

# Enhancing Smoking Cessation of Low-Income Smokers in Managed Care

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- BACKGROUND Although office-based and telephone support services enhance the rate of smoking cessation in managed care systems, it is not clear whether such services are effective for very low-income smokers. We evaluated the comparative effectiveness of usual care (physician-delivered advice and follow-up) and usual care enhanced by 6 computer-assisted telephonic-counseling sessions by office nurses and telephone counselors for smoking cessation in very low-income smokers in Medicaid managed care.
- METHODS A randomized clinical trial comparing the 2 approaches was conducted in 3 Michigan community health centers. All clinicians and center staff received standard training in usual care. Selected nurses and telephone counselors received special training in a computer-assisted counseling program focusing on relapse prevention.
- RESULTS The majority of the study population (233 adult smokers with telephones) were white (64%) women (70%) with annual incomes of less than \$10,000 (79%) and with prescriptions of nicotine replacement therapy (>90%). At 3 months, quit rates (smoke-free status verified by carbon monoxide monitors) were 8.1% in the usual-care group and 21% in the telephonic-counseling group (*P*=.009) by intention-to-treat analysis. Special tracking methods were successful in maintaining participants in treatment.
- <u>CONCLUSIONS</u> Smoking cessation rates are enhanced in a population of very low-income smokers if individualized telephonic-counseling is provided. State and Medicaid managed care plans should consider investing in both office-based nurse and centralized telephonic-counseling services for low-income smokers.
- <u>KEY WORDS</u> Smoking cessation; lowincome population; counseling; recurrence. (*J* Fam Pract 2000; 50:138-144)

Clinical practice guidelines on smoking cessation advocate that clinicians identify all smokers, advise them to quit, and arrange follow-up care. Arranging systematic follow-up care is often the

most difficult of those steps in a primary medical practice because counseling for smoking cessation is often not reimbursed.2 Telephone support counseling services offering proactive follow-up with scheduled sessions have achieved long-term success rates from 25% to 30%.38 We were able to achieve a long-term quit rate of 36% in a community-based trial of computer-assisted telephone support counseling by nurses and telephone counselors trained in computer skills and relapse prevention.9 In this study more than 57% of the practice-based participants were covered by Medicaid insurance. There were no statistically significant differences in quit rates for Medicaid (33%) and non-Medicaid (36%) smokers at 6 months using a community denominator analysis approach.9

Managed care provides an advantageous system for the delivery of preventive services. 10 Most indemnity insurance plans cover few preventive services, mostly limited to screening and immunizations, despite "findings . . . that the counseling and education services are among the most effective interventions available to clinicians to achieve the goals of health promotion and disease prevention."10 Group Health Cooperative (GHC) of Puget Sound has demonstrated with a comprehensive systematic population-based health care approach that the prevalence of smoking can be reduced from 25% to 15.5% over 10 years among more than 550,000 adult enrollees.11 This tremendous change within a population was achieved by multiple approaches, including identification, tracking, community outreach, comprehensive clinician and staff education, free coverage of services to participants, accessible telephone counseling, and self-help materials.11 This is an outstanding example of an effective comprehensive program on smoking cessation within a private managed

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care system resulting in the overall reduction of smoking for a large population. It serves as a model for other preventive services concerning such common topics as alcohol consumption abuse, cancer screening, or coronary artery disease.

The prevalence of smoking among Medicaid health maintenance organizations (HMOs) versus commercial HMO participants is reported to be much higher. In recent Michigan surveys of health plans, 19.4% of the participants in commercial HMOs reported being current smokers compared with 44.1% of Medicaid HMO participants.12 Medicaid participants are clearly a high-risk population for tobacco use and the medical consequences of smoking. Many states are moving from a fee-for-service approach to Medicaid coverage as a prospective capitated payment approach within managed care. Before the course of our study all Medicaid participants were moved into managed care plans by the State of Michigan. This context provided the ideal setting for examination of the impact of a systematic approach to smoking cessation by office-based and telephone counseling follow-up care for smokers covered by Medicaid managed care.

Brief advice on smoking cessation from a physician alone results in long-term quit rates of less than 10%.<sup>13</sup> With the supplementation of brief physician advice with higher-dose nicotine gum or transdermal nicotine in randomized-controlled settings, long-term quit rates are increased to 15% to 25%.<sup>14-16</sup> In the context of community practice relying on general volunteers, long-term quit rates are lower than strictly controlled trials.<sup>17</sup> It seems that pharmacotherapy clearly enhances brief advice by physicians for smoking cessation.<sup>16</sup> In a primary care medical practice-based

study, Daughton and colleagues18 state that "data clearly indicate that counseling seems to maximize smoking cessation rates with the nicotine patch." Most studies (including that by Daughton and coworkers) have examined the relative effectiveness of pharmacotherapy against placebo. Our study proposes to answer the following questions: What is the comparative efficacy in quit rates by adding nurse and telephone counseling support for follow-up care to physician advice alone when all smokers receive the same pharmacotherapy? Does added behavioral support actually improve quit rates when all smokers use pharmacotherapy, or is there no difference? Can significant quit rates be achieved in low-income populations? Are there special measures required to maintain follow-up and protocol compliance in Medicaid smokers? What are the barriers to decreasing the high prevalence of smoking among participants in Medicaid managed care plans?

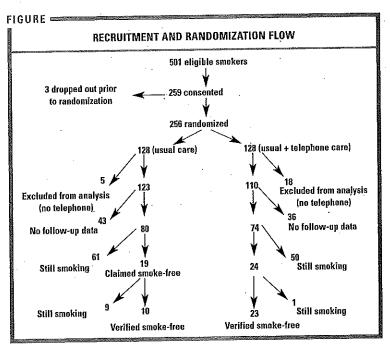
# METHODS

# Recruitment of Participants

Participants were enrolled from January 19, 1998, to June 20, 1998, from 3 community heath center sites (Hackley, Baldwin, and Muskegon) in Michigan. Each practice site had the designation of a federally underserved site with the majority of care provided to very low-income patients. Each practice site had 5 to 7 providers with approximately 10,000 to 15,000 active patients on record. All participants were smokers older than 21 years with Medicaid managed care insurance. Participants were covered by 4 different managed care plans that agreed to allow the participation of their patients in the study. All participants had no medical contraindications to the use of transdermal nicotine, including pregnancy, and were willing to commit to quitting smoking within the next 30 days. Smokers were invited to participate in the study during their usual office visits and were offered 21-mg transdermal nicotine for 8 weeks as covered by Medicaid and determined appropriate by their providers.

# Recruitment Rates

During the 6-month recruitment period, 501 smokers on Medicaid managed care were identified as eligible by office nurses and referred to participate in our study at the 3 practice sites. Of the referred group, 259 (52%) enrolled in our study and were randomized to either usual or relapse prevention care. A total of 233 (48% of the referred group) participated in our study. Participation was defined as receiving brief physician advice for the usual care group or brief physician advice and 1 telephonic-counseling session for the telephonic-counseling care group. These rates of enrollment were consis-



### FREQUENCY OF SESSIONS AND RANDOMLY ASSIGNED INTERVENTIONS

		Intervention		
Session O (Recruitment/intake	No. of Days After Quit Date and random assignment)	Usual Care Group Physician/intake visit	Telephonic-Counseling Group Physician/intake visit	
1	1		Practice nurse call	
2	3		Practice nurse call	
3	. 7		Practice nurse call	
4	14	Physician	Counselor call	
5	30	visit*	Counselor call	
6	60		Counselor call	
90-day follow-up	90	Assessment call <sup>†</sup>	Assessment call <sup>†</sup>	

'At least one physician follow-up visit between 7 to 30 days after the quit date, †Invited to carbon monoxide monitor verification if 7 days smoke-free by self-report.

tent across the 3 study sites. Participants were excluded from the final analysis if it was discovered after randomization that they did not have telephones. The informed consent process was approved by the institutional review board of Michigan State University. The Figure shows the recruitment and randomization flow.

# Training of Providers and Staff

A total of 20 primary care physicians were trained to provide brief advice for smoking cessation consistent with the national guidelines.1 Physician training consisted of a 2-hour update session on the guidelines, an overview of the study protocol, and role playing. Physicians received continuing medical education credit for participating. Ten nurses34 per site and 10 telephone counselors were trained in computer-assisted relapse prevention. 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 on case examples between training sessions. Their intervention skills were evaluated before they began counseling study participants. Quality assurance of counseling performance was performed through weekly audiotape review by research assistants. The computer program ("I'd Rather Cope than Smoke") provided a continuing record of counseling time and accuracy of data collection per nurse and counselor.

# Study Design and Counseling Interventions

The participants who were assigned to the usual-care group participated in an intake session, received brief advice on smoking by their provider according to the guidelines, were given a prescription for transdermal nicotine if medically appropriate, and had a follow-up scheduled for at least 1 visit (usually 7 to 30 days after the quit date) consistent with their medical condition. All participants also

received "Clearing the Air" (National Cancer Institute publication no. 95-1647). The intake session lasted approximately 45 minutes. The intake was conducted by study staff (not the nurses providing telephone counseling) to prevent selection bias. Randomized assignment to either usual care or telephonic-counseling care groups occurred immediately after the intake session.

The participants assigned to the relapse prevention telephonic-counseling group received an intake session, usual care, a copy of "Clearing the Air," a diary of coping responses the size of a cigarette pack, and 6

telephonic-counseling sessions. 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 is consistent with previously reported studies by the authors9 and other investigators. 48 As previously reported, the computer software program, "I'd Rather Cope than Smoke," was developed to assist in compliance with the relapse prevention protocol.9 All counseling sessions were done telephonically. Trained office nurses who used the software on laptop computers performed the first 3 treatment sessions. The intake and follow-up data of the first 3 sessions were electronically transferred to a computer network at Michigan State University where trained telephone counselors provided sessions 4 to 6.

# Barriers to Maintaining Telephone Treatment

Before the study onset, focus group analysis of low-income smokers reported that the majority preferred counseling sessions on relapse prevention to be done by telephone rather than in person by the office nurse at the practice sites. We anticipated frequent disruptions in telephone service for the study population, so several innovative methods to maintain telephone treatment were developed, such as: (1) immediately contacting directory assistance for disruptions in service; (2) verifying site records for phone numbers changes; (3) contacting participants during subsequent clinic visits to update phone numbers; and (4) mailing a self-addressed stamped postcard requesting immediate feedback.

# Independent Variables

Participants were evaluated for standard demographic characteristics of sex, age, socioeconomic status, education level, and working status. Baseline smoking activity was evaluated on the basis of the number of cigarettes smoked per day, the number of years of smoking, the mini-Fagerstrom Tolerance Questionnaire (FTQ),<sup>19</sup> household activity, confidence in quitting, and personal reasons for quitting. Medicaid insurance status was verified. Personal patterns of relapse triggers and coping response were recorded.

### **Outcomes Measured**

The main outcome measure was carbon monoxide verified smoke-free status at a telephone follow-up 90 days after the quit date in both usual and telephonic-counseling groups. Multiple attempts were made to contact participants, regardless of the level of participation at 3 months. Participants reporting 7-day smoke-free status at 3 months were invited to have carbon monoxide verification at the office and were paid \$50 for their time.

The secondary outcome measures included physician, nurse, counselor, and participant compliance with protocols; provider and staff satisfaction with the program; and nicotine replacement use.

# Statistics

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 Student *t* test for continuous variables. Several continuous variables were categorized and analyzed by both methods.

The study denominator was based on intention-to-treat assignment as in randomized controlled trials<sup>20,21</sup> for evaluation of pharmacotherapy for nicotine addiction. Participants who refused follow-up, failed to call back, gave incorrect contact numbers, or dropped out were counted as smokers.

Smoking quit rates at 90-day follow-ups were compared using the z score for equality of proportions. Adjustments were made in self-reported outcomes based on carbon monoxide verification rates.

# RESULTS

# Demographic Comparison of Study Groups

A total of 238 smokers participated in the study (N=123 usual care group, and N=110 in the telephonic-counseling group) and patient demographics are reported in Table 2. The smoking characteristics of the study groups are provided in Table 3. Adjustments for participants without telephones did not induce any significant differences.

As shown in Table 4, the most common reasons for quitting by far were personal health reasons and health problems related to smoking. Very few participants reported advice from their physician as the reason to quit smoking. The

TABLE 2™

Demographîc	Usual Care Group (n=123)	Telephonic- Counseling Group (n=110)
Age, years	38.7	44*
Ethnicity, %		
White	58	61
African American	31	29
Other	11	10
Sex, % women	72	. 69
Marital status, %		
Married	19	22
Widowed	6 .	8
Single	33	24
Divorced	27	39
Separated	14	6
Other	. 2	1
Employment status, %	s	
Disabled	33	35
Unemployed	27	31
Full-time .	15	89
Part-time	12	9
Homemaker	6	. 5
Retired	3	8
ncome status/year, %	,	
<\$10,000	. 81	- 86
\$10,000-\$19,999	14	10
\$20,000-\$29,999	`1	3
Refused to report	. 4	1
/ears of education, %		
1-8	9	14
9-12	79	67
13-20	12	19

TABLE 3 ==

# SMOKING CHARACTERISTICS OF PATIENTS IN STUDY Usual Care Group (n=123) Age at smoking onset, years 16 Number of cigarettes/day Confidence in quitting\* 7.67 7.42 Fagerstrom score of dependencet 5.5 SMOKING CHARACTERISTICS OF PATIENTS IN STUDY Telephonic-Counseling Group (n=110) 16 16 7.67 7.42 Fagerstrom score of dependencet 5.5 5.16

NOTE: No significant differences in characteristics detected, 'Scale of 1 to 10, where 1 = lowest and 10 = highest level of confidence, tScale of 0 to 7

TABLE 4 ■

	Usual Care Group (n = 123)		Telephonic-Counseling Group (n=110)	
Reason	No.	(%)	No.	(%)
Personal health	70	(57)	68	(62)
Family health	20	(16)	12	(11)
Smoke-related health problems	14	(12)	14	(13)
Nasty habit	8	{7}	4.	(3)
Workplace	6	(5)	- 5	(4)
Social pressure	1	(1)	2	(2)
My doctor said I should	0	(0)	2	(2)
Other	3	(2)	3	(3)
Don't know	1 .	(1)	. 0	(0)

groups were comparable and did not differ significantly in their reasons for quitting.

# Smoke-Free Status

Of the 233 patients with telephones enrolled in the study, 80 (65%) in the usual care group and 74 (67%) in the telephonic-counseling group were successfully contacted. Of those contacted, 19 in the usual care group and 24 in the telephonic-counseling group reported that they were smoke free. However, smoke-free status was successfully confirmed using carbon monoxide (CO) monitoring in only 56% of patients claiming to be smoke free in the usual care group, while 95% of patients in the telephonic-counseling group had their smoke-free status confirmed. Thus, in the per-protocol analysis, smoke-free status was confirmed in 10 of 80 (12.5%) in the usual care group and 23 of 74 (31%) in the telephonic-counseling group (P=.004).

In the intention-to-treat analysis we assumed that all missing cases were smoke free and used denominators of 123 and 110 for the usual care and telephonic-counseling groups, respectively. In this intention-to-treat analysis, the rates of self-reported smokefree status were 15% and 19% (P=ns). In the intention-to-treat analysis of CO-verified smoke-free status, patients in the telephonic-counseling group were more likely to be smoke free (8.1% vs 21%, P<01).

# Nicotine Replacement Use

Prescriptions for nicotine replacement were received by 91% of the usual care and 99% of the telephonic-counseling care participants. At follow-up evaluation, 73% of the usual care and 67% of telephoniccounseling care participants reported using at least an initial course of nicotine replacement. These proportions of use did not differ significantly between the study groups

# DISCUSSION

Smoking has been shown to be one of the most

modifiable health risks significantly related to higher health care charges, even after controlling for age, sex, race, diabetes, and heart disease.22 Although indemnity plans have been largely unsupportive of services for smoking cessation counseling, managed care plans have shown considerable success at decreasing the prevalence of smoking by offering comprehensive smoking cessation services.23,24 In fact, offering full coverage of both behavioral and pharmacotherapy services results in a greater reduction in smoking prevalence than partial coverage.24 The studies mentioned on smoking cessation were conducted with partici-

pants who were employed and had commercial insurance coverage.

Our study examined the effectiveness of a comprehensive program for smoking cessation provided by nurse and telephone counselors who were assisted by a computer-guided program focusing on relapse prevention in very low-income smokers covered by Medicaid managed care. The intention-totreat results of a 21% quit rate at 3 months were consistent with our previously reported study,9 which included a sizable subpopulation of Medicaid patients. If adjustments are made in the denominator based on community trials17 as our previous study9 for reasonable loss-to-follow, then the CO-verified quit rates at 3 months would be 13% (usual care) and 31% (telephonic care) (P=.011). Our report is unique because we directly compared the effectiveness of telephone counseling support with usual care (brief physician advice and follow-up) in a true experimental trial in community practice. Though most participants received prescriptions for transdermal nicotine, the variation in usage was similar in both study groups because randomization allows a true comparison of the behavioral intervention effects. recruitment data showing that approximately 50% of referred smokers in primary care are willing to enroll in a program is consistent with our previous study and other reports.<sup>24</sup> This demonstrates that Medicaid smokers are generally as willing to participate in smoking cessation services as other smokers.

Although all providers received formal training on the smoking cessation guidelines, were aware of the study, and had "green card" reminders on study charts, they offered appropriate follow-up care only 26% of the time at return visits (based on post-study chart audit documentation). These findings are consistent with national surveys of physicians in primary care practices that show follow-up care as the greatest shortcoming. It seems that physicians need to have comprehensive office systems in place to ensure even brief follow-up care for smoking ces-

sation. Telephone counseling support with a guided computer system definitely enhances follow-up care. By closely tracking participants for changes in addresses and telephone services, reasonable follow-up can be maintained even in low-income smokers. In our study, 60% of the participants in the telephonic-counseling group received at least 4 treatment sessions. Opinions of providers and staff during post-study focus groups were very positive. All 3 practices decided to continue a nurse-based approach for relapse prevention counseling after the study and expressed a need for the telephone support services to continue.

# Limitations

One of the possible weaknesses of this study is the lack of long-term follow-up at 6 to 12 months for quit rates to ensure continued differences in effectiveness. Because of lack of funding, we were only able to obtain follow-up at 3 months. However, our findings are similar to the data in our previously reported community demonstration trial,9 which did not have a usual care comparison. Though the 2 reports refer to different populations, in our previous report9 using an intention-to-treat denominator the CO-verified quit rates were approximately 20% at 6 months in the Medicaid population. When using a community-based denominator that accounted for loss to follow-up, the 6-month quit rate was 33%. These results are consistent with strictly controlled trials where the majority of participants used nicotine replacement therapies.16

It is of interest to note that in this very low-income population, providing \$50 to verify self-reported smoking cessation by CO monitor not only yielded considerable follow-up at 3 months but may have biased self-reporting in the usual care group where only 56% of the reports were verified. This finding shows the importance of using biochemical verification of smoking cessation even in community-based clinical trials.

### Continued Research

Our study poses several questions for further research. Are the quit rates obtained by the described telephonic-counseling program sustainable over time at 1 to 2 years post-treatment in lowincome populations? Can these approaches for relapse prevention be adapted to meet the needs of special groups, such as pregnant smokers, difficult to reach smokers at home, and high-risk smokers With diseases such as diabetes, heart disease, asthma, and severe disabilities when offered in conjunction with disease management services within managed care plans? This is of particular importance When the majority of low-income smokers report Personal, smoking-related, and family health problems as reasons for quitting smoking. Though such behavioral support services are reported to be costeffective in commercial managed care populations,<sup>25</sup> what is the cost-effectiveness of these services when adapted to meet the needs of special populations?

# CONCLUSIONS

Telephonic-counseling for smoking cessation supported by a computer-guided program on relapse prevention is both practical and effective even for low-income smokers covered by Medicaid managed care. Special tracking approaches are required to maintain low-income smokers in treatment and to ensure provider follow-up. State Medicaid programs and insurance plans should consider investing in both office-based and centralized telephonic smoking cessation services to enhance smoking cessation for low-income smokers.

### · ACKNOWLEDGMENTS ·

Our 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, PbD, RN, and professor in the College of Nursing at MSU, was overall project manager. Wei Pan, MS, provided data management and statistical support. Kathy Ives, research assistant, contributed project coordination, data entry, and analysis. Dorothy Pathak, PhD, biostatistics consultant, verified the statistical analysis. We thank the Medicaid managed care plans of Wellness, Care Choices, Physicians Health Plan, and Community Choice for allowing patient participation and covering pharmacotherapy during the study. We thank the community bealth center physicians and staff in the Michigan communities of Hackley, Baldwin, and Muskegon for participating in the study.

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JEP

# **Conflict Avoidance**

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Was it her words Or sunken eyes, That led me to think Of words' disguise?

"I don't want to rock the boat,"
She said, not once but twice,
As we spoke of disagreement
Among her fellow doctors on the ward.

"I prefer to let things ride," She pressed the group in a shy aside, Which led me to wonder more About her choice of metaphor. Years before, she fled her country, Traded war for open sea, A raft, a log, a boat, a dare, A hope for safety anywhere.

Here, for once, no cliché, No mere *façon de parler*, But today, on a hospital ward, The old terror came ashore.

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