addressing smoking with their patients. They were concerned about offending the patients and subsequently losing them from the practice. Therefore, during the stage II general seminar, specific techniques were illustrated for dentists to use when counseling the patients who smoke. A videotape developed at the University of California, San Francisco, was used to show physicians talking to patients about smoking. Shown is an interaction to assess a patient's interest in quitting, establishing a quit date, and receiving educational materials and encouragement. Also shown is an interaction between a physician and a patient who had made a quit attempt and then relapsed before the office visit. One segment depicts a conversation with a patient who is interested in discussing exercise but not smoking.

The videotape is very adaptable for the dental setting, and the taped interactions illustrate a positive, nonthreatening approach to smoking counseling. For example, rather than lecturing patients and emphasizing the health consequences of smoking, the physician role models ask questions such as, "Have you thought about quitting?" and "Are you ready to make another quit-smoking attempt?" The vignettes illustrate how to tailor the counseling for patients who have varying degrees of interest in stopping smoking. Dental teams were encouraged to use these skills with their patients who smoke.

After viewing the videotape, dental teams were encouraged to practice the techniques demonstrated on the tape. Despite the fact that the role models were physicians, the dental teams reported that the information was of great value to them.

At the conclusion of the general seminar, dentists and their office staffs were given copies of the "Quit for Good" pamphlet. They were informed that copies would be provided at no charge to their offices for patients who smoke.

During the second half of the seminar program, specific techniques pertaining to each intervention condition were outlined and discussed with the offices randomly assigned to those interventions. Dental practices in the control group were given the same booklet that the stage I group was given and were encouraged to follow the step-care protocol for counseling their patients who smoke. Dental practices in the other two interventions received the same instruction as the control group plus additional instruction based on their assigned condition.

Those persons in the free nicotine polacrilex method supported by research staff were instructed in basically the same manner as their counterparts in the stage I method. They were informed that red fluorescent stickers would be placed by research assistants on the charts of patients who were

eligible to receive the nicotine replacement product. The dental teams were made aware that the stickers would be permanently removed once the product had been prescribed. The uses, indications, contraindications, and side effects of nicotine polacrilex were discussed in detail. The requirements for storing the product were also reviewed. Offices were provided with log books for recording when the product was dispensed, and participants were encouraged to enter on the patients' charts the date that the product was dispensed.

Offices assigned to the nicotine polacrilex prescription method supported by office staff were instructed on the use, indications, contraindications, side effects, and record-keeping procedures for nicotine polacrilex in a manner identical to the free-product group. However, because the purpose of this trial was to determine the feasibility of a dental team's carrying out the step-care protocol of a cessation program with only minimal support from the research team, this group of participants was taught how to perform the procedures needed to support the program on their own. This group was told that it was the responsibility of the office staff to take the provided stickers and label the charts of the patients listed on the enrollment roster. As stated in the results section, 77 percent of the charts were flagged by office staff as a result of the weekly roster of eligible patients.

Instead of offices being provided with free nicotine polacrilex to dispense to their patients, these offices were instructed on how to prescribe the product and were given a carbon-copy, prestamped prescription pad. The carbon copy allowed research personnel to periodically check when the product had been prescribed. Office personnel were instructed on the method for flagging the charts of eligible patients. They were informed that the research assistant would provide a list of patients recruited that week who were eligible for a prescription and who should have a sticker placed on their chart. The research assistant periodically checked charts to determine if stickers had been placed. As with the second group, dentists and hygienists were encouraged to review the product usage instructions with the patient and to record in the chart when the product had been prescribed. Those dentists and staff unable to attend any of the scheduled seminars (about 10 percent) were given a similar in-office presentation.

One week before each office began the study, the study coordinator and research assistant assigned to that office visited the office to deliver program material and review the program again with the dental team. Initiation of dental offices in stage II was again staggered for optimum recruitment and followup procedures. Of the 42 offices initially trained, 35 completed the program.

Results

To determine the extent to which the office staffs performed the tasks requested of them, office charts of the patients enrolled in the study were examined. In comparison with the 100 percent of charts that were flagged in the research-support condition, 77 percent of the charts were flagged in the office-staff condition.

Not surprisingly, the behavior of the dentists in counseling smokers was affected by the intervention condition. Office exit interviews of patients showed that 16 percent of control group patients, 20 percent of office-staff patients, and 34 percent of research-support patients (p=0.07) reported that their dentist had talked to them that day about smoking. Also, the percentages of patients given or prescribed the nicotine substitute were 6 percent, 14 percent, and 46 percent, respectively, for the control, office-staff, and research-support conditions ($p < 0.0001$). Neither the 6-month nor 12-month smoking cessation results produced statistically significant differences among the three groups, although the rates for the 12-month point were 3.1 percent, 6.9 percent, and 9.2 percent (p=0.10) for the control, office-staff, and research-support conditions, respectively.

Special Resources Or Procedures

In stage II, the work of the dental office as a team was emphasized. Developing rapport with the entire office was a major priority. Research assistants worked at making staff members feel they were an integral part of the success of the program. Some new procedures were integrated into stage II to aid implementation of the program. One such procedure was the requirement that one member of the office staff serve as the office program coordinator. Communication on specific program details was relayed through the office coordinator. In return, any problems or concerns regarding the in-office mechanisms of the program were communicated to the research staff through the office coordinator. The use of this new position was vital for opening the lines of communication and avoiding misunderstandings that arose in some of the offices involved in stage I.

Another procedure involved a scheduled weekly visit by the research assistant to the office. Regardless of the number of patients interviewed in each office in a given week, the research assistant made a visit to each office on the same day and time each week. The day and time were established by the office staff and then worked into the research assistant's schedule as closely as possible. This established a routine for the program and allowed staff members to share questions, concerns, or ideas about the program and present them to the research assistant at one time. Also at this time, and depending on the conditions mandated by the intervention technique assigned, the research assistant verified that there were ample supplies, checked the log book with the nicotine polacrilex count to determine if all of the product dispensed had been recorded, checked prescription pads to see if the product had been prescribed, and reviewed charts to see if stickers had been placed. The research assistant became a routine part of the office through the use of these weekly visits and, in addition, met with staff members once a month to field questions from the group as a whole. This fostered an exchange of ideas and emphasized the team approach to the program. The meetings lasted 10 to 15 minutes and usually were made a part of the regular monthly staff meeting. For those offices that did not hold regular monthly meetings and were unwilling to assemble as a group, the research assistant continued to conduct a monthly meeting with the office coordinator to discuss the program.

Incentives were also used as a new special resource in stage II. At the beginning of the recruitment period, offices were informed that a free lunch at a local restaurant would be awarded to each office that reached its quota for the number of patients recruited (i.e., 50 patients per dentist during the first year). The number of patients recruited to date was also reviewed at each staff meeting to continually motivate the teams toward their goal. For offices that were particularly struggling but making progress, coffee and donuts were given as an incentive to keep up the good will among the staff.

These special resources provided a vital connection in propelling the dental team toward a successful implementation of the smoking cessation program.

Barriers or Problems Overcome

There were fewer barriers and problems in stage II. Problems that had occurred in stage I could be anticipated and solved before they progessed in stage II. Continued emphasis was given to developing a rapport with the dental team, and approaches for handling familiar problems were refined. Problems such as high staff turnover and finding a means for determining patients' smoking status still occurred, but experience from stage I aided in the adoption of procedures discussed previously. No new problems surfaced in stage II that had not been confronted in stage I.

What Worked And Why

In stage II, the focus of a team approach brought together a group of interested staff members who all felt involved and consequently were more willing to work toward their goal. Those offices in which the program was most successful integrated the smoking cessation program with their office routine (Cohen et al., 1990). Those offices that never allowed the research assistant to get involved with their office routine never really integrated their programs. In successful offices, the research assistant was perceived as part of the office team. Dental staff turnover was great in many participating offices, and this hampered the ability of the research assistant to form a rapport with the team. To best sum up the success of this program, stages I and II required a dedicated research team, an interested dental team, and a trusting relationship.

What Did Not Work and Why

During stage I, the target of the intervention and training was the dentist. In stage II, it was the entire practice. The initial assumption, that dentists in stage I would orient and organize their staffs, proved faulty. The dentists were simply too busy to concentrate on orienting their staffs. Many tried to delegate their duties to a staff member, but a lack of communication often led to misunderstandings, and interest declined. Without the team approach, other staff members felt slighted and made no effort to become involved in the program.

There were some dental offices where the dentist did very well and accepted primary responsibility for the program. In most of these cases, however, the office had previously developed a true commitment to the values of the program and were motivated to succeed. Some dentists signed

up for reasons other than the desire to help their smoking patients quit. These offices rarely developed successful programs (unless a motivated staff member, such as the hygienist, had enough influence and interest to keep the program going). In some cases, dentists later admitted becoming involved only to look good in the dental community or because they hoped to receive a free product to hand out to their patients.

What Would Be Done Differently Now

Two areas should be emphasized in implementation of office-based smoking cessation programs. The first is the fostering of a team approach and team spirit when implementing the program. The second is the creation of the conditions so that the program not only is integrated into routine care but also is sustained after the project support system is no longer present. Were the program to be implemented again, the investigators not only would continue to emphasize the team approach but also would concentrate more on clearly defining each of the roles involved in the office-based system for smoking cessation and including them as part of the written job roles and responsibilities for appropriate office staff. Furthermore, one of the roles needed was that of instructor for new office staff in their program responsibilities. Ideally, the instructor's role would be the responsibility of the office coordinator.

One task that could have been performed better was the instruction of patients in the use of a nicotine substitute. To increase the likelihood of the patient's adherence to the proper use of a nicotine substitute, free, individually packaged samples (from the manufacturer) could be provided for trial use in the office. This would allow the dentist or other health professional to field questions about correct use of the product before the prescription is purchased.

Another task that could have been improved was the use of chart reminders. In both stages I and II, stickers were provided to flag the charts of patients who were smokers. When a chart did not have a sticker, it was not readily apparent whether the patient was a nonsmoker or had never been asked about smoking. Ideally, receptionists could be trained to use stickers that identify patients as smokers or nonsmokers. They could immediately distinguish smokers from nonsmokers and identify those patients whose smoking status has not yet been obtained. This type of reminder system requires commitment on the part of the receptionist and office team but is an appropriate measure of long-term commitment by the practice to a smoking cessation program.

Because the investigators were interested in having a sample size sufficient to test the hypotheses under investigation, they enrolled all practices interested in participation. Had this not been a research study, the investigators might have produced better results by establishing a certain number of prerequisites before allowing a practice to participate. Just as the time and effort to counsel smokers will produce maximal results with those most ready to change their behavior, so too, the time and effort needed to train

practitioners may be best spent with those most amenable to making changes. In making such a determination, it may be best to avoid offices that have a high level of staff turnover.

In future cessation programs involving dentists, the nature of the training sessions could be modified to produce a more personalized training session. The office could be given a list of very specific job duties to be distributed to all staff members with the understanding that a commitment to each person's responsibilities is necessary to make the program work under a team approach. Specific emphasis would be placed on a team member accepting the role of trainer when new office personnel are hired. This list would go one step beyond telling the office to make it a team commitment by demonstrating how the tasks can be distributed. Also, group training at the office would be more effective than in a large group session held away from the clinic environment. The general background seminar could still be accomplished through a large group program, but individual intervention techniques might be better demonstrated in site visits with small groups to further personalize the program. Although these changes would increase considerably the time demands on the research team, the final payoff of increased team commitment would make the initial investment of time worthwhile.

DIFFERENCES BETWEEN DENTAL AND MEDICAL PROGRAMS

In some respects, a dental practice is an easier environment for establishing a smoking cessation program as part of routine care. First, the purpose for most visits is prophylaxis, so patients start with a prevention orientation and often are not there for acute care. Another important factor is the amount of time a patient spends in the office. Most dental visits last from 30 minutes to 1 hour, whereas medical visits are often scheduled at 15-minute intervals. Thus, the time for adequate counseling is more available in most dental settings than in most medical settings. On the other hand, physicians perceive counseling patients about smoking as part of their clinical responsibility, while many dentists still are not comfortable with the role of smoking cessation counselor. This is demonstrated by many dentists having much greater interest in continuing education about smokeless tobacco than in cigarette smoking cessation.

Progress is continuing through a number of excellent dental team training programs conducted through the National Cancer Institute. The availability of materials tailored for the dental team appears to facilitate the willingness of dentists and their staffs to be involved in the national effort to make counseling about smoking cessation a routine part of health care.

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The Tobacco Reduction and Cancer Control (TRACC) Program: Team Approaches to Counseling In Medical and Dental Settings[5]

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INTRODUCTION Physicians and dentists are effective smoking interventionists (Cohen et al., 1989a and 1989b; Cummings et al., 1989; Janz et al., 1987; Li et al., 1984; Ockene, 1987a; Wilson et al., 1988). Although surveys of physicians indicate that about half report advising "most" of their patients to stop smoking (Fortmann et al., 1985; Wells et al., 1984), the consistent success of controlled physician intervention studies emphasizes the need for improvements in smoking interventions delivered through the medical care setting. Wells and colleagues (1984) presented a model that related physician practices used in counseling smokers to personal habits, the reimbursement system, clinical training, motivation, perceived risk of smoking, perceived skill in counseling, and perceived benefit. To this model should be added the time constraints faced by so many physicians, particularly those in prepaid group practice settings.

Physician-delivered smoking interventions have distinct advantages and disadvantages. The advantages include the credibility of the physician, the teachable moment created by the juxtaposition of that credibility with an illness experience, and the potential for reinforcement of the intervention over many years. Disadvantages of physician interventions include inconsistent compliance by physician interventionists, variable levels of counseling skills, lack of training, lack of time, lack of incentive, and competition from more acute medical problems.

The Tobacco Reduction and Cancer Control program was designed as a mechanism for using the strengths of physician interventions while overcoming the disadvantages (Vogt et al., 1989). The general approach of TRACC has three steps: (1) randomized efficacy trials of intervention approaches; (2) demonstration studies of large-scale implementation; and (3) evaluation of the demonstration programs and dissemination to large medical care systems. TRACC was initiated in 1987 as a group of five randomized studies designed to determine effective methods for integrating

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smoking counseling into the medical care setting. It addressed interventions in outpatient, inpatient, and dental settings and included direct outreach to adolescents. TRACC interventions were, in most situations, introduced by providers but conducted by other appropriately trained medical personnel. Centralized systems identify smokers and also keep track of quit dates so that supportive followup calls can be made by trained phone callers. These approaches are applicable to other aspects of cancer control and behavior change as well. Currently, TRACC is completing step 1 (randomized efficacy studies) and is moving into a large-scale demonstration program. The following section discusses the approaches used in TRACC interventions and their impact on smoking behavior of patients in the Northwest Region of Kaiser Permanente, the Nation's largest managed care health maintenance organization.

NURSE-ASSISTED COUNSELING

Medical office smoking interventions generally rely on physicians to assess patient smoking status, provide advice and materials, determine readiness to quit, deal with barriers to change, and encourage patients to set quit dates and develop effective strategies for coping with withdrawal symptoms. Although motivated physicians with an appropriate training program and a well-organized system for monitoring and reinforcing physician compliance can significantly enhance cessation rates among patients (see reviews by Kottke et al., 1988; Ockene, 1987a; Pederson, 1982), it is less clear that such programs can be widely disseminated and easily sustained, especially in medical settings that are not research oriented.

In many primary care settings, physicians may spend only 15 minutes with the average patient. That time must be used to diagnose, discuss, and treat the presenting complaint; arrange needed referrals or routine screening; and respond to a variety of other patient concerns. As important as it is, smoking counseling frequently gets short shrift or is avoided altogether because of the pressures of acute care delivery. Physician-centered counseling also makes little use of nurses and other intervention resources available in clinical settings. Kottke et al. (1988) have concluded that various and repeated messages from all staff members through a number of communication channels constitute the most effective way to enhance impact.

Our initial aim was to develop a smoking intervention in the medical care setting for Kaiser Permanente, Northwest Region. To be practical, it had to be not only effective but also relatively easy to implement and sustain within a large managed care setting. We concluded that the intervention should contain the following components: (1) assessment of smoking status; (2) firm advice to stop smoking; (3) cessation videos, manuals, and mailings; (4) encouragement to set a specific quit date; and (5) a followup phone contact to check on progress. Assessment of smoking status at each visit highlights the importance of cessation to patients and is needed to direct intervention to those who need it. A physician's firm advice to quit takes advantage of his or her credibility and authority and creates a teachable moment. To reduce the burden on staff, information on cessation strategies

and how to overcome barriers can be provided effectively and economically in the form of videos, manuals, and followup mailings. Patients who are ready to quit should be encouraged by staff to make a commitment to a personal action plan and select a specific quit date. To enhance perceived support and accountability, a followup call should be scheduled for 1 or 2 days after the quit date. Although all of these components may be helpful, we thought it unrealistic to expect that most primary care providers would consistently carry out all of these steps with their smoking patients. Instead, we decided to minimize the burden on the provider and test a team approach involving physicians, nurses, and other clinic staff.

The team approach to counseling offered several advantages over a physician-centered model. This approach took advantage of the physician's prestige and credibility to initiate the intervention process. Physician time and effort were minimized, however, by having nurses or other clinic-based staff reinforce the stop-smoking message, provide stop-smoking videos and manuals, encourage patients to set quit dates, and provide followup phone contacts. To reduce the burden on support staff, most of the motivational and educational information was delivered through manuals and videos tailored to the needs of the local patient population. Periodically, newsletters and other cessation materials were mailed by centralized clerks using a computerized patient tracking system.

The purpose of this project was to assess the feasibility and effectiveness of nurse-assisted outpatient smoking intervention procedures. The primary outcome was a comparison of the impact of physician-nurse team approaches to smoking counseling to brief physician advice alone. The study methods and findings are described below, and a more detailed presentation is available elsewhere (Hollis et al., 1991; Lichtenstein and Hollis, 1992).

Intervention Setting And Methods

A phase III randomized clinical trial was carried out within two large Kaiser Permanente medical offices. All 60 internal medicine and family practice providers in the two medical offices were invited, and all participated in the intervention. The physician's role was simple; it included 30 seconds of clear advice to quit plus a referral to a nurse smoking counselor for additional intervention. Physician training was carried out in a single 1-hour meeting with some individual clinic followup. Training emphasized how to deliver brief cessation advice and refer patients to the clinic-based smoking counselor (e.g., a nurse). Role-playing, questions, and discussion were encouraged.

Procedure

The nurse-delivered components were provided by several project staff members, headed by a lead counselor who was a nurse with no previous smoking cessation experience. Each counselor could handle the smoking patients of 16 to 20 physicians. The training for the counselors included role-playing from an intervention outline, observing a stop-smoking class, and several weeks of pilot testing. Others of the clinic staff were oriented to their roles during regular weekly staff meetings with some individual followup.

Receptionists asked all primary care patients to complete a brief health habits questionnaire while waiting for their appointments. Regular clinic nurses or clinical assistants collected the questionnaires as the patients were taken to exam rooms and attached a colored form to the medical chart of smokers to alert physicians to deliver the cessation advice and referral message.

Physicians delivered a 30-second stop-smoking advice message that was designed to minimize defensiveness and create a teachable moment. The form on the chart included the following script, but physicians were free to deliver the message in their own words:

> The best thing you can do for your health is to stop smoking, and I want to advise you to stop as soon as possible. I know it can be hard, and many try several times before they finally make it. You may or may not want to stop now, but I want you to talk briefly with our smoking specialist who has some tips to make stopping easier when you decide the time is right.

At the end of the visit, patients saw the on-site smoking counselor (i.e., a trained nurse). Two random digits in the patient's health record number were used to assign patients randomly to one of the following four conditions: advice only, self-quit training, group recruitment, or a combination treatment. Advice-only control subjects received the physician advice message and the brief National Cancer Institute pamphlet, "Why Do You Smoke?" Although little information on how to stop smoking was offered, clear and systematic physician advice was expected to be more effective than no treatment or usual care.

Self-quit subjects received physician's advice, and the nurse tested them for carbon monoxide. Patients were then left alone to watch a 9-minute video on how to quit on their own. The video was produced by Independent Video Services and Anthony Biglan, Ph.D., at the Oregon Research Institute, and it is available from Dr. Biglan. The video focuses on the steps other patients had used to quit successfully, the frequent need for repeated efforts, and the importance of setting a quit date and using substitutes for smoking. Patients were given a stop-smoking kit (e.g., gum, toothpicks, cinnamon sticks, quit tips) and a choice of one of three stop-smoking manuals (provided by the National Cancer Institute and the American Lung Association). Patients could also call a local stop-smoking hotline or attend a free 90-minute session on how to stop smoking, although those resources were almost never used. The counseling nurse also encouraged patients to set a specific quit date and a followup call was planned, usually within 2 to 4 weeks, to check on progress toward cessation. Finally, patients were mailed a set of stop-smoking tip s heets and, on request, a series of six attractive bimonthly newsletters devoted to smoking cessation.

Group-recruitment subjects also received physician advice, the carbon monoxide assessment, and a video. In this condition, the video encouraged patients to join the HMO's intensive nine-session stop-smoking program known as Freedom From Cigarettes (Stevens and Hollis, 1989). Patients were provided a brochure, a group schedule, and a time-limited coupon to waive the program fee. Patients were then invited to sign up for an upcoming group, and reminder postcards were sent 1 week prior to the scheduled meeting. The counseling nurse also called patients several days after the meeting to provide support for any progress.

Combination-treatment subjects also received advice, the carbon monoxide test, and a third video, which describes both self-directed cessation techniques and the pros and cons of joining a professionally run program. The self-help manual, stop-smoking kit, and the group materials and coupons were all provided. Subjects were encouraged to set a quit date or sign up for an upcoming group, and a phone call was arranged to check on progress. Tip sheets and the bimonthly newsletters also were provided.

Results

Recruitment

About 24 percent of this outpatient population reported smoking, and a total of 3,161 eligible smokers were identified over the year-long recruitment period. Of these, 2,707 (86 percent) received brief stop-smoking advice from a medical care provider. In this intent-to-treat design, all smokers who received physician advice were considered randomized subjects even if they failed to see the nurse for additional intervention. Fortunately, the vast majority of advised patients (87 percent) agreed to see the clinic counselor (Table 20). This rate was similar across the four groups. The four treatment conditions were similar also in terms of baseline age, sex, race, education, occupation, cigarettes per day, contemplation status, confidence in ability to quit, perception of weight status, and subjective health status.

Table 20
Cessation activities, by treatment condition

	Percentage in Treatment Condition				
	Advice Only	Self-Help	Group Recruitment	Combination Treatment	p <
Saw Counseling Nurse	89%	88%	85%	87%	0.06
Set a Quit Date	0	28	3	22	0.001
Attended Group Program	1	0	11	8	0.001

Acceptance of Intervention

Two-thirds of all randomized self-quit (69 percent), group-recruitment (68 percent), and combination-treatment (67 percent) patients completed a baseline carbon monoxide test as part of the intervention, and some what fewer saw the stop-smoking videos (63 percent, 57 percent, and 62 percent, espectively). Manuals and small, inexpensive "quit kits" were provided by hand (or mailed) to a majority of self-quit (91 percent) and combination-treatment (90 percent) patients. A brochure and fee waiver coupon for the group cessation program were accepted by 82 percent of group-recruitment patients, but only 60 percent of combination-treatment patients accepted. Table 20 also shows that 28 percent of all self-quit subjects agreed to set quit dates, usually within 2 to 4 weeks of the initial visit. It was our sense that encouraging patients gently to set quit dates was an important part of the process, and those who agreed to a specific quit date were significantly more likely to achieve abstinence than those who did not (16 percent vs. 11 percent, $p < 0.02$). About 11 percent of group-recruitment subjects attended at least one session of the HMO's intensive cessation program, but only 1 percent in the advice-only condition attended. Combination subjects chose a mix of cessation strategies.

Three months after the visit, subjects were mailed a brief survey and a subsequent reminder. Those who did not respond were contacted by phone and the survey was administered as a structured interview. The followup rates (88 percent) were similar across conditions.

At 3 months (Table 21), subjects in all three nurse-assisted conditions were significantly more likely to report one or more serious quit attempts than were those who received only physician advice. The three nurse-assisted conditions had similar abstinence rates (i.e., no cigarettes in the preceding week, with nonrespondents counted as smokers), and all three nurse-assisted interventions led to significantly higher quit rates (about 80 percent) than the rate for brief physician advice alone. Similar outcomes were noted when abstinence was defined as no tobacco use of any kind.

Table 21
Outcomes at 3-month followup

	Percentage in Treatment Condition				
	Advice Only	Self-Help	Group Recruitment	Combination Treatment	p <
Recalled Advice To Quit	56.4%	57.8%	60.8%	60.0%	NS
A Serious Quit Attempt	39.0	50.2	44.8	46.3	0.001
No Cigarettes in 7 Days[a]	7.6	12.9	14.1	13.0	0.001
No Current Tobacco Use[a]	6.2	11.0	12.0	10.6	0.002

[a] *Survey nonrespondents counted as smokers.*

Patients were asked on the baseline questionnaire if they were seriously interested in quitting in the next 6 months. Logistic regression analyses indicated that those contemplating quitting prior to intervention were significantly more likely to quit than were precontemplators, i.e., those not considering quitting (odds ratio=2.82, 95-percent confidence interval=1.95-4.08). However, contrary to our predictions, contemplation status did not interact with any of the three nurse-assisted treatment conditions. This indicates that the nurse-assisted interventions enhanced cessation equally for precontemplators and contemplators alike.

Discussion

About 3 to 5 minutes of physician counseling is an effective stop-smoking intervention, but many physicians find it difficult to consistently spend this amount of time in counseling. Team intervention approaches involving physicians, nurses, and other clinic staff offer two important advantages over traditional physician-centered approaches. First, they shift the time-consuming components of the intervention to other staff and to videos, thus facilitating physician participation in training and implementation. In this way, the approach minimizes what has been a major barrier to widespread dissemination of clinic-based smoking interventions. Furthermore, this shift does not produce a large burden for the nurse. With an organized system of information collection, physician referral, and use of videos, nurses can deliver the intervention in approximately 2 to 3 minutes of additional time per smoker. Second, relative to brief physician advice alone, the additional attention, support, and cessation tools provided by the clinic-based smoking counselor significantly enhanced both quit attempts and successful short-term abstinence. Preliminary analyses of 1-year followup data suggest that these positive effects are being maintained.

This study was unique in that it tested both a self-quit intervention and an approach designed to recruit smokers into an intensive stop-smoking class of the type that normally only a small minority of smokers (< 2 percent) are willing to use (Epstein et al., 1989; Ockene, 1987a and 1987b). In this intent-to-treat design, the abstinence rate for the group-recruitment condition included all subjects randomized to this treatment, whether they elected to attend the intensive program or not. Though actual attendance was modest (11 percent), it was 10 times greater than that for the advice-alone (1 percent) condition. Combination-treatment subjects received all intervention components. They chose a mix of cessation strategies but did no better than self-quit and group-recruitment subjects. Because all three nurse-assisted approaches similarly boosted the quit rates over physician advice alone, the most economical approach would seem most attractive. Analyses of cost-effectiveness are currently under way, but it is probable that training patients to quit on their own will be the easiest and least expensive to implement in most settings. However, heavier smokers may do better if referred to intensive stop-smoking programs, and some referral lists should be available.

As would be expected, patients who were seriously contemplating quitting prior to intervention were more likely than precontemplators to be abstinent 3 months later. We also expected that the nurse-assisted interventions would be more effective for contemplators than for precontemplators. There was no evidence that treatment interacted with contemplation status, however, and the nurse-delivered components increased quit rates roughly 80 percent for both contemplators and precontemplators alike. Still, because precontemplators were much less likely to quit, it may be worthwhile to tailor the intervention to the patient's level of readiness and to focus limited intervention resources on those who are seriously considering quitting in the near future.

Special features of this intervention that appeared to work well included the clinic team concept and the brief physician message that was so essential in gaining physician cooperation and consistency. Although it would certainly be useful for physicians with time and interest to do more of the smoking counseling themselves, even a minimal 30-second advice and referral message can be effective if a nurse can carry through with brief counseling immediately after the visit. The videos were also well received by staff as they reduced the time needed to motivate and teach patients how to quit. It was not possible to determine the separate impact of the videos on quit rates, but by reducing staff burden they may increase the chances of success. Another key element was the face-to-face contact with a trained and supportive nurse who provided strong encouragement to set a specific quit date in the near future.

Some aspects of the intervention did not work well. Receptionists did not hand out the lifestyle questionnaires consistently, and some patients did not complete the instrument. A better approach would be to have the nurse simply ask for smoking status when placing the patient in the exam room. Very few patients called the heavily promoted stop-smoking telephone hotline (Glasgow et al., 1991a). Even fewer chose to attend the well-publicized single-session stop-smoking programs (i.e., one 90-minute class).

In replicating this approach, we would (1) eliminate the baseline survey and have nurses or physicians assess smoking status; (2) simplify the nurse intervention by dropping the carbon monoxide assessment; (3) have the nurse assess readiness to quit after showing the video; (4) tailor the nurse intervention to each patient's stage of change; and (5) see that smoking status is reassessed and that stage-appropriate followup counseling is repeated at every subsequent visit.

Intervention can be tailored to the patient's level of readiness to quit in a variety of ways. First, the video that all smokers see should contain different segments relevant to smokers at the precontemplation, contemplation, and action stages of change. After the video, patients who are ready to quit should be encouraged to set a specific quit date in the near future and review strategies for cessation in a stop-smoking manual. Arrangements should be

made for a followup call 1 or 2 days after the quit date. Patients who are contemplating quitting but who are not ready to set a quit date should be asked about their perceived barriers to cessation (e.g., fear of failure or weight gain) and should be encouraged to read relevant sections of a self-help manual. The staff should also express confidence in the patient's ability to quit and look for other ways to enhance self-efficacy. Contemplators can then be asked to consider the benefits of quitting between now and their next visit. We recommend that the counseling staff devote less time to precontemplators, who have little or no interest in quitting. There is little to be gained from lecturing such individuals. They should simply be encouraged to look over a manual and consider the benefits of quitting. The staff members should let these patients know that they are there to help when the patient decides the time is right.

Perhaps the most important findings to date are the attractiveness of this team approach to physicians and nurses and the relative ease with which it was implemented and maintained within a busy outpatient medical care delivery setting. After long-term effectiveness is confirmed, the effectiveness of nurse-assisted counseling within entire health plan populations will be evaluated and disseminated. This will require some additional training for nurses and a modest readjustment of their traditional role in outpatient settings. Fortunately, many nurses are eager to play a more active role in counseling patients about health-related behaviors and disease prevention. Though this study was conducted in an HMO, we believe a physician and nurse team approach to counseling smokers would be well suited to any medical office with personnel interested in seriously addressing the tobacco problem.

INTERVENTION WITH HOSPITAL PATIENTS

The most powerful smoking intervention strategy may be to identify situations in which smokers are most likely to quit on their own and then tailor interventions to take advantage of those teachable moments. Because patients' concerns about health are among the most frequently cited reasons for wanting to stop smoking (Pederson, 1982), interactions with health care providers provide some of the best opportunities for smoking intervention. In particular, health crises associated with hospitalization dramatically increase patients' concerns about smoking and provide a strong stimulus to stop. The purpose of the study reported here was to develop and evaluate a brief, inexpensive smoking cessation and relapse prevention program for hospitalized smokers.

Although relatively little is known about smoking cessation attempts and success among hospitalized patients, what is known is encouraging. Studies of patients with cardiovascular and pulmonary diseases (Daughton et al., 1980; Ockene et al., 1985) have produced relatively high but widely varying estimates of cessation rates, ranging from 20 to 51 percent among patients with pulmonary disease and from 22 to 62 percent among survivors of myocardial infarction (Burling et al., 1984; Ockene, 1987a). Outside of

these special population studies, there have been very few studies of smoking cessation in the general population of hospitalized patients.

Effects of Hospitalization on Smoking

In the Northwest Region of Kaiser Permanente, inpatient medical care is provided in two hospitals—the 220-bed Bess Kaiser Medical Center and the 236-bed Sunnyside Medical Center. A preliminary study that was conducted prior to implementation of a smoke-free hospital policy assessed the natural history of smoking cessation associated with hospitalization (Glasgow et al., 1991b). The purpose of the study was to determine the frequency of various cessation-related behaviors of patients during and after hospitalization and to identify variables associated with those behaviors. A heterogeneous sample of 526 HMO members who smoked prior to hospitalization and were hospitalized for nonterminal and not pregnancy-related conditions was surveyed 12 to 18 months later. Three events were studied: not smoking while hospitalized, attempting to quit after hospitalization, and smoking status 1 year after hospitalization. Similar factors were associated with not smoking in the hospital and quit attempts; for example, older persons and patients admitted with circulatory or respiratory problems were less likely to smoke in the hospital and more likely to try to quit. Self-reported abstinence from smoking for 1 month or longer at the time of follow-up included 16 percent of the former hospital patients. Overall, this initial study suggested that the hospital can be an effective setting for smoking cessation programs, especially those aimed at heavy smokers.

Survey of Hospitalized Smokers

Smoke-Free Hospitals

Both of the HMO's hospitals adopted a strict no-smoking policy in mid-1988. This policy prohibits smoking by staff, visitors, and patients inside the buildings. As a result, most hospitalized smokers do not smoke during their stay, although a few do leave their beds to smoke outside. This policy results in an enforced period of abstinence from smoking at a time when patients are highly motivated to take health-protective actions. Initial results from subjects hospitalized subsequent to the hospital smoking ban are consistent with the earlier results. Approximately the same proportion of patients (18 percent) reported cessation after the policy was in effect as did those hospitalized before the ban. These results and conclusions of reviews of other smoking interventions (Glasgow and Lichtenstein, 1987; Schwartz, 1987) suggest that a smoke-free policy, by itself, is unlikely to result in permanent cessation for many patients.

Although the smoke-free hospital setting may not increase long-term smoking cessation by itself, it does provide an opportunity to reach patients with stop-smoking advice, counseling, and support. Typically, the immediate effects of nicotine withdrawal are surprisingly mild when patients are hospitalized, possibly because of other medical, surgical, and pharmacological interventions; the unique environment; and the fact that patients may attribute their discomfort to other sources. In any case, a stay in a smoke-free hospital provides a period of not smoking, often the longest period of abstinence since the patient started to smoke, and thereby provides an excellent opportunity for

health care professionals to counsel patients in relapse prevention strategies (e.g., Curry et al., 1988; Marlatt and Gordon, 1985; Stevens and Hollis, 1989) before they return home.

Design and Intervention Methods

Study Design

The study was designed as a test of the efficacy of smoking cessation services provided to the general population of hospitalized smokers. Because of our interest in developing interventions applicable to the broadest possible population, we included virtually all of the nonobstetric adult patients, regardless of diagnosis or motivation to quit smoking. The only patients excluded were those whose hospital stay was less than 36 hours, postpartum patients, the terminally ill, and those who were hospitalized for alcoholism, drug abuse, or mental illness.

Smoking status and research consent were assessed by questionnaire at hospital admission. Those who reported smoking regularly any time during the preceding 3 months and who did not object to being contacted again in the next year were eligible for the study. To maximize the participation rate, the intervention was not mentioned in the explanatory portion of the initial questionnaire. Consent to participate in the intervention portion of the project was requested in person by the interventionist.

Randomization

Assignment of smokers to either the intervention condition or the usual-care control condition presented considerable logistic difficulties. Because most hospital rooms were doubles, simply randomly assigning patients to a condition might result in control participants' watching and listening to their roommates receiving the intervention. Therefore, randomization was accomplished by having the intervention team move back and forth between the two hospitals. During the first month, all research subjects in the first hospital received the smoking cessation intervention, whereas those in the second hospital received usual care. In the second month, the intervention team moved to the second hospital, and all of the participants in that hospital received the intervention while those in the first hospital received usual care. By alternating between the hospitals, the intervention team was able to minimize contamination between groups while dividing their efforts equally between the two hospitals. Subjects assigned to the control condition were not identified to the hospital staff or other health care providers and therefore received usual care. Usual care undoubtedly included advice to quit smoking in some cases.

While controlling for contamination between conditions, this research design had the disadvantage of not involving the nurses and other hospital staff members in the intervention effort. Our concern was that, once sensitized and trained in smoking cessation techniques, most hospital staff members would not be willing to limit their counseling efforts to intervention patients and not provide the smoking intervention to the control group patients. This conservative design provides a clean test of the effectiveness of the intervention without the addition of supportive efforts from nurses, an adjunct that would be expected to increase intervention effectiveness.

Intervention

Hospital-based intervention components included a bedside counseling session, a 12-minute videotape, an array of printed self-help material, chewing gum and other cigarette substitutes, and access to a free telephone advice service. Attempts were made to provide all of these components to each intervention patient, although logistic difficulties and patient requests sometimes interfered. After leaving the hospital, subjects received a 1-week followup call from the smoking counselor, a monthly series of followup mailings, and continued access to the telephone advice service. These intervention components are described below.

Experienced smoking counselors with master's degrees attempted to contact all intervention patients prior to their discharge from the hospital. Although some patients were seen in an intermediate care unit, most were seen in the general medical and surgical wards. Counseling began with asking the patients if they would be willing to talk to a smoking counselor. Only 4 percent declined to see the counselor. After obtaining consent, counselors assessed readiness to quit by asking patients whether they had smoked since entering the hospital and whether they planned to resume smoking after leaving the hospital. Because of the hospital smoking ban, only 20 percent reported leaving their beds to smoke (typically 1 to 2 cigarettes per day), and more than half of the intervention patients indicated a desire to remain nonsmokers after leaving the hospital. Patients were then asked if they would be willing to watch a 12-minute videotape produced for hospital patients. Those who agreed were shown the tape, but counselors had the option of not showing the tape if the patients were heavily drugged and likely to fall asleep while watching the tape. The videotape included discussion of advantages of quitting smoking during hospitalization, interviews with ex-smokers who stopped smoking as a result of hospitalization, advice about what to expect on returning home (for example, strong urges to smoke), and tips on how to deal with urges to smoke while in the hospital and after going home. Of the 78 percent of intervention subjects who saw a counselor, 44 percent viewed the videotape.

In addition to showing the videotape, the counselors spent about 15 minutes with each patient discussing smoking cessation methods. Patients who were not considering quitting (precontemplators) were urged to consider the hospital stay as a golden opportunity to quit. It was pointed out to patients that, in spite of their not having had much control over their health, one positive thing they could do was to plan to quit smoking.

Those who were already contemplating quitting were encouraged to consider themselves ex-smokers from this point on and to make a resolution to not smoke when they returned home. Those who had resolved to not start smoking again (recent quitters) were encouraged to anticipate upcoming difficult situations and to develop specific plans of action to deal with those situations. The focus of this part of the intervention was to carefully prepare for dealing with urges to smoke that were likely to occur after the return home.

At the end of the counseling session, the interventionist scheduled a followup phone call with the patient. The purpose of this call, made about 1 week after discharge, was to provide the patient with continued support and provide an opportunity for the counselor to give further advice regarding relapse prevention. A second call was attempted a few weeks later to all of those who reported not smoking 1 week after discharge.

Additional self-help materials and six issues of a bimonthly newsletter were mailed to participants after their discharge from the hospital. The purpose of the mailings was to reinforce the efforts of those who had stopped smoking and to trigger renewed efforts to quit for those who were still smoking. Newsletters included testimonials from those who had stopped smoking, tips on how to quit on your own, and phone numbers to call to obtain further self-help information. Each issue included a reminder that TRACC participants had access to a special 24-hour advice line.

Smoking Cessation Followup

All intervention and control participants were surveyed approximately 3 months after hospital admission. Those we were unable to contact between 60 and 120 days after hospitalization were considered lost to followup. The questionnaire response rate was excellent, with 49 percent returned by mail, 39 percent completed as an interview, 5 percent refused, and 6 percent lost to followup. Return rates did not differ between the intervention and control groups.

Results from the 3-month assessments of 1,114 patients are encouraging, with 13.6 percent of the control subjects and 20.4 percent of the intervention subjects reporting no smoking in the previous 7 days (χ^2=8.7, p=0.003), and 9.5 percent of the controls and 14.6 percent of the intervention subjects reporting no smoking for 2 months or more (χ^2=6.59, p=0.01). Subjects who refused assessment or were lost to followup were considered smokers. Table 22 presents the 3-month outcome data, by hospital.

Implementing a Hospital-Based Intervention

The essential elements of this intervention could be readily implemented by most acute-care hospitals. Probably the most important component of the intervention was the bedside counseling session. This portion of the intervention could be delivered by nurses, respiratory therapists, health educators, or other qualified staff after they received training in smoking cessation counseling techniques. Such training is now available in most American cities. Potential counselors will be much more effective with 30 to 40 hours of training. They will be most effective if they can quickly assess a patient's readiness to change, and if they have some experience dealing with denial, overconfidence and, most important, relapse prevention techniques. A skilled smoking counselor will be more effective than an inexperienced one in the hospital setting. This is in contrast to the outpatient setting, where minimal training and skills are sufficient.

The written self-help materials used in this project were obtained either directly from the National Cancer Institute, the American Lung Association,

Table 22
Participants from hospitals reporting no smoking for at least 7 days at 3-month followup

	Percentage in Each Treatment Condition		
	Usual Care	Intervention	p Value
Bess Kaiser Medical Center (n=601)	14.4%	21.1%	0.032
Sunnyside Medical Center (n=513)	13.4	21.0	0.022

and the American Cancer Society or adapted from materials obtained from those sources. New written materials are probably unnecessary, except for special populations for which there are no available materials.

The video developed for our program would be appropriate for the Pacific Northwest, but developing new videos for use outside this area, with regionally appropriate scenes and with local ex-smokers as role models, is recommended. Tapes for the current study were produced for about $1,000 per minute. Quality tapes can be produced for $500 to $1,500 per minute or less if other, prepared tapes are used as a source. The relatively low cost of modern videotape production allows for the customizing of materials for the intended audience. In the future, this research team hopes to expand the audience by using interactive videodiscs to assure that the models in each segment match the viewer in age, sex, and ethnic identity.

After hospital discharge, a followup phone call about 1 week later is an important relapse prevention tool. One week after leaving the hospital, most patients who stopped smoking in the hospital had not yet relapsed and reported that a followup call was helpful. Perhaps a call from a centralized source, that is, someone other than the original counselor, would be as helpful as it was in the outpatient study. As in the outpatient study, very few persons called the advice line, and unless such a telephone resource is available from local agencies at no cost, we do not recommend it as a prerequisite for the intervention. Followup mailings may have been of some help, but we have no way to evaluate their impact.

ST INTERVENTION FOR DENTAL PATIENTS

Although the proportion of the American population that smokes has been steadily declining over the past 25 years (US DHHS, 1986), consumption of chewing tobacco and moist snuff (smokeless tobacco, ST) has been increasing (Marcus et al., 1989). Although less research has been done on the health effects of smokeless tobacco, there is a clear association between ST use and oral cancer as well as cancer of

the esophagus, larynx, and stomach (US DHHS, 1986). The growing body of evidence about the harmful effects of smokeless tobacco has led to an increasing interest in intervention programs for ST users.

There have been few published reports of smokeless tobacco intervention effects. There are published reports of ST cessation programs with adolescents (Eakin et al., 1989) and adults (DiLorenzo et al., 1991) that have used smoking cessation methods with smokeless tobacco users in small-group treatment. The results of those interventions have been encouraging, but a more cost-effective program is needed to affect large numbers of ST users. The study described here evaluated routine dental clinic visits as an opportunity to intervene in the use of smokeless tobacco. Because a large proportion of the population receives some dental care annually (Cohen et al., 1989a) and because the oral health effects of ST use are often obvious during an oral examination, the dental office is an ideal setting in which to conduct an ST cessation program.

Building on the success of smoking cessation programs delivered in medical offices (Cohen et al., 1989b; Secker-Walker et al., 1987), the investigators developed an ST cessation program suitable for the dental care setting. The intervention program was designed for delivery by dental hygienists and dentists in the context of regular oral health care. The dental care providers used this opportunity to assess any oral health effects of each patient's use of smokeless tobacco and then give the patient unequivocal advice to stop. It was hypothesized that this is a time when ST users would be most receptive to advice to quit. A regularly scheduled oral health visit to the dentist could provide a unique teachable moment for counseling the ST user.

Survey of Dentists, Hygienists, and Patients

Prior to the project intervention, a survey was conducted to determine the receptivity of both patients and dental office staffs to ST interventions (Severson et al., 1990). Overall, 42 dentists, 44 hygienists, and 1,506 age-eligible male patients completed the survey. The survey of patients indicated that 4.7 percent used smokeless tobacco and 39.0 percent of the ST users were interested in receiving cessation advice. One-third of the ST users reported that they would consider such advice.

Dentists were more comfortable giving advice to ST users than to smokers. The relevance of chew and snuff to oral health is the most obvious explanation for this. Dentists and hygienists reported that they customarily discussed health hazards of ST use (77 percent) and sometimes advised smokeless tobacco users to quit or cut down (23 percent).

Results of the dental office survey were encouraging. Patients reported being receptive to cessation advice (41 percent) and, in fact, expect it from dental professionals. That receptivity to advice from dentists and hygienists is supported by data from in-depth interviews with smokeless tobacco users (Severson et al., 1990). Dentists and hygienists were interested in having

specific materials on smokeless tobacco and receiving training in giving cessation advice, and they felt more comfortable and effective in giving advice to ST users than to smokers.

Intervention Setting and Methods

Setting

This project was conducted in the Kaiser Permanente Dental Care Program, a prepaid, managed-care, group-practice, HMO program that currently provides comprehensive dental care to more than 160,000 members in the Pacific Northwest. The project was a randomized clinical trial in which patients were assigned to either usual care (control) or the smokeless tobacco intervention condition. Patients were identified as ST users via a tobacco use survey that they completed when coming for a routine dental hygiene visit. Emergency patients and those appearing for surgery or orthodontic care were excluded.

Intervention

When they arrived at the clinics, patients aged 15 or older were asked by the receptionist to complete a one-page questionnaire on tobacco use. Those who agreed to complete the survey and reported current use of smokeless tobacco became participants in the study. Eligibility was assessed by the clinic receptionists, who then assigned the patient to a usual-care or an intervention group. Although most patients complied with the request to complete the tobacco use survey, the member assistant (receptionist) often neglected to give out the survey, and approximately 60 percent of eligible members actually completed the questionnaire. Despite frequent prompts by the research project staff, most noncompletion was because of the receptionist's failure to pass out the survey instrument.

After completing the tobacco use survey, patients assigned to the control condition did not receive special attention from the dental clinic staff. No mention of their involvement in the study was made in the patients' dental care charts, and their status as ST users was not revealed to the hygienists and dentists. Depending on the individual practice habits of the dental care providers, patients receiving usual care may or may not have been advised to stop using tobacco. For patients assigned to the intervention condition, an envelope was put into each dental chart identifying them to the hygienist and dentist as ST users and intervention participants. The envelope included special data collection forms as well as self-help intervention materials.

Intervention activities were designed to fit comfortably into the usual routine of any dental office. Typically, the visits begin with the hygienist making a complete oral exam and then providing prophylactic treatment. This routine includes feedback on oral health status and advice on how to improve oral self-care procedures. When seeing an intervention patient, the hygienist recorded plaque and inflammation data on a special research data form and made a thorough examination of soft tissues, looking for keratotic lesions (leukoplakia). Although a soft tissue exam is routine, the research protocol called for a more detailed report of all lesions and their precise location in the mouth. The hygienist also asked the patient to show where

he kept tobacco in his mouth. After assessment and dental treatment, the hygienist gave the patient direct advice to quit using all tobacco products.

Routine clinic procedures call for the dentist to examine patients after they have seen the hygienist. The dentists also discussed keratotic lesions with patients, discussed the harmful effects of smokeless tobacco, and gave their own brief message to stop using tobacco. It was emphasized that care providers must deliver an unambiguous message to ST users: All tobacco products are harmful to health and they should stop now. This constituted the counseling component of the special intervention.

As part of the intervention, the patient was asked to view a 10-minute videotape at the end of the visit. The video produced for this project begins with a humorous segment designed to help the patient relax and includes an interview with a dentist discussing the health consequences of ST use. The video also includes a series of interviews with former users describing the benefits of quitting and the methods they used to quit. After viewing the video, the hygienist encouraged the patient to use a self-help booklet, "Enough Snuff," provided to them and to call a 24-hour advice line for further assistance. The hygienist also attempted to get the patient to set a specific quit date and noted whether he was willing to do so. At the end of this brief counseling session, the subject was given a quit kit containing chewing gum, toothpicks, a nontobacco mint-leaf tobacco substitute, and a set of tip sheets with advice on how to quit.

Followup Phone Calls

About a week after the dental clinic intervention, subjects were called by a project staff member to reinforce the clinic-based intervention activities and to offer further advice and support for quitting efforts. Additional support activities after the clinic visit included bimonthly mailings of tip sheets and a newsletter.

Followup Data Collection

To assess the effects of intervention, all intervention, control, and comparison-site participants were surveyed approximately 2 to 3 months after being seen at the dental office. Sixty days after entering the study, all subjects were sent a followup questionnaire about their tobacco use since their dental office visit. If they did not return the questionnaire within 14 days, they were sent a second copy, and if a questionnaire was not returned after another 14 days, they were called and asked to complete the questionnaire as a telephone interview. Those not contacted within 120 days after their dental visit were considered lost to followup.

Results

A total of 245 intervention subjects and 272 usual-care controls were recruited for the study. As expected, the use of smokeless tobacco was highest in the younger age groups (15- to 19-year-olds and 20- to 29-year-olds). The portion of ST users who did not also smoke was also highest in the youngest groups. Thirty-five percent of the chew-only group was in the 20 to 29 age range.

Acceptability of Intervention

The hygienists and dentists provided excellent cooperation in this study. Most were enthusiastic about delivering the intervention, and they failed to do so only on rare occasions. However, the clinic receptionists sometimes neglected to administer the tobacco use survey. The busy nature of the clinic and demands on staff time made the administration of a separate tobacco survey problematic. It is recommended that those implementing similar programs include smoking questions as part of a routine intake form or use other identification methods that do not make additional time demands on receptionists.

Somewhat surprisingly, the intervention was acceptable to the vast majority of patients. Fewer than 5 percent of the intervention subjects refused intervention completely, and an additional 10 percent refused to watch the video.

Three-Month Followup

The followup questionnaire response rate was excellent, with 47 percent returned by mail and 43 percent completed as telephone interviews. Of the remainder, 7 percent of the participants declined to complete the interview and 3 percent were lost to followup. The overall followup rate for the intervention group was 91 percent, and for the usual-care group 89 percent.

Self-reported abstinence from all tobacco use at 3 months included 22 percent of the intervention subjects and 14 percent of the control subjects. Table 23 shows a breakdown of tobacco use at 3 months according to tobacco use at baseline. The success of the intervention appears higher for patients who report using only smokeless tobacco at baseline (26 percent abstinent at followup) than for men who used both cigarettes and chew (12 percent abstinent at followup). This was true for both intervention and control subjects. Of additional interest is the fact that very few of the ST-only subjects reported cigarette use only at followup (1 percent and 4 percent for intervention and control subjects, respectively), so we have some confidence that quitting smokeless tobacco use did not prompt the use of cigarettes as an alternative.

Discussion

The 3-month followup data of the dental office intervention for smokeless tobacco cessation support the efficacy of the intervention. Twenty-two percent of the ST-using patients randomly assigned to the brief intervention reported they had quit the use of all tobacco, whereas only 14 percent of the usual-care subjects reported quitting. This significantly higher rate of self-reported quitting is strong support for the use of office visits for oral health care as teachable moments for advising patients to quit using smokeless tobacco.

The results of this study are similar to other tobacco-use interventions in outpatient settings that have also reported a significant effect of having dentists (Cohen et al., 1989a) and medical office staff provide direct advice to quit (Glynn, 1988). Glynn reports that most physician advice and minimal

Table 23
Three-month followup tobacco use, by baseline tobacco use

	Followup Tobacco Status										
	No Tobacco		Chew Only		Chew and Smoke		Smoke Only		No Followup		Total
	%	(n)	%	(n)	%	(n)	%	(n)	%	(n)	(n)
Intervention Participants, Baseline Use											
Chew only	26	(45)	57	(97)	3	(5)	1	(2)	12	(21)	170
Chew and smoke	12	(9)	12	(9)	27	(20)	32	(24)	17	(13)	75
Total	22	(54)	43	(106)	10	(25)	11	(26)	14	(34)	245
Control Participants, Baseline Use											
Chew only	17	(33)	67	(128)	3	(5)	4	(7)	9	(18)	191
Chew and smoke	6	(5)	19	(15)	46	(37)	17	(14)	12	(10)	81
Total	14	(38)	53	(143)	15	(42)	8	(21)	10	(28)	272

interventions offered in medical settings report average quit rates of 10 to 12 percent at 1 year. It is likely that the 3-month self-reported quit rates for smokeless tobacco will decline over the year as many patients relapse. However, even if 50 percent of the patients in both study conditions relapse between the 3-month and 1-year evaluations, the ST quit rates would still appear to be consistent with previous research using a 1-year biochemically confirmed quit assessment.

For the intervention group, men who reported using only smokeless tobacco reported a 25-percent quit rate, whereas men who reported at baseline that they used both cigarettes and chew had only a 17-percent quit rate. The two quit rates are significantly different ($p < 0.01$). It appears that men who use both cigarettes and smokeless tobacco find it more difficult to quit.

This intervention was implemented by the dentist and hygienist in the context of routine oral health care. Although the demands on receptionists should be minimized, dentists and hygienists reported that brief, direct advice to quit using smokeless tobacco fit well within the time allotted for the regular oral health exam. In practice, this intervention would require even less time, since the research protocol required extra data collection forms. Hygienists played the key role by pointing out the smokeless tobacco-related oral health effects to the patient, showing the video, providing a self-help manual, and encouraging the patient to set a quit date. This brief interaction was critical, and most of the patients were

willing to take the extra time to be briefly counseled. Dental hygienists were comfortable pointing out oral lesions and relating them to ST use but less comfortable in asking the patient to watch a video or providing counseling advice. The video viewing was sometimes a problem because of lack of privacy.

Previous studies have confirmed that smokeless tobacco users expect to receive a message to quit from their physician or dentist and are receptive to it. In a recent interview of ST users, 54 percent reported wanting to quit in the next year and 69 percent reported recent attempts to quit (Severson et al., 1990). Dentists and hygienists have an opportunity to advise users of smokeless tobacco to quit, and the context of an oral health care office visit provides a unique teachable moment in which the user may be most receptive to cessation advice. Although the long-term cessation rates are not yet known, these early results suggest that dentists and hygienists can have a significant impact on smokeless tobacco use and thus on public health.

SMOKING CESSATION AMONG ADOLESCENTS

Any comprehensive effort to reduce the prevalence of smoking among members of an HMO should include a program to prompt cessation among adolescents. Adolescence is the time when most smokers begin smoking. Many novice smokers are not yet addicted, so cessation could prove easier than it is for adults. Moreover, it would seem appropriate to have a program that is uniquely tailored to the needs and interests of adolescent smokers, rather than offering them the same program that is provided to adults.

Purpose and Target Group

On the other hand, the efficacy of a smoking cessation program for adolescents cannot be assumed. A number of programs that have been evaluated have not produced significant quitting among adolescents (Diguisto, personal communication, August 1990). Therefore, the authors developed and evaluated a smoking cessation program for adolescent members of Northwest Kaiser Permanente.

Methods

Intervention

The program was designed to provide continuing contacts with adolescent smokers in an effort to increase their willingness to quit, prompt them to make quit attempts, and provide skills and social reinforcement for quitting. The centerpiece of the program was an office visit with a nurse practitioner at a convenient Kaiser Permanente clinic.

Adolescents were invited to attend these visits during in-home assessments that were made in the course of a survey of adolescent health behavior. However, the majority of visits (70 percent) were actually scheduled through phone contacts. These recruitment methods were dictated by the need for experimental evaluation of the program. It is unlikely that they would be used by a clinic in normal circumstances. Rather, contact with adolescent smokers would most likely occur in the course of their coming to the clinic for treatment of other problems.

Sessions typically lasted 60 minutes. They began with a brief discussion of family history of cancer and the provision of information about breast self-exam to girls and testicular self-exam to boys. The family smoking history and the young person's smoking history and current behavior were then discussed. Reasons for quitting and barriers for quitting were discussed next. Most patients reported having tried quitting and failed.

Carbon monoxide testing was done initially, but it was later dropped because of the low CO levels resulting from the relatively low level of smoking by the young people (Biglan et al., 1985). Giving the adolescents feedback about their carbon monoxide levels thus tended to suggest that their smoking was not a problem.

A key component of the program was a videotape that was made especially for this program. It was designed to make smoking cessation seem like a popular option for teens and to provide information from attractive young people about how to quit. After the video, the nurse practitioner discussed its contents with the teenager and provided information about quitting. The discussion centered on the situations in which smoking occurred and the barriers to quitting. With light smokers, two questions that helped get at the need to quit were, "Do you have cravings?" and "When do you have your first cigarette?" These opened up discussion of getting hooked and the value of trying to quit. The adolescent was then given a "quit kit" that contained the same materials that were given to adults (a cinnamon stick, sugarless chewing gum, a rubber band, and a refrigerator magnet with the number of our quit-smoking hotline).

Most teens indicated a desire to quit smoking, and they were assisted in developing a plan for quitting. It included specific things to do in situations where smoking was most likely, a plan to talk to friends and family members who were likely to be helpful, and ideas for self-rewards for accomplishing small goals such as a day without cigarettes. In the initial work, an explicit quit date was elicited from each teen; however, very few actually quit on their quit date. The practice was subsequently discontinued, because failure to quit on the targeted date seemed likely to undermine commitments to the other features of the plan.

In an additional effort to reinforce quitting, a lottery was developed. Teens received chances for a $100 gift certificate. They had to be abstinent to win.

Followup phone calls were routinely made. The investigators tried to contact each adolescent 1 week after the office visit. This sometimes proved very difficult, because many teens were hard to reach by phone. In the event that young patients did not want to attempt to quit at the time of the office visit, they were asked if they could be called a month later. Repeated contacts by phone were common. They occurred over a period of 2 to 3 months and only when the adolescent expressed continued interest in quitting and in having phone contacts.

Experimental Evaluation

The evaluation of this program was designed to reveal whether the program reduced the prevalence of smoking among adolescents aged 14 to 17 whose families were members of Northwest Kaiser Permanente and who were identified as smokers at the outset of the program. For the assessment, 16,399 teens were sent a questionnaire on a variety of health habits. Of these teens, 8,126 returned the questionnaire. The 1,155 teens (14.2 percent) who reported having smoked a cigarette in the prior 7 days (as well as a small sample of nonsmoking comparison adolescents) were asked to participate in an extensive assessment of teen health that was conducted in their homes. Among the girls, 325 (46.0 percent) agreed to participate, whereas 168 boys (37.2 percent) agreed to participate. This difference was statistically significant.

In the home assessment, adolescents were asked about their smoking behavior and asked to provide samples of expired air CO (Biglan et al., 1985) and saliva, which were analyzed for cotinine (Jacob et al., 1981). They also answered extensive questions about their engagement in other forms of problem behavior. A parent—typically the mother—was also asked to complete a questionnaire about the adolescents' behavior, family interactions, and parental health behavior. Subjects completing the home assessment were randomly assigned to either a smoking cessation program or a no-treatment control group. There were 229 smokers and 61 nonsmokers in the cessation condition, and 257 smokers and 52 nonsmokers in the control condition.

These same home assessment procedures were repeated 12 months and approximately 18 months later. Data from the 1-year assessment are currently available.

Results

There was simply no evidence that the intervention program prompted the adolescents to stop smoking. Table 24 presents means and tests of differences between treatment and control subjects who reported smoking at the time of the screening questionnaire. The groups do not differ on any self-report or physiological measure of smoking behavior. The subjects in the treatment program reported more quit attempts, but the difference was only significant at p=0.06.

Can Adolescents Be Prompted To Quit?

Our results, thus far, cast doubt on the utility of smoking cessation programs for adolescents. It can, of course, be argued that a different program—perhaps one that involved more extensive contacts—could be successful. However, the nurse practitioners who conducted this program would point out that it was very difficult to achieve the small amount of contact that was achieved with these young people. An effort to increase contact might be very costly in practitioners' time.

It might also be argued that a program that worked only with those adolescents who volunteered that they wanted to quit might prove efficacious. However, our contacts with this sample of young people make us skeptical. Although most said they wanted to quit, when asked, it was extremely rare

Table 24
Effects of the program on adolescent smoking

	Treatment	Control	F	p
Variable				
Cigarettes in past month	194.83	228.24	0.02	0.89
Percentage who smoked in past 7 days	36.00	34.00	30.00	0.59
Percentage who smoked in last 30 days	27.00	25.00	3.00	0.87
Cigarettes in past 24 hours	6.02	7.11	0.00	0.98
Current smoking	6.59	6.98	2.31	0.13
Carbon monoxide	5.91	6.34	0.02	0.90
Cotinine	93.14	117.09	0.27	0.61
Index of smoking	-0.15	-0.08	0.04	0.96
Attempts to quit in past year	2.78	2.30	3.45	0.06

for a young person to contact us in response to our mailed advertising about the cessation program; most contacts were prompted by our phone calls or invitations delivered at the first home assessment.

Some hints as to why it is hard to get these young people to stop smoking are provided by analysis of the correlates of their smoking behavior. The multiple correlation between an index smoking behavior and measures of seven other problem behaviors (alcohol consumption, high-risk sexual behavior, poor grades, lack of prosocial behavior, antisocial behavior, use of illicit drugs other than marijuana, and use of marijuana) was 0.60, accounting for 36 percent of the variance in smoking. The multiple correlation predicting smoking from measures of five aspects of family interaction and six aspects of peer influence was also 0.60. Thus, cigarette smoking occurs in the context of many other problems and in the context of a problematic social environment. It may be impossible to excise this behavior from such a context. Instead, it may be necessary to develop programs that comprehensively address the social conditions that produce the above-mentioned problem behaviors.

It may be premature to conclude that programs focused solely on smoking cessation among adolescents will not work. However, given the evidence thus far, it seems probable that some radically different approach to prompting quitting among adolescents will be needed.

SUMMARY AND IMPLICATIONS The implementation and outcome data presented for the four TRACC interventions provide consistent support for the team approach. Not only was it possible to enlist clinic assistants, nurses, physicians, dental hygienists, dentists, and counselors to provide brief cessation advice and counseling augmented by written materials and videos, but also, once under way, the program received strong support from providers and

their staffs. Some receptionists found the patient screening, recruitment, and consent process burdensome, but these problems could be minimized or avoided in a nonresearch environment. With this exception, staff and providers found the "required" activities to be feasible and convenient. Providers had positive feelings about the interventions because they perceived that they were addressing an important, previously neglected health issue in a nonburdensome manner.

The data also consistently show that patients—who were being seen for typical medical or dental problems—both accepted and responded to the interventions. Most patients agreed to receive the interventions, and the short-term data for adult patients show significant treatment effects. Providers need not worry about patients' negative reactions to raising the smoking issue.

The three projects aimed at adult tobacco use all yielded significant reductions in tobacco use, indicating that the team approach is at least as effective as sometimes more intensive physician or dentist interventions (Cohen et al., 1989b; Cummings et al., 1989; Janz et al., 1987; Li et al., 1984; Ockene, 1987a; Wilson et al., 1988). One-year followup data are needed before assessment of the long-term impact of these interventions is made. The preliminary 1-year results are consistent with the data presented here.

The single, and unfortunate, exception is the failure of the trial intervention to affect adolescent tobacco use. Whether health care settings can affect adolescent tobacco use remains an open question. Certainly, adolescent motives for smoking and patterns of use (as well as adolescent health and psychology) suggest that interventions in the medical care setting are unlikely to have a major short-term impact on adolescent smoking. School and peer-group approaches are more promising.

The investigators are already moving toward institutionalizing the adult tobacco use interventions in outpatient and hospital settings by turning them over to provider staff, as was done originally in the dental clinic intervention. For example, nurses—again assisted by videos—can provide most of the outpatient intervention with respiratory therapists leading the inpatient program.

There is the potential for applying this team approach in many settings, including the private sector. Nurses are typically interested in expanding their treatment and educational responsibilities. Video interventions are feasible in many health care settings, and video materials can reduce the instructional burden on staff. The exciting potential of interactive video is being explored also. This new technology permits patients to select change strategies suitable to their particular needs and can even further reduce staff counseling time.

A key role remains for the physicians: They must initiate or sanction the introduction of the smoking issue. Moving the interventions out of a research context will permit better use of repeated prompts and messages, for example, outpatient followup of hospitalized patients.

The interventions all were enhanced by a sophisticated, computerized tracking system that triggered the delivery of telephone and mail prompts (and data collection). Other large health care systems would also have such systems available. They can also be conscripted to yield other information relevant to cancer control, such as that pertaining to cervical or breast screening.

The TRACC projects illustrate the potential for low-cost, population-based cancer control interventions that exploit the teachable moments in medical settings. The keys to successful implementation and maintenance included promoting change at the organization or system level, applying available technology (computerized tracking, tailored videos), and using support staff to assist primary care providers in counseling patients. This approach appealed to providers and patients, and it overcame many of the barriers to implementation of cessation advice in medical settings.

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APPENDIX A
Screening Form for Study on Assessing Patient's Health Risks

Date _____

Subject No. _____

The health center thanks you for considering being in our study.

We are assessing health risks to patients in our practice. If you decide to enter the study, you will benefit by having your physician discuss one of your risks in depth and provide you with free health information.

Before you decide whether to enter our study, we would like you to answer the following questions to determine whether you are eligible for the study.

1. Your age: _____
2. Your sex: male female (please circle one)
3. Do you exercise regularly? Yes No
4. Do you smoke cigarettes daily? Yes No
5. Do you consider yourself overweight? Yes No
6. Do you use safety belts regularly? Yes No
7. Do you drink alcohol? Yes No

Please return this screening form to the practice research coordinator to determine if you are eligible for the study. The coordinator will inform you of your eligibility and provide you with further information if you are interested.

APPENDIX B
Study on Physician Advice for Smoking Cessation

You are invited to be in a study on physician advice about smoking. The study only requires you to stay a few minutes longer so your physician can talk to you about smoking. In addition, based on chance, you may receive a prescription for nicotine gum. A follow-up visit to further discuss smoking will be offered to you. You and a spouse or friend will be asked to fill out a one-page questionnaire 2 weeks and 6 months from now. If at 6 months you are not smoking, you will be asked to return to the clinic to give a breath sample. For this inconvenience you will receive $10.

The only risk of this study will be possible withdrawal symptoms and side effects from nicotine gum. Serious side effects from the gum are rare. Minor side effects such as irritated throat, nausea, upset stomach, hiccups, jaw ache, and dependence on the gum occur in less than 25 percent of smokers. These side effects can be controlled by how vigorously you chew the gum.

Although we can foresee no significant risk for this research, in the event that this research activity results in a physical injury, medical treatment will be available, including first aid, emergency treatment, and followup care [as] needed. Payment for any such treatment must be provided by you and your third-party payor, if any (such as health insurance, Medicare, and so forth).

If you should decide not to participate, or to withdraw from this study, your decision will not prejudice your future medical care.

If you have any questions about this study, please contact Dr. William Wadland at the University of Vermont [phone number]. You may contact Caryn Gronvold at the University of Vermont [room number, phone number] for more information about your rights as a research subject or for more information about how to proceed should you believe that you have been injured as a result of your participation in this study.

— —

You are making a decision whether or not to participate. Your signature indicates that you have read the information provided and have decided to participate.

_____ _____

signature date

_____

signature of research coordinator

APPENDIX C
Entry Questionnaire

Entry Date _____
Subject No. _____

1. Give the full name of your cigarettes:

   _____

   Check the blanks which describe your cigarette:

   Filtered _____
   King Size _____
   120mm _____
   100mm _____
   85mm _____
   Regular _____
   Menthol _____
   Hard pack _____
   Lights _____
   Ultralights _____

2. The average number of cigarettes you smoke per day _____ (only one number please).
3. Your age when you started smoking on a regular basis. _____
4. Do you use cigars, pipes, or smokeless tobacco?

   ___ Yes ____ No

5. Do you inhale? Always Sometimes Never (circle one)
6. Do you smoke more during the morning than during the rest of the day?

   ___ Yes ____ No

7. How soon after you wake up do you smoke your first cigarette? _____ minutes _____ hours
8. Which cigarette would you hate to give up? _____
9. Do you find it difficult to refrain from smoking in places where it is forbidden, e.g., in church, at the library, cinema, etc.? Yes ____ No ____
10. Do you smoke if you are so ill that you are in bed most of the day? Yes ____ No ____
11. Circle the highest grade you have completed:

    0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 16+

12. What is your major present occupation? (Describe fully, including student, housewife, unemployed, or retired. Also describe your business as small, medium, or large.)

    _____

13. Are you married? Yes ____ No ____
14. Does insurance pay for any part of your prescriptions?

    ___ Yes ____ No
15. How many of the people who live with you smoke cigarettes? _____
16. For the purposes of the study, we need to know your total family yearly income. (This will be kept confidential.)

    Less than $15,000 ____

    $15,000 to $29,000 ____

    $30,000 to $44,999 ____

    More than $45,000 ____
17. Most people have mixed feelings for and against their smoking, with a part of them wanting to stop and a part of them wanting to go on smoking.

    a. How much would you say that you want to *stop* smoking?

    _____ not at all _____ a little _____ some _____ a lot _____ don't know

    b. And how much does a part of you want to *go on* smoking?

    _____ not at all _____ a little _____ some _____ a lot _____ don't know
18. Do you intend to quit smoking in the next month or so?

    ___ definitely not ___ probably not ___ possibly ___ probably ___ definitely ___ don't know
19. If you decided to give up smoking within the next month, do you think you would succeed?

    ___ definitely not ___ probably not ___ possibly ___ probably ___ definitely ___ don't know

We need to collect identification data from you so that we can find you 6 months from now:

20. What is your full name? _____
21. Give your full home address.

    Street: _____

    City, Zip: _____

    Phone: _____
22. Give your work address.

    Company: _____

    Immediate supervisor: _____

    Street: _____

    City, Zip: _____

    Phone: _____

23. Give name and address of spouse/friend who can act as your observer. This person will verify your smoking status.

    Name: _____

    Street: _____

    City, Zip: _____

    Phone: _____

APPENDIX D
Medical Screening Form

Name _____

Subject No. _____

Date _____

Physician _____

Heart attack in the last 6 months	Yes	No
Irregular heart or arrhythmia	Yes	No
Active temporomandibular joint disease	Yes	No
Worsening or unstable angina	Yes	No
Pregnant or planning to be	Yes	No
Breast-feeding	Yes	No
Able to chew gum	Yes	No

Other _____

OK for patient to be on nicotine gum:

_____

Physician's signature

APPENDIX E
Generic Reminder Sheet

1. Ask if ever thought about quitting and reason. If none, volunteer one.
2. State reversibility of symptom (2 weeks), disease (1 year), or risk (10 years).
3. Recommend cessation (use word "I").
4. Describe "Quit and Win":
    a. It's for habit part of smoking.
    b. Tips from successful ex-smokers.
    c. Use as menu. Choose 3 to 5 strategies that are do-able.
5. Open assignment envelope.

APPENDIX F
Reminder Sheet for Gum Group

6. Instructions on gum.

   Give rationale: to decrease withdrawal.

   It works.

   Stop smoking abruptly.

   Chew PRN early in craving.

   Chew slowly to control side effects. Side effects decrease in first week.

   Use till no craving, and then decrease gradually.

   Biggest mistakes: use too little for too short a time.

   Keep gum with you.

   Read booklet.

   The Rx is good for 6 months in case you decide to quit later.

7. Ask for questions.
8. Ask for commitment to quit.
9. Ask for quit date.
10. Offer followup by appointment or phone.

APPENDIX G
Reminder Sheet for No-Gum Group

6. Ask biggest fear:
    a. Generic responses
        Withdrawal symptoms are transient.
        Distract yourself by keeping busy.
        Decrease demands on yourself.
        Avoid tempting situations for a while.
        Use time-outs or remember reason for cessation for urges.
        Increase activity (not necessarily exercise).
        Read booklet.
    b. Specific responses for weight:
        Weight gain doesn't necessarily occur or last.
        To counteract loss of anorectic and oral behavior, watch snacks and sweets but don't change meal sizes.
        To counteract decreased BMR, increase activity.
7. Ask for questions.
8. Ask for commitment to quit.
9. Ask for quit date.
10. Offer followup by appointment or phone.

APPENDIX H
Physician Data: Initial Visit

Subject No. _____

Date _____

Physician _____

Did you obtain a commitment to quit? Yes No

Did you obtain a quit date? Yes No

If so, what is the date? _____ _____ _____
Month Day Year

APPENDIX I
Exit Questionnaire #1
(All Patients)

Subject No. _____

Did your physician:

1. Ask you a reason to stop smoking?

   _____ Yes _____ No

2. Tell you that the effects of smoking are reversible?

   _____ Yes _____ No

3. Tell you about the booklet to aid the habit part of smoking cessation?

   _____ Yes _____ No

4. Ask you to try to quit?

   _____ Yes _____ No

5. Ask you for a quit date?

   _____ Yes _____ No

6. Offer to see you 1 to 2 weeks after your quit date?

   _____ Yes _____ No

Please answer the following questions. Some are the same questions you answered prior to receiving physician's advice.

7. Most people have mixed feelings for and against their smoking, with a part of them wanting to stop and a part of them wanting to go on smoking.

   a. How much would you say that you want to *stop* smoking?

      ____ not at all ____ a little ____ some ____ a lot ____ don't know

   b. And how much does a part of you want to *go on* smoking?

      ____ not at all ____ a little ____ some ____ a lot ____ don't know

8. Do you intend to quit smoking in the next month or so?

   ___ definitely not ___ probably not ___ possibly ___ probably ___ definitely ___ don't know

9. If you decided to give up smoking within the next month, do you think you would succeed?

   ___ definitely not ___ probably not ___ possibly ___ probably ___ definitely ___ don't know

10. Rate how much your physician convinced you to stop smoking.

    0=Not at all

    1=A little

    2=Somewhat

    3=Very much

11. Rate how confident your physician was in giving you advice to stop smoking.

    0=Not at all

    1=A little

    2=Somewhat

    3=Very much

APPENDIX J
Exit Questionnaire #2
(No-Gum Group)

Subject No. _____

Did your physician:

1. Ask your biggest fear about cessation?
   ____ Yes ____ No
2. Give you a way to combat your feared problem with cessation?
   ____ Yes ____ No

APPENDIX K
Exit Questionnaire #3
(Nicotine Gum Group)

Subject No. _____

Did your physician:

1. Tell you about nicotine gum to aid the withdrawal part of smoking cessation?

   ____ Yes ____ No

2. Tell you that if you use the gum you should:

   Stop abruptly?

   ____ Yes ____ No

   Use the gum when you have an urge for a cigarette?

   ____ Yes ____ No

   Chew the gum slowly to avoid side effects?

   ____ Yes ____ No

   Chew the gum till you have no craving for cigarettes, and then taper off the gum?

   ____ Yes ____ No

   Read a booklet about the gum when you get it at the pharmacy?

   ____ Yes ____ No

APPENDIX L
One- to Two-Week Followup for Smoking Cessation Study

Subject No. _____

Date _____

Please fill out this form and return in the self-addressed envelope as soon as possible. If we do not receive the form within 1 week, we will need to call you at home.

1. Have you tried to stop smoking since you entered the study?

   ____ Yes ____ No

   IF YES, ANSWER QUESTIONS 2-6.

   IF NO, YOU ARE FINISHED. THANK YOU.

2. How many times have you tried to stop since you entered the study? _____

3. When was the first time you tried to stop after seeing your physician?

_____	_____	_____
Month	Date	Year
(1-12)	(1-31)	(19--)

4. Are you smoking cigarettes now? ____ Yes ____ No

5. Rate how helpful your physician's advice was in stopping smoking.

0	1	2	3
not at all	somewhat	moderately helpful	most helpful

6. Rate how helpful the "Quit and Win" booklet was in stopping smoking.

0	1	2	3
not at all	somewhat	moderately helpful	most helpful

APPENDIX M
Six-Month Followup for Smoking Cessation Study

Subject No. _____

Date _____

Please fill out this form and return in the self-addressed envelope as soon as possible. If we do not receive the form within 1 week, we will need to call you at home.

1. Have you tried to stop smoking since you entered the study?

   ____ Yes ____ No

   IF YES, ANSWER QUESTIONS 2-4.

   IF NO, YOU ARE FINISHED. THANK YOU.

2. How many times have you tried to stop since you entered the study? ____

   2a. When was the first time you tried to quit after you entered the study?

_____	_____	_____
Month	Date	Year
(1-12)	(1-31)	(19--)

3. Are you smoking now? ____ Yes ____ No

   3a. If you are not smoking, when did you last have a cigarette?

_____	_____	_____
Month	Date	Year
(1-12)	(1-31)	(19--)

4. Are you using cigars, a pipe, or smokeless tobacco?

   ____ Yes ____ No

APPENDIX N
Followup Questionnaire on the Use of Nicotine Gum

Subject No. _____

Date _____

You received a prescription for nicotine gum from your physician. Please answer the following questions and return in the self-addressed envelope.

1. Did you fill the prescription?

   ____ Yes ____ No

2. Rate how helpful you found the nicotine gum in quitting smoking:

0	1	2	3	4
not at all	somewhat	moderately	most helpful	didn't use

If you answered yes to question #1, please complete the following questions.

Please name the pharmacy that you used to obtain nicotine gum.

_____
(pharmacy name)

_____

_____
(address of pharmacy)

_____
(telephone of pharmacy)

We will contact your pharmacy to verify your use of the nicotine gum. We appreciate your assistance.

THANK YOU.