Enhancing Smoking Cessation Rates in Primary Care

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BACKGROUND. The Agency for Health Care Policy and Research (AHCPR) guidelines on smoking cessation recommend that primary care physicians provide both brief advice against smoking and follow-up care for all smokers. Surveys show that although physicians understand the importance of smoking cessation, the actual implementation of these guidelines is limited. The main objective of our study was to evaluate the comparative effectiveness of 2 different approaches to smoking cessation counseling: practice-based and community-based.

METHODS. Both smoking cessation approaches consisted of 1 recruitment session and 6 computer-assisted counseling sessions. In the practice-based approach, counseling was provided by office nurses and telephone counselors; in the community-based approach, the counseling was given by telephone counselors only. Four practices in 3 mid-Michigan communities participated, including 120 physicians and 487 patients who were smokers. The physicians were trained to provide brief advice for smoking cessation consistent with the AHCPR guidelines; the nurses and telephone counselors were trained in relapse prevention, computer skills, and individual case management. Sixty-two percent of the participants obtained free nicotine replacement therapy.

RESULTS. At 6 months, quit rates (7-day smoke-free status) were 35% in the practice-based group and 36% in the community-based group. Participants who completed at least 4 sessions showed higher quit rates than those who did not.

CONCLUSIONS. Nurses in primary care practices and counselors can be trained to deliver effective relapse-prevention counseling during office visits and by telephone. Our study showed an increase in the reported rates of smoking cessation by using these counseling methods.

KEY WORDS. Smoking cessation; primary health care; counseling. *(J Fam Pract 1999; 48:711-718)*

The efficacy of brief advice by the primary care physician for smoking cessation was first documented by Russell and colleagues in 1973.[1] Since then, the Agency for Health Care Policy and Research (AHCPR) has published clinical practice guidelines that reiterate the importance of brief advice by the primary care physician.[2] According to these guidelines, clinicians are to identify all smokers, advise them to quit smoking, assist those who are ready to quit, and arrange follow-up care.[2] Pharmacotherapies for smoking cessation have further enhanced the role of the primary care physician in smoking cessation.[3-8] The act of prescribing these medications and discussing their usefulness with patients provides additional opportunities for smoking cessation counseling in primary care. Questions remain concerning the intensity of the counseling that can be realistically offered in primary care practice settings and its effectiveness when compared with community-wide support services offered by telephone. Developing effective and accessible smoking cessation programs is an immediate challenge for many health systems and managed care organizations.

Brief advice on smoking cessation from the physician alone results in long-term quit rates of less than 10%.[1] When the physician's advice is supplemented with nicotine replacement therapies, especially higher-dose nicotine gum and transdermal nicotine in randomized controlled settings, long-term quit rates are increased to 15% to 25%.[9-11] The long-term quit rates are lower in community-based studies relying on general volunteers than in strictly controlled trials.[12] In primary medical practices, smokers are mostly advised or persuaded by physicians and care providers to quit smoking with varying degrees of arranged follow-up care. Surveys of primary care physicians have shown that although physicians understand the importance of smoking cessation and espouse its value, the actual implementation of guidelines in practice is quite limited.[13,14] Finally, the expectation of systematic follow-up care as advocated

Submitted, revised, May 26, 1999.
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by the AHCPR guidelines cannot be easily accommodated in most primary care practices, as long as counseling for smoking cessation is not reimbursed.[15]

Behavioral therapies, delivered mostly in groups and supplemented with nicotine replacement, have received some of the highest reported long-term success rates (35% to 40%) for smoking cessation.[16,17] However, it is reported that less than 5% of smokers will accept a referral and actually attend group sessions.[2,18] Busy clinics cannot provide group therapy for the large number of smokers in primary care. Behavioral specialists are often not widely available to deliver these treatments. Accessibility and availability are major barriers to group therapies for smoking cessation, which remain as secondary care services funded by hospitals or employers, or out of pocket by the participants.

The feasibility and effectiveness of incorporating cognitive behavioral methods to enhance smoking cessation in primary care needs evaluation. Primary care smoking cessation services should be available at the patient's first visit and should be easily accessible through medical practices or by a community telephone service. Since more than 80% of smokers in primary care who attempt to quit relapse, preventing and coping with relapse seem to be the most important features of cognitive behavioral therapies for primary medical care.[19,20] Several reports have shown that nurses can be trained to provide office-based smoking cessation counseling to improve the accessibility of this service.[21,22] Several telephone support counseling services offering proactive follow-up with scheduled sessions have achieved long-term success rates from 25% to 30%.[23-28] Telephone counseling is most effective if it includes multiple proactive sessions with personalized relapse prevention.[26]

Interventions must be offered with and without pharmacotherapy, fit easily into the daily routines of primary care practice, and be reasonably affordable. Several questions result from these previous studies. Can office nurses be trained to provide personalized relapse prevention as provided by behavioral counselors? Is there a higher success rate if counseling originates in the practice by the physician and office nurses than with self-referral to telephone counseling alone?

We conducted a demonstration project that evaluated the feasibility and effectiveness of offering relapse prevention counseling for smoking cessation in primary care. Our main objective was to evaluate the comparative effectiveness of 2 approaches to smoking cessation counseling. Both approaches used computer-prompted relapse prevention, but in one approach counseling was provided by both office nurses and telephone counselors; in the other, counseling was provided by telephone counselors alone. Secondary objectives were to evaluate the feasibility of training nursing staff and lay counselors in computer-prompted relapse prevention counseling, and to study the ease of integrating protocols into the daily routine of busy medical practices.

METHODS

Study Sites and Recruitment

For the practice-based intervention, subjects were consecutively recruited during the study period (March 24 through August 1, 1997) from 4 model family practice centers affiliated with the Department of Family Practice at Michigan State University. Two sites (St. Lawrence and Sparrow Family Practice) were located in Lansing, Michigan. One site (Genesys Family Practice) was located in Flint, Michigan, and the last (Saginaw Family Practice) was located in Saginaw, Michigan. Each site has approximately 15,000 active patients on record and provides care to unrestricted populations including 40% to 50% low-income and Medicaid patients. The practices function as models to prepare resident physicians for community practice. More than 40% of the patients in these practices are covered by managed care insurance. Each practice received $1000 to minimally cover the costs of training and nurse counseling time during the study.

The majority of care (60% to 70%) at these practices is provided by faculty physicians who are paid at a rate consistent with that of private community practice physicians. Smokers were invited to participate in our study during their usual office visits with their providers. If interested, they were referred to the nurse counselor for intake and informed consent.

For the community-based intervention, subjects were consecutively recruited through newspaper advertisements and public service announcements in the same mid-Michigan communities where the practices were located. These communities (Lansing, Flint, and Saginaw) are located within 1 to 2 hours of one another and are similar in population size (600,000 to 700,000 people), ethnic diversity, and industrial employment. Study participants called a telephone hotline and then began the intake and treatment sessions.

The only exclusion criteria for participants in each study group were age less than 18 years and an unwillingness to commit to quit smoking within 30 days. It was hoped that participants would mirror the population of smokers who are currently using over-the-counter medications. Participants were informed at the onset of the availability of free nicotine replacement therapies. The informed consent process focused on the need for verified long-term follow-up at the end of the study. Participants were offered $20 for each home visit to verify self-reported smoke-free status by carbon monoxide monitoring.

Two pharmacies in each community dispensed supplies of nicotine replacement therapies (21-mg nicotine patch for 6 weeks, 14 mg patch for 2 weeks, and 7-mg patch for 2 weeks; or 2 or 4 mg nicotine gum for 10 to 12 weeks) at no cost to participants. The pharmacies were paid a minimal incentive of $5 per participant visit. Physicians, nurses, and telephone counselors advocated the use of nicotine replacement therapy as an adjunct to

the behavioral treatment and provided vouchers to interested patients either at the practices or by mail. The decision to use nicotine replacement was made by the participants after reading the package inserts at the pharmacy.

TRAINING

A total of 40 faculty physicians and 80 resident physicians were trained to provide brief advice for smoking cessation consistent with the AHCPR guidelines.[2] Physician training consisted of a 2-hour update session on the AHCPR guidelines, an overview of our study, and role playing. Physicians received continuing medical education credit for participating. Twelve nurses (2 or 3 per practice) and 14 telephone counselors were trained in computer-assisted relapse-prevention counseling. Nurse and telephone counselor training consisted of 3 2-hour sessions on relapse prevention, computer skills, and individual case management. Nurses and counselors were encouraged to practice between sessions with case examples. Their intervention skills were evaluated before the counseling of any study participants. Graduate students monitored protocol compliance of nurse counseling throughout the study by performing audiotape reviews. The computer program also provided an ongoing record of counseling time and accuracy of data collection.

COUNSELING INTERVENTION

The intervention consisted of one recruitment/intake session and 6 treatment sessions, either during an office visit or by telephone. Table 1 lists the method used in each session. During the intake session (session 0) we explained the study program, obtained informed consent, set a date for smoking cessation within the next 30 days, offered free nicotine replacement gum or patch, recorded baseline demographic data, and arranged follow-up sessions. The informed consent process was approved by the institutional review boards of Michigan State University and the participating community hospital systems. All enrolled participants received the booklet called *Clearing the Air* (National Cancer Institute publication no. 95-1647) and a diary the size of a cigarette pack with suggestions for coping responses. The intake session lasted approximately 45 minutes. The sequence of follow-up sessions was determined according to the quit date: session 1 was scheduled for 1 day after the quit date; session 2, 3 days; session 3, 7 days; session 4, 14 days; session 5, 30 days; and session 6, 60 days. Follow-up sessions lasted approximately 15 to 20 minutes. This sequence of follow-up sessions is consistent with other studies and usual relapse patterns after attempting to quit smoking.[24,29]

The computer software program *I'd Rather Cope Than Smoke* was developed to assist compliance with the relapse prevention program. The relapse prevention methods were pilot tested in both group therapy and face-to-face nurse-delivered care before their use in our study. The computer program prompts counselors to ask smokers about relapse situations and assists in developing personalized coping strategies. The program lists more than 70 relapse situations and 90 coping responses.[30]

For the practice-based intervention, the role of the physician was limited to identification of smokers, assessment of the level of addiction, an offer of brief advice, and referral of interested smokers to the treatment program. The first 3 treatment sessions were performed by trained office nurses who used the software on a laptop computer for counseling prompts and record keeping. These sessions were scheduled into the office routine and provided face-to-face counseling. Practice-based intake and follow-up data were electronically transferred to a computer network at Michigan State University in East Lansing, Michigan, where trained telephone counselors continued the personalized relapse prevention counseling for sessions 4 to 6.

For the community-based intervention, all sessions were conducted by telephone with participants who responded to advertisements in local newspapers and public service announcements. Both practice-based and community-based participants were offered vouchers for free nicotine replacement therapy.

INDEPENDENT VARIABLES

Participants for both groups were evaluated for standard demographic characteristics of age, sex, socioeconomic

TABLE 1

Frequency of Sessions and Intervention Method Used at Each Session

Session	No. of Days After Quit Date	Intervention	
		Practice-Based Group	Community-Based Group
0 (Recruitment/Intake)		Visit	Call
1	1	Visit	Call
2	3	Visit	Call
3	7	Visit	Call
4	14	Call	Call
5	30	Call	Call
6	60	Call	Call
180-day follow-up	180	Call	Call

Note: Session sequence consistent with Zhu and colleagues.[24]

status, and education level. Baseline smoking activity was evaluated on the basis of the number of cigarettes smoked per day, the number of years the participant has been a smoker, the mini–Fagerstrom Tolerance Questionnaire (FTQ),[31] household smoking activity, and confidence in his or her ability to quit. Insurance coverage assessment included Medicaid, managed care, and indemnity plans. Personal patterns of relapse triggers and coping strategies were recorded for each participant.

Main Outcome

The key outcome measure was self-reported 7-day smoke-free status at a 6-month telephone follow-up. Multiple attempts were made to contact participants, regardless of the level of participation at 6 months. Because the primary intervention involved attending to lapses and recycling relapses, it was decided that a point-prevalence measure at 6 months fit the study intervention better than continuous abstinence starting from the quit date. Participants reporting 7-day smoke-free status at 6 months were invited to have carbon monoxide verification at their convenience.

Secondary Outcomes

We calculated the total number of smoke-free days per participant in each treatment group at 6 months, and monitored the number of treatment sessions per participant. We also monitored nurse compliance with treatment protocols. Physician, nurse, and counselor satisfaction with the program was evaluated by focus group methods after the study period. Smoker participant satisfaction was evaluated by standardized questions at the 3-month telephone follow-up. Nicotine replacement use was assessed at each session and at 6 months.

Evaluation

Comparisons of study group characteristics were made using standard statistical measures. Categorical variables were tested using the chi-square test for contingency tables and the *t* test for continuous variables. Several continuous variables were categorized and analyzed by both methods.

Prevalence smoking quit rates were calculated using 2 approaches for denominator definition. Denominator 1 was adjusted for lack of follow-up as in community-based studies.[12] By this method, participants were not included in the denominator if they were lost to follow-up because they: had disconnected phones; moved out of the region and could not be contacted; were unable to respond because of severe illness, such as stroke, or were on life support; gave incorrect telephone numbers; or could not be reached after 6 attempted phone calls. Denominator 2 was developed on the basis of intention-to-treat assignment as in randomized controlled trials.[32] For both methods, participants who refused follow-up, failed to call back, gave incorrect contact numbers, or dropped out were counted as smokers.

Smoking quit rates at 6-month follow-ups were compared using the z score for equality of proportions. Logistic regression was used to compare the smoking quit rates between the 2 groups, after adjusting for demographic variables, such as work status, insurance coverage, incomes, sex, and degree of education.[33] To assess the effect of the number of sessions completed on smoking quit rates, both partitioning of chi-square and logistic regression approaches were used.[34] The number of sessions completed was dichotomized at 3, and quit rates for those who completed 3 or fewer sessions were compared with those who completed 4 or more sessions.

RESULTS

Demographic Comparison of Study Groups

Most of the combined study population was white (81%), women (70%), married (49 %), employed (89%), educated to at least grade 12 (82%), nicotine dependent (mean Fagerstrom = 6.54; standard deviation [SD] = 2.52), and showed a confidence in quitting (mean = 7.38; SD = 2.13 on a scale of 1-10). Table 2 describes the smoking and insurance coverage characteristics of the participants. The 2 groups differed significantly ($P < .05$) on the following characteristics: income below $10,000 (practice-based group, 36%; community-based group, 22%); Medicaid coverage (practice-based group, 57%; community-based group, 22%); managed care coverage (practice-based group, 47%; community-based group, 32%); mean years of education (practice-based group, 12.54 years; community-based group, 13.19 years); and nicotine replacement use (practice-based group, 75%; community-based group, 64%).

Recruitment Rate

Because of time constraints, only 1 site (Flint) tracked full recruitment. For this site, 37% of all identified smokers agreed to a referral by their physician to the trained office nurse for counseling. After intake discussion with the nurse, 50% of the referred group (or 18% of all smokers identified) participated in the study.

Smoke-Free Status

The 7-day smoke-free quit rates for 6 months comparing practice-based and community-based groups (using the Denominator 1 calculation consistent with community-based trials) were 35% and 36% for practice-based and community-based groups, respectively. Quit rates adjusted for demographic variables, confidence in ability to quit, and number of sessions completed did not change the conclusions. There was no statistically significant difference between community-based and practice groups at 6 months (odds ratio [OR] = 1.05; $P = .83$). When using the Denominator 2 criteria of controlled randomized trials, the quit rates also did not differ significantly between the groups at 6 months (22% vs 26%, respectively). The

TABLE 2

Smoking and Insurance Coverage Characteristics of Study Participants

Characteristic	Overall (N = 487)	Practice-Based Group (N = 168)	Practice-Based Group (N = 319)	P
Fagerström dependence score*	6.59	6.96	6.32	>.60
Confidence in quitting	7.34	7.19	7.48	
Nicotine replacement use, no. (%)				
Yes	330	125 (74)	205 (64)	<.008
No	157	43 (26)	114 (36)	
Medicaid, no. (%)				
Yes	153	84 (57)	69 (22)	<.000
No	334	84 (50)	250 (78)	
Managed care, no. (%)				
Yes	307	63 (38)	244 (76)	>.004
No	180	105 (63)	75 (24)	

*Score is given as a mean.

respective OR from logistic regression at 6 months was 1.06 ($P = .83$). Carbon monoxide verification was obtained in 51% (61 of 120) of the participants who reported smoking cessation by 6 months. Carbon monoxide levels of less than 10 ppm, which was a cutoff point for nonsmokers, were verified in 93% (57 of 61) of these participants, which is consistent with studies of self-reported quit rates.[18,35] The quit rates were adjusted on the basis of the variation with carbon monoxide verification.

There were no significant differences in the self-reported smoke-free days between the practice-based (50.23 days) and community-based (50.65 days) groups at 6 months. There were no statistically significant differences in quit rates for Medicaid (33%) and non-Medicaid (36%) participants at 6 months.

Effect of Number of Sessions Completed

An increased quit rate was noted for participants who completed at least 4 sessions compared with those who completed 3 sessions or less. The observed quit rates by number of sessions were 22%, 25%, 37%, 49%, 32%, and 46% for sessions 1 through 6, respectively. The OR for the dichotomous variables of 4 sessions or more compared with 3 or fewer was 2.2 ($P = .005$), indicating a significant increase in quit rates for individuals who completed at least 4 counseling sessions. There was no statistically significant difference between the practice-based (63%) and community-based (64%) groups for completion of session 6, the final treatment session.

Nicotine Replacement Use

Ninety-two percent of the participants recruited by a practice and 89% recruited by telephone received a voucher for patch or gum; the receipt rate was not significantly different between groups ($P = .267$). Only 75% of practice-based and 64% of community-based participants redeemed the voucher for the first month's supply of nicotine replacement therapy. The redemption rates were significantly different between groups ($P = .014$). Of those who redeemed the voucher, 95% used the 21-mg transdermal patch, and 5% used the 2 or 4 mg gum. The mean total use of transdermal nicotine was 33.8 days (SD = 1.4). There was no statistically significant difference in duration of use between intervention approaches. There were no participants taking buproprion during the analysis. The primary outcomes reported include both users and nonusers of nicotine replacement. At 6 months, the quit rates for nicotine replacement users and nonusers were 39% and 25% ($P < .05$), respectively.

Satisfaction of Study Participants

Focus groups with physicians, nurses, and counselors were conducted after the study. Physicians, nurses, and patients evaluated the program positively. The physicians indicated that having referral resources for follow-up care was helpful. Many described positive case reports of patients who had not previously been able to quit. Caregivers reported that the intervention minimally interrupted their routines. In general, nurses reported enjoying the counseling more than regular nursing; however, they found the computer program cumbersome at first, and at times were unable to schedule office visits during busy days. The only change recommended by office nurses was to have all follow-up sessions conducted by telephone, since it was often difficult for patients to return for scheduled visits. Physicians and nurses both commented that financial incentives and dedicated scheduling were needed to sustain the program. All practices reported continuing a variation of nurse counseling for relapse prevention using written documentation after the withdrawal of the computer support services.

Smokers were asked about program satisfaction at the 3-month follow-up. One hundred percent of the participants felt their experience with the program was positive. Even participants who continued to smoke said they liked the program. All participants indicated that they particularly appreciated the personalized approach and the proactive coping methods. Eighty-six percent of

the participants reported that all of their smoking triggers were listed in the project coping package.

DISCUSSION

This study explored the feasibility of introducing into primary care an intensive individualized smoking cessation counseling program, and assessed the effectiveness of the program using 2 different counseling approaches: (1) Office nurses counseling patients initially in primary care practices, with follow-up care provided by telephone counselors, and (2) telephone counseling alone. A computer-guided counseling system was developed to lead the nurses and the relatively inexperienced counselors. Both nurses and telephone counselors were able to counsel according to a fairly complex protocol after limited training sessions. The computer program clearly enhanced and shortened the training.

Though our study was not randomized, differences between the groups did not affect treatment outcomes. Nicotine replacement therapy was provided at no cost to patients so it might be thought that our study is not realistic. However, many insurance companies now provide such therapy free of charge. In Michigan, for example, all Medicaid patients have the right to pharmacologic aids to smoking cessation at no cost. Given the importance of smoking as a source of chronic health problems, it is likely that pharmacologic aids will become more freely available to patients in the future.

Are the use and outcome rates in this study similar to those achieved by over-the-counter nicotine replacement therapies? Strict outcome comparisons are difficult to make.[36-39] At least one study, however, did report on the duration of use of over-the-counter nicotine replacement therapy.[40] Irrespective of dose, patients used the medication for approximately 16.5 days. Patients in our study who chose to use nicotine replacement therapy did so for an average of 33.8 days. It appears then that there is some advantage to providing nicotine replacement therapy with supportive counseling.

One site was able to collect reliable data on patient recruitment. Eighteen percent of all smokers who were seen in the clinic during recruitment for the study enrolled in the counseling program. This number is comparable with those of other recruitment studies.[41] Though carbon monoxide sampling for all participants was not performed because of cost, more than 50% of those who reported being smoke-free at 6 months were visited at home, and adjustments were made in the outcomes, consistent with reported studies.[18,35]

The evaluation of the effectiveness of this study was made by comparing smokers recruited from primary medical care practices with those who self-referred to a telephone support service through community advertisements. Given the potential difference in motivation between the 2 groups — self-referred patients are by definition more highly motivated than patients who are encouraged by their primary care provider to undertake smoking cessation — one would have expected a difference in outcome. There was no difference. Primary care providers' efforts to assist patients to stop smoking can be enhanced through telephone-based counseling programs. Not only are these services effective, but primary medical practices also have access to smokers for recruitment to the programs. Intensive newspaper advertising was required to yield a sufficient number of the self-referral participants; recruitment during the same period in 4 medical practices, however, yielded sufficient participants at minimal or no cost. Since many states are struggling to find methods to help low-income patients become tobacco free, it is important that there was no difference in smoking cessation rates between Medicaid and non-Medicaid recipients.

The study raises questions about the most appropriate denominator calculation for community interventions. In strict efficacy trials using the intention-to-treat approach, subjects are commonly screened in sequences and are highly motivated to comply with protocols that enhance follow-up. In controlled trials, patients are carefully selected with multiple exclusions. Community demonstration trials, however, mimic real life with minimal exclusions. In our study, nicotine replacement therapy was offered at no cost, but there was no expectation that the participants would commit to its use. The main outcomes were reported, including both users and nonusers of nicotine replacement therapy to reflect the overall success of both approaches. It can be assumed that nonuse would lessen the overall outcome. Since there is no consensus on the best way to present the outcomes of community trials in smoking cessation, outcomes were presented in this study using the 2 approaches.[12,32,42] Even when using the stricter intention-to-treat denominator, the long-term quit rates for our study (~25%) are comparable with strictly controlled trials where the majority of participants used nicotine replacement therapies.[11] The telephone counseling system in this study clearly seems to enhance long-term smoking cessation in primary medical care.

This study also poses several questions for further research. What is the actual enhancement of a primary care physician's brief advice by relapse-prevention telephone support under experimental randomized conditions? What are the critical differences of relapse prevention for special subgroups, such as sex, race, and socioeconomic status? Do relapse coping approaches vary by individual over time? What are the true costs and benefits of systematic approaches for smoking cessation to populations in managed care?

CONCLUSIONS

The lack of difference in long-term smoking cessation between the 2 study groups (practice-based and community-based) cannot be explained by either sociodemo-

graphic variables or confidence in quitting using logistic regression. Our study demonstrates that since more than 60% of the participants continued the programs through the final session with reported high levels of satisfaction, a relatively complex counseling program can be made accessible and easily available. Such a program can support the delivery of smoking cessation therapy in primary care and enhance the brief advice and limited follow-up provided by physicians. The strength of the telephone counseling alone suggests that it could be offered independent of primary care practice or provided without initial office-based nurse counseling. Health systems and insurance programs should consider investing in such telephone services to enhance smoking cessation in primary care. Our study supports a new model for enhanced primary care to help clinicians fulfill the advocated guidelines on smoking cessation and prevention.[2,43,44]

ACKNOWLEDGMENTS

This research was supported by a grant from the Michigan Department of Community Health to the Institute for Managed Care of Michigan State University (MSU) as a subproject on "Cancer Prevention, Outreach and Screening/Detection for Cancer Patients." Joseph Farrell, MA, director of the Institute for Managed Care, acted as the overall project director. Barbara Given, FAAN, PhD, RN, and professor in the College of Nursing at MSU, was the overall project manager. Bryan Coyle, MA, performed all software programming. Nicotine replacement therapy, for all qualified participants, was provided by SmithKline Beecham. Kathy Ives, BS, a research assistant in the Department of Family Practice, directed the subproject management. Wei Pan, MS, provided data management. Dorothy Pathak, PhD, MS, professor in the departments of Family Practice and Epidemiology, provided biostatistical consultation. We wish to thank the participating community pharmacies and family practice residencies of Lansing (St. Lawrence and Sparrow), Flint (Genesys), and Saginaw, Michigan.

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