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RESEARCH ARTICLE

The Effectiveness of Covering Smoking Cessation Services for Medicare Beneficiaries

Geoffrey F. Joyce, Raymond Niaura, Margaret Maglione, Jennifer Mongoven, Carrie Larson-Rotter, James Coan, Pauline Lapin, and Sally Morton

Objective. To examine whether reimbursement for Provider Counseling, Pharmacotherapies, and a telephone Quitline increase smoking cessation relative to Usual Care.
Study Design. Randomized comparison trial testing the effectiveness of four smoking cessation benefits.
Setting. Seven states that best represented the national population in terms of the proportion of those $\geq$ 65 years of age and smoking rate.
Participants. There were 7,354 seniors voluntarily enrolled in the Medicare Stop Smoking Program and they were followed-up for 12 months.
Intervention(s). (1) Usual Care, (2) reimbursement for Provider Counseling, (3) reimbursement for Provider Counseling with Pharmacotherapy, and (4) telephone counseling Quitline with nicotine patch.
Main Outcome Measure. Seven-day self-reported cessation at 6- and 12-month follow-ups.
Principal Findings. Unadjusted quit rates assuming missing data = smoking were 10.2 percent (9.0–11.5), 14.1 percent (11.7–16.5), 15.8 percent (14.4–17.2), and 19.3 percent (17.4–21.2) at 12 months for the Usual Care, Provider Counseling, Provider Counseling + Pharmacotherapy, and Quitline arms, respectively. Results were robust to sociodemographics, smoking history, motivation, health status, and survey nonresponse. The additional cost per quitter (relative to Usual Care) ranged from several hundred dollars to $6,450.
Conclusions. A telephone Quitline in conjunction with low-cost Pharmacotherapy was the most effective means of reducing smoking in the elderly.

Key Words. Smoking cessation, elderly, Medicare

Efforts to reduce smoking in the United States have primarily targeted the young before they become habitual smokers. However, there is increasing evidence that quitting smoking, even after decades of exposure, can have a

substantial effect on rates of smoking-induced disease (Burns 2000). Recent work has shown that lung function and circulation begin to improve immediately after quitting, while the risk of coronary artery disease and cerebrovascular accidents decrease to nonsmoker levels within 1–5 years after cessation (Hermanson et al. 1988; Tell et al. 1989; U.S. Department of Health and Human Services 1990). A person smoking 20 or more cigarettes per day and who quit at age 65 could expect to increase their life expectancy by 2–3 years, in addition to any improvements in quality of life (Sachs 1986). While older smokers are less likely to attempt quitting than younger smokers, those who do try are more likely than younger smokers to seek assistance and to be successful in their efforts (Burns 2000).

Both clinical trials and real-world demonstrations have shown that a combination of behavioral counseling and Pharmacotherapy can increase quit rates (Fiore et al. 1996). Used alone or in combination, buproprion (Zyban), nicotine patches, and Provider Counseling have been shown to double quit rates in some studies (Hurt et al. 1997; Jorenby et al. 1999). As such, current treatment guidelines recommend that every patient who uses tobacco should be counseled by a health care provider to quit smoking and should be offered tobacco dependence treatments in the absence of contraindications (Fiore et al. 1999).

Despite their demonstrated efficacy and safety, a minority of private and public health plans fully cover smoking cessation services (Schauffler 1997; Curry et al. 1998; Rigotti et al. 2002). One reason for this is a lack of evidence on the effectiveness of insurance coverage in increasing long-term abstinence, particularly among older adults who in most cases have been smoking for over 40 years. The Medicare Stop Smoking Program (MSSP) was the first large-scale demonstration designed to test the effectiveness and cost-effectiveness of Medicare coverage for smoking cessation therapy. The MSSP had the following three aims: (1) To test the effectiveness of three variations in a Medicare smoking cessation benefit (reimbursement for Provider Counseling only,

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Address correspondence to Geoffrey F. Joyce, Ph.D., Senior Economist, RAND, 1776 Main Street, Santa Monica, CA 90407-2138; e-mail: gjoyce@rand.org. Raymond Niaura, Ph.D., Professor, is with the Department of Psychiatry and Human Behavior, The Warren Alpert Medical School of Brown University, Butler Hospital, Providence, RI. Margaret Maglione, M.P.P., is with the RAND Corporation, Santa Monica, CA. Jennifer M. Mongoven, M.P.H., is with Qualidigm, Middletown, CT. Carrie Larson-Rotter, M.P.P., is with the Cedars-Sinai Medical Center, West Hollywood, CA. Pauline Lapin, M.H.S., and James F. Coan, B.A., are with the Office of Research, Development, and Information, Centers for Medicare and Medicaid Services, Baltimore, MD. Sally C. Morton, Ph.D., is with RTI International, Research Triangle Park, NC.

Provider Counseling+Pharmacotherapy, and a telephone Quitline with over-the-counter Pharmacotherapy) against one another and against Usual Care, (2) to evaluate the feasibility, by program acceptance and utilization, of each of the smoking cessation benefits, and (3) to evaluate the program costs and cost-effectiveness of alternative smoking cessation benefits.

METHODS

Overview

We used a longitudinal comparison trial to test the effectiveness of four intervention arms in seven U.S. states. The intervention arms were (1) Usual Care (participants received smoking cessation information only), (2) Provider Counseling, (3) Provider Counseling+Pharmacotherapy, and (4) a telephone counseling Quitline with optional Pharmacotherapy. Enrollment was conducted between October 2002 and October 2003, and the interventions were available for 1 year. Six- and 12-month follow-up data on smoking cessation were collected.

Selection of States and Randomization Strategy

The goal was to implement a randomized design that, to the extent possible, would achieve national representativeness, and therefore wide generalizability. Randomization at the person level was impossible because two of the four interventions involved interaction with the participant's primary care provider, and contamination may have occurred if that provider was required to deliver two different services to his or her patients. Thus, randomization at the geographic locale level rather than at the person level was deemed the best possible approach.

Seven states—Alabama, Florida, Ohio, Oklahoma, Missouri, Nebraska, and Wyoming—were chosen for the demonstration in order to mirror in aggregate the nation as best as possible in terms of a number of factors, including smoking rate, and proportion of population of age 65 years and older. These seven states also had sufficient numbers of older smokers for adequate statistical power to answer the key study questions. States were chosen so as to enroll a participant sample that represented the nation as closely as possible in terms of smoking rate and proportion of population $\geq$ 65 years of age. States that already had a telephone-counseling program were excluded. Five states were each divided into four geographic areas; Wyoming and Nebraska were combined and divided into four areas. Divisions were designed to maximize

the likelihood that patients and their providers remained in the same area. Using a restricted randomization method, each area in a state was randomized to one of the study arms so that each state had all four arms represented within it. Data from the 1990 Census were used to assess the balance across arms with respect to percent of the ≥ 65 population who resided in a rural area, were white, and lived below the poverty threshold.

Recruitment and Study Sample

Subjects were recruited via standardized recruitment methods across the four intervention arms. A general recruitment message announcing new services for Medicare beneficiaries who smoke was disseminated through the media (newspapers, TV, and radio), community outreach efforts, and, in some states, through direct mailing. For example, over an 8-week period, a message was inserted in the Medicare summary notices mailed to all Medicare beneficiaries residing in the demonstration areas who received medical services in the preceding month, informing them of a demonstration that would provide smoking cessation counseling coverage through a potential new Medicare benefit. All Medicare-eligible primary care providers who practiced in the areas of the study were eligible for reimbursement.

Beneficiaries were directed to call a toll-free telephone number where they were screened. Callers were eligible for the study if they met the following criteria: a current Medicare beneficiary in a fee-for-service plan with Part B coverage, age 65 or older, a current smoker, an interest in trying to quit smoking, and anticipated residence in the study locale for at least 9 months. If eligible, a baseline survey was administered, collecting information on demographics, comorbidity, and smoking history.

The enrollment center received 30,726 calls from 23,279 unique callers. Of the total calls, 13,143 (43 percent) were informational calls that primarily consisted of general inquiries about the program.[1] From the remaining 17,583 calls, 13,577 individuals began a qualification survey to determine whether the caller was eligible for and would consent to be part of the study. Among those individuals, 8,904 met the eligibility criteria and 7,354 enrolled in the study. The most common reasons for ineligibility were age under 65 (2,187) and participation in a managed care plan (1,170). More than 1,500 eligible smokers did not enroll due to active refusal (1,081) or because their call was suspended (469) and they could not be recontacted. This resulted in an acceptance rate of 31.6 percent relative to the number of unique callers and a rate of 82.6 percent of eligible beneficiaries who began the qualification survey.

Some degree of imbalance was inevitable due to the nonrandom distribution of eligible beneficiaries within states. However, the largest imbalance occurred in the Provider Counseling arm due to low enrollment in Southeast Florida. This had a dramatic effect on total enrollment in the Provider Counseling arm because Florida represented about 40 percent of all eligible smokers in the seven study states. We explored several possible reasons why enrollment was lower in this area, including blocked telephone access from specific geographic areas. However, an internal review by the telephone company did not reveal any evidence to support this hypothesis. Most important to the validity of the findings, there were no statistically significant differences across treatment arms in beneficiaries health status, smoking behavior, and lifetime quit attempts.

Interventions

All participants received a self-help kit consisting of educational materials published by the U.S. Public Health Service (PHS). Usual Care beneficiaries received the U.S. PHS Consumer Version of the Clinical Practice Guideline: Treating Tobacco Use and Dependence (U.S. Department of Health and Human Services [USDHHS] 2000). Provider Counseling beneficiaries received Medicare coverage for a maximum of four brief counseling sessions. Providers (physicians) could bill Medicare an additional $36.98 for cessation counseling minus a 20 percent patient copayment. Brief counseling services consisted of three to 10 minutes of counseling about smoking cessation based on the patients' stage of readiness to change. Reimbursement caps included two sessions per cycle, based on two 12-week cycles per year, for a maximum of four counseling sessions per year. Reimbursement to physicians for cessation advice was in addition to any charges for the office visit. Providers identified by Medicare beneficiaries enrolled in the MSSP were notified (by letter) of the program and the availability of coverage for cessation counseling. In addition, these physicians were sent a Continuing Medical Education program on providing smoking cessation counseling based on the PHS Clinical Practice Guideline Treating Tobacco Use and Dependence. Thus, both physicians and patients were aware of the program and the availability of covered services (USDHHS 2000).

Provider Counseling + Pharmacotherapy beneficiaries received counseling as described previously as well as coverage for the nicotine patch or bupropion for a $5 copayment. To access the benefit, beneficiaries submitted orders with copayment to a mail-order pharmacy company contracted to

provide this service. Beneficiaries using the nicotine patch received dosages according to the package insert, with most receiving recommended step-down dosages of 21 mg to 14 mg to 7 mg. If bupropion was requested, a prescription was required. Participants were allowed one refill (for a total of two 12-week courses) of either therapy.

Quitline beneficiaries received coverage for telephone-based counseling, including two mutually exclusive options: a reactive hotline, in which participants called and received prerecorded messages or ad hoc counseling, and a proactive helpline, in which calls were initiated by the Quitline counselor at predetermined times. The counseling protocols were designed for people older than 50 who were trying to quit smoking and were tailored to the stage of cessation readiness for older smokers using evidence-based standards as defined by the 2000 PHS Smoking Cessation Guidelines (Fiore et al. 2000). Those who chose the reactive helpline had unlimited access to services during their 12-month intervention period. Those who selected the proactive helpline could receive five counseling calls per 12-week cycle, with a two-cycle maximum per year. Helpline participants also received (1) a Clear Horizons manual designed for smokers >50 years (Orleans et al. 1989) and (2) coverage for the nicotine patch for a $5 copayment via the same mail-order pharmacy procedures described above.[2]

Survey Data Collection

Surveys were administered at baseline and at 6 and 12 months subsequently. Data collected included self-reported demographic, health, smoking history, and pharmacological treatment variables. The baseline survey was administered by telephone. At 6 and 12 months, mail surveys assessed any smoking that had occurred in the previous week as well as services used over the past 6 months. After 1 month, nonrespondents were sent a reminder and another survey. Continued nonrespondents were telephoned up to six times so as to complete the survey via telephone. The main outcome measure was 7-day self-reported cessation at the 6- and 12-month follow-ups. Pharmacy claims were collected by the pharmacy benefit manager, while use of telephone counseling was tracked by the Quitline vendor. The overall response rate for the 6-month survey was 67.5 percent. The response rate for the 12-month survey was slightly lower than for the 6-month survey: 60.6 percent, 21 percent responded by phone, and an additional 50 enrollees (1.1 percent) agreed to answer just the two smoking questions over the phone. Response rates differed significantly by intervention arm, but the magnitude of the differences

was small (largest differences: 5.8 and 7.5 percent for the 6- and 12-month surveys).

Data Analysis

Program utilization was measured via (1) counseling services reported in the 6- and 12-month surveys, and Quitline telephone logs, (2) Pharmacotherapy use as reported in the 6- and 12-month surveys, and pharmacy claims data. Our analyses include Pharmacotherapy or counseling services received through the MSSP, as well as services received independently (i.e., reimbursed by other third-party payers or by the participant).

Smoking status of nonresponders was imputed using two approaches. The first assumed that nonresponders were smoking at the time of each follow-up (Hall et al. 2001). Because this approach may differentially underestimate the effectiveness of each intervention, smoking status was also imputed based on nonresponders' demographic characteristics, health status, and smoking history. A probit model was estimated on the probability of smoking among responders to the 6- or 12-month survey and the estimated parameter estimates were used to predict the smoking status of nonresponders based on their individual attributes.

The results presented here reflect intent-to-treat analyses, where smoking for the 7,354 enrollees in the MSSP is examined regardless of treatment compliance and response to follow-ups. The primary dependent variable is the 7-day point prevalence of smoking abstinence at 6 and 12 months. We present unadjusted rates of smoking prevalence, as well as adjusted rates that control for sociodemographic characteristics (age, sex, marital status, household income, education), motivation to quit (stage of change), smoking history/dependence variables (daily rate of smoking, years smoking, # quit attempts, length of longest quit attempt in the past 12 months, length of longest quit attempt), and co-occurring conditions (counts of chronic conditions, heavy drinking). The models also include binary indicators for each state (combining Nebraska and Wyoming) and the quarter of enrollment to control for unmeasured geographic and time-varying factors.

Cost-Effectiveness

Those enrolled in the demonstration were more motivated to quit smoking than the average Medicare-eligible smoker (based on their decision to call

the enrollment center and enroll). Thus, a more pertinent comparison is the cost-effectiveness of the three active interventions relative to Usual Care, evaluated from the perspective of the Medicare program.

We categorized costs into developmental and operational expenses. Development costs captured activities performed before enrollment, such as the design of survey instruments, enrollment protocols and data systems, as well as staff recruitment and training. Operational costs included operating the enrollment center and the telephone hotline, survey administration, data collection, and claims processing.

The cost of developing and operating the enrollment center totaled $4,027,946, of which 22 percent were development costs incurred before the start of enrollment and 78 percent were operational expenses incurred between October 2002 and December 2004. Some development costs were applicable to the demonstration itself and would not be incurred if any of the services were to become a part of a Medicare benefit (e.g., survey instruments, some data collection). Other development costs were one-time expenses that comprised a small fraction of total program costs (e.g., developing data systems). Those costs were excluded from our analysis. The remaining development costs were apportioned equally across the three active interventions (not Usual Care).

The costs associated with each active intervention included the costs of cessation treatments received by participants in that arm, regardless of whether the service was paid for by the MSSP. Including the cost of cessation services used outside of the MSSP captures the true costs of the intervention were it to become a national Medicare benefit. The incremental costs associated with Provider Counseling (relative to Usual Care) consisted of reimbursements to physicians for providing counseling services. These were computed by multiplying the fraction of enrollees in the treatment arm who reported receiving cessation advice from their provider during the MSSP (40.7 percent, regardless of who paid) by the net cost per visit ($29.58), assuming each enrollee that received counseling averaged 1.5 sessions in the year.[3] Similarly, the incremental costs associated with the Quitline include the costs of Pharmacotherapy plus the expense of operating the telephone hotline. Based on pharmacy claims, the average cost of a 150-mg dose of Zyban® was $295 per 84-day supply, inclusive of the dispensing fee and net of the patient copayment. The cost of the nicotine patch ranged from about $30 for a 14-day supply (7 or 14 mg) to $90 for a 42-day supply (21 mg). For comparison purposes, we standardized the sample size in each arm to the number of enrollees in Usual Care ($N = 2,230$).

RESULTS

Comparison of Study Arms

Of the 7,354 enrollees, 2,230 (30.3 percent) were assigned to Usual Care, 829 (11.3 percent) to Provider Counseling, 2,605 (35.4 percent) to Provider Counseling+Pharmacotherapy, and 1,690 (23.0 percent) to the Quitline. A majority of enrollees were female, had at most graduated from high school, and had an annual household income under $35,000 (Table 1). More than half were not married or living with a partner. About 90 percent had smoked for at least 40 years; almost all had tried to quit. About 29 percent of enrollees were heavy smokers ($\geq$ 25 cigarettes/day). Nearly two-thirds rated their overall health as good to excellent. Enrollees differed on race, education, income, quit attempts, and stage of change. While statistically significant, these differences were absolutely small. These variables were included as covariates in the regression models used to test for intervention effects.

Use of Smoking Cessation Services

Although Pharmacotherapy was not covered in the Usual Care and Provider Counseling arms, nearly 20 percent of participants in those arms reported using bupropion and about 25 percent reported using the nicotine patch (Table 2). In comparison, 39.8 percent of participants in Provider Counseling + Pharmacotherapy and 47.2 percent of Quitline participants used the nicotine patch. Receipt of counseling services ranged from 21.6 percent in Usual Care to 44.7 percent in the Quitline based on participants' self-reports.

Quit Attempts

The rate of quit attempts was highest in Provider Counseling + Pharmacotherapy and Quitline arms at both 6 and 12 months (Table 3). More than half of the beneficiaries enrolled in these interventions attempted to quit smoking for at least 24 hours within the first 6 months of the study and nearly seven out of 10 had attempted to quit at 12 months. These patterns were consistent among respondents of the 6- and/or 12-month surveys and after adjustment for covariates (not shown).

Rates of Smoking Cessation

Table 4 presents rates of smoking cessation at 6- and 12 months, by intervention arm, assuming that survey nonrespondents were smoking. At 6 months, the Provider Counseling + Pharmacotherapy and Quitline arms significantly outperformed the Usual Care arm, Usual Care and Provider

Table 1: Sociodemographic Characteristics and Smoking History at Baseline among Enrollees in Each Treatment Arm

	Usual Care (N= 2,230)	*Provider Counseling (N= 829)*	*Provider Counseling + Pharmacotherapy (N= 2,605)*	*Telephone Quitline (N= 1,690)*
Sociodemographics				
Age				
65–69	44.3	45.6	47.8	49.3
70–79	49.2	47.9	46.2	45.4
80+	6.5	6.5	6.0	5.3
Gender				
Male	39.3	42.4	38.5	42.1
Race†				
White	94.6	89.1	92.7	90.9
Black	3.2	5.6	4.3	6.4
Other	2.2	5.3	3.0	2.7
Education†				
Less than high school	16.3	21.9	18.7	20.4
High school	37.2	37.1	38.7	36.2
College	46.5	41.0	42.6	43.4
Marital status				
Married/living with partner	44.2	44.2	45.2	45.8
Widowed/separated/ divorced/never married	55.8	55.8	54.8	54.2
Income†				
Under $10,000	18.2	21.4	18.7	19.7
$10,000–$15,000	19.8	20.7	20.5	20.4
$15,000–$35,000	43.8	44.2	46.5	46.3
$35,000 or more	18.2	13.7	14.3	13.6
Health behaviors				
Level of smoking				
Heavy (25+ cigarettes/ day)	28.9	27.0	28.7	30.3
Years smoking				
<40	9.3	9.4	10.8	9.6
40–49	21.6	25.3	22.3	23.3
50 or more	69.1	65.3	66.9	67.1
Quit attempts (lifetime)				
0	7.4	6.5	6.3	7.6
1–3	40.4	44.4	44.5	42.9
4–6	24.0	25.4	21.7	22.6
7+	28.2	23.7	27.5	26.9
Smoking environment				
Spouse/partner smokes	14.9	13.7	16.7	16.2

continued

Table 1. *Continued*

	Usual Care (N= 2,230)	*Provider Counseling (N= 829)*	*Provider Counseling + Pharmacotherapy (N= 2,605)*	*Telephone Quitline (N= 1,690)*
Stage of change†				
Preparation	33.4	32.3	30.3	30.8
Contemplation	65.5	66.7	69.3	68.8
Precontemplation	1.1	1.0	0.4	0.4
Alcohol use				
Heavy drinker	5.8	3.9	4.7	4.8
Health status				
Self-reported health				
Excellent/very good	29.9	24.5	26.5	27.5
Good	35.5	36.5	37.5	36.3
Fair	24.7	26.2	25.3	25.8
Poor	10.9	12.7	10.7	10.4

†Statistically significant differences across treatment arms, based on χ^2 test (p-value $<.05$).
All figures are in percentages.

Counseling were statistically indistinguishable, and the Quitline arm significantly outperformed Provider Counseling + Pharmacotherapy. At 12 months, all active treatment arms outperformed Usual Care, Provider Counseling and Provider Counseling + Pharmacotherapy were statistically indistinguishable, and the Quitline arm significantly outperformed the Provider Counseling and Provider Counseling + Pharmacotherapy arms.

Table 2: Self-Reported Use of the Smoking Cessation Services

Treatment	*Usual Care*	*Provider Counseling*	*Provider Counseling + Pharmacotherapy*	*Telephone Quitline*
Nicotine patch	25.8	24.8	39.8†	47.2†
	(24.0–27.6)	(21.9–27.8)	(37.9–41.7)	(44.8–49.5)
Bupropion	17.6	19.4	33.3†	13.3†
	(16.0–19.2)	(16.7–22.1)	(31.5–35.1)	(11.6–14.9)
Counseling	21.6	33.2†	36.2†	44.7†
	(19.9–23.3)	(30.0–36.4)	(34.4–38.0)	(42.4–47.1)
Any use	42.0	49.3†	63.4†	59.8†
	(40.0–44.1)	(45.9–52.7)	(61.6–65.3)	(57.5–62.2)

Self-reported rates of service use received as part of the Medicare Stop Smoking Program or purchased independently.
95% confidence intervals in parentheses.
†Statistically different from Usual Care at the 5% level of significance.

Table 3: Rates of Attempts to Quit Smoking for at Least 24 Hours within the First 6 and 12 Months

	Usual Care	*Provider Counseling*	*Provider Counseling + Pharmacotherapy*	*Telephone Quitline*
Full sample ($N = 7{,}354$)				
6 months	47.8	47.9	53.7†	55.0†
	(45.8–49.9)	(44.5–51.3)	(51.8–55.7)	(52.7–57.4)
12 months	64.2	63.4	69.1†	69.2†
	(62.2–66.2)	(60.2–66.7)	(67.4–70.9)	(67.0–71.4)
Respondents only ($N = 5{,}619$)				
12 months	78.4	78.5	83.7†	86.9†
	(76.5–80.4)	(75.2–81.7)	(82.1–85.3)	(85.0–88.7)

Based on self-reports of attempts to quit smoking for at least 24 hours at the 6- and 12-month surveys. The full sample ($N = 7{,}354$) assumes that survey nonrespondents did not attempt to quit smoking over the relevant period. Respondents ($N = 5{,}619$) refer to participants responding to either the 6- or 12-month survey.

†Statistically different from Usual Care at the 5% level of significance.

Quit rates, adjusted for covariates, were very similar to the unadjusted values (not shown). Similarly, imputed quit rates, where the smoking status of each nonresponder is predicted based on his/her individual characteristics, were higher in absolute terms, but differences across treatment arms were substantively unchanged.

Cost-Effectiveness

Because those enrolled in the MSSP are more motivated to quit smoking than the average Medicare-eligible smoker (based on their decision to enroll), we

Table 4: Rates of Smoking Cessation at 6 and 12 Months

Unadjusted Rates	*Usual Care*	*Provider Counseling*	*Provider Counseling + Pharmacotherapy*	*Telephone Quitline*
6 months	9.9	11.9	15.8†	21.2†
	(8.7–11.2)	(9.7–14.2)	(14.4–17.2)	(19.2–23.1)
12 months	10.2	14.1†	15.8†	19.3†
	(9.0–11.5)	(11.7–16.5)	(14.4–17.2)	(17.4–21.2)

Figures represent the percentage of participants in each intervention arm who reported not having smoked in the last 7 days at the time of the 6- and 12-month surveys. All survey nonrespondents are assumed to be smoking.

95% confidence intervals in parentheses.

†Statistically different from Usual Care at the 5% level of significance.

compared the cost-effectiveness of the three active interventions relative to Usual Care. The results (not shown), indicate that the additional cost to Medicare per quitter (relative to Usual Care) ranged from $463 to $6,450, with the average cost per quitter increasing with the intensity of resource use. Using imputed (higher) quit rates lowered the incremental costs per quitter by 35–40 percent. The analysis assumed that the costs of cessation counseling and Pharmacotherapy were borne by the Centers for Medicare and Medicaid Services (CMS) regardless of whether those treatments were provided through the MSSP. This more accurately reflects the costs to CMS if any of the services were to become a part of a Medicare benefit, which would "crowd out" treatments currently paid for by other third-party payers or Medicare beneficiaries. These estimates are comparable to a prior analysis of working-age adults, which found that the average cost to the health plan per quitter ranged from $797 to $1,171 depending on the extent of insurance coverage for cessation services(Curry et al. 1998).

DISCUSSION

The MSSP is the first large-scale demonstration to test the effectiveness of three variations of a Medicare smoking cessation benefit in real-world settings. Each treatment significantly outperformed the Usual Care intervention by 12 months, and increasingly intensive treatments significantly outperformed less-intensive treatments, with the Quitline producing the highest quit rates. At the inception of the study, it was unclear whether any one evidence-based intervention would outperform another. The results here are somewhat mixed, with the Provider Counseling arm failing to outperform Usual Care at 6 months, but not at 12 months, and the Provider Counseling + Pharmacotherapy arm outperforming the Provider Counseling arm at 6 months but not 12 months. Unequivocally, however, the Quitline arm outperformed all other treatment arms at both follow-up intervals. Rates of confirmed smoking cessation in the MSSP compared favorably with quit rates in the general population and were higher than expected for older adults. Further, differences across treatment arms were robust to a broad set of covariates and survey nonresponse.

Although quit rates were highest in the Quitline, physician counseling alone or in conjunction with Pharmacotherapy was more cost-effective. The fact that Provider Counseling, which had the lowest quit rate among the three active interventions, was in some cases the most cost-effective treatment is not

surprising. Interventions that are more resource intensive are typically more effective than less resource intensive programs, but the costs of the former tend to be proportionally higher than those of the latter (Warner 1997). Different approaches to smoking cessation may be more or less effective (and cost-effective) for different groups or people. Seniors who successfully quit smoking while using high-intensity interventions such as physician counseling with NRT may not be successful with low-intensity interventions. The search for the single most effective or cost-effective intervention may be misguided, for it presumes that all smokers have similar preferences in choosing a cessation method.

An important question is how our results generalize to the Medicare population given that enrollees in the MSSP were more motivated to quit smoking than the average Medicare-eligible smoker. Absolute quit rates at 12 months were 10 percent in Usual Care, 14–16 percent in the physician counseling arms, and 19 percent in the telephone Quitline. This suggests that providing coverage for cessation services would increase quit rates by 50–100 percent among older smokers motivated to quit, depending on the type of service.

The majority of Quitline participants had five or more contacts with a counselor. The Quitline counselors delivered a structured intervention tailored to both senior smokers in general and to the individual smoker's circumstances in particular. In addition to greater frequency of counseling received in this arm compared with the Provider Counseling arms, the intervention included support in the proper use of the nicotine patch and dealing with side effects. Thus, it is not surprising that this highly structured, proactive, and individualized counseling experience, when combined with the opportunity to use low-cost nicotine patches, produced superior outcomes.

A larger increase in cessation was observed when participants were also given the opportunity to use Pharmacotherapy at minimal cost. This is consistent with meta-analytic studies, which have shown that use of the nicotine patch or bupropion significantly increases quit rates compared with placebo or minimal treatment (Fiore et al. 1996; Hurt et al. 1997; Jorenby et al. 1999). This study is one of the few to directly manipulate the addition of Pharmacotherapy to behavioral treatment, and the results support the assertion that the addition is beneficial. Hughes et al. (2003) proposed several hypotheses by which behavioral and pharmacologic treatments might combine to increase efficacy, including: (1) Pharmacologic treatment provides relief of withdrawal early on and provides the necessary bridge through the most difficult period, whereas behavioral treatment provides skills necessary to prevent relapse

subsequently, (2) behavioral skills may be specifically helpful for a subset of smokers, whereas pharmacologic treatment helps another subset, and (3) one treatment may increase compliance with the other.

There are two justifications for offering cessation services through health care providers. First, the vast majority of older smokers have contact with a physician each year, with multiple occasions to provide cessation interventions (USDHHS 1994). Second, smokers who receive even brief clinical interventions demonstrate significantly increased cessation rates compared with those who receive no advice, and there is a dose-dependent relationship between the intensity of person-to-person contact and successful cessation outcome (Fiore et al. 1996, 2000). One disadvantage of a provider-based intervention is that clinicians do not take full advantage of opportunities to intervene with their patients who smoke. Only about half of current smokers report that their physicians have either asked them about smoking or advised them to quit (Goldstein et al. 1997). Providing adequate reimbursement for counseling services would remove an important barrier, but can substantially increase the costs of the program (Niaura and Abrams 2002).

A national telephone Quitline provides a single access point for smokers and has been shown to be effective. One disadvantage of a telephone Quitline is that treatment must be initiated by the beneficiary. One can, however, envision systems where health care providers refer their smoking patients to a free national Quitline while providing them with pharmacologic assistance, if warranted.

Our analysis has several limitations. Most prominent was low enrollment in southeast Florida. While enrollees differed across intervention arms in a statistical sense with regard to race, education, income, lifetime quit attempts, and stages of change, the differences were modest in absolute terms. Further, we controlled for these factors in multivariate models and included binary indicators for each state. The fact that the unadjusted and adjusted quit rates were nearly identical provides strong evidence that the randomization process worked despite the enrollment problem in southeast Florida.

Second, we did not know the number of counseling sessions received in the Provider Counseling arms nor the quality of the advice. The initial 6-month survey asked participants about the number of Provider Counseling visits. However, to increase response rates, shortened versions of the follow-up surveys were sent to those who did not initially respond. The short-form surveys only asked participants whether they had tried any of the methods listed, and if they did, whether that particular quit method was offered as part of the MSSP.

Finally, self-reported measures were likely to underestimate actual use of counseling services as participants may not recall whether counseling occurred, how counseling was reimbursed, or what constitutes counseling. Thus, we may underestimate the costs of providing coverage for cessation counseling by providers.

In 2005, Medicare began covering cessation counseling for beneficiaries diagnosed with a smoking-related illness or who were taking medications complicated by tobacco use. Further, the Department of Health and Human Services recently launched a national telephone Quitline for all smokers in the Unites States. The results of this study suggest that a fully integrated benefit structured around low-cost Pharmacotherapy in conjunction with available free Quitline services would substantially reduce the prevalence of smoking and smoking-related illness among elderly beneficiaries motivated to quit, at a relatively modest cost. Future work should examine the reduction in medical costs associated with cessation among older smokers to assess how coverage of these services affects total Medicare outlays.

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NOTES

1. We obtained very limited information on callers who did not begin the qualification survey. As a result, we cannot reliably describe the characterization of these callers.

2. More than 95 percent of Quitline participants enrolled in the proactive Hotline with coverage of the nicotine patch.
3. The cost-effectiveness analysis assumed that all participants who received counseling advice from their provider received 1.5 counseling sessions per year (Provider Counseling arms only). This assumption was based on the average responses of participants who completed the long-form survey, which asked them to report the number of times they received cessation advice from their health care provider.

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SUPPORTING INFORMATION

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Appendix SA1: Author Matrix.

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