RESEARCH ARTICLE

Incentives and Patches for Medicaid Smokers: An RCT

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Introduction: Most successful trials of financial incentives for smoking cessation have offered large rewards contingent on outcomes. This study examines whether more modest incentives to encourage engagement, non-contingent on outcomes, also increase cessation; whether sending medications directly to participants boosts quitting; and whether these strategies are effective in Medicaid.

Study design: Three-group RCT of usual care (UC); nicotine patch (NP); and NP and financial incentive (NP+FI).

Setting/participants: Medicaid beneficiaries calling the California Smokers' Helpline, 2012 −2013 (N=3,816). Data were analyzed in 2017.

Intervention: All participants enrolled in evidence-based, multisession telephone counseling. All received proof of enrollment with which they could obtain free quitting aids at their pharmacy. NP and NP+FI also received nicotine patches sent to their homes. NP+FI received up to $60 for completing counseling calls.

Main outcome measures: Quit attempt rate, 7-day and 30-day abstinence at 2 and 7 months, and 6-month prolonged abstinence (primary outcome).

Results: In both complete-case and intention-to-treat analyses, outcomes trended upward from UC to NP to NP+FI. Differences between NP and UC were generally nonsignificant. By contrast, the NP+FI group significantly outperformed the other groups on all measures. In intention-to-treat analysis, compared with UC, NP+FI was more likely to make a quit attempt (68.4% vs 54.3%, $p < 0.001$); be abstinent for 7 days at 2 months (36.1% vs 25.5%, $p < 0.001$) and 7 months (21.2% vs 16.1%, $p=0.002$); be abstinent for 30 days at 2 months (30.0% vs 18.9%, $p < 0.001$) and 7 months (21.5% vs 16.7%, $p=0.004$); and achieve 6-month prolonged abstinence (13.2% vs 9.0%, $p=0.001$).

Conclusions: Financial incentives increased treatment engagement and short- and long-term smoking cessation, despite being modest and non-contingent on outcomes. The study found that incentives can be effective in a Medicaid population, and can feasibly be integrated into existing quitline services.

Trial registration: The trial is registered at www.clinicaltrials.gov NCT01502306.

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INTRODUCTION

Tobacco use in Medicaid presents an enormous public policy challenge. About one third of adult Medicaid beneficiaries smoke, nearly double the rate of the general population in the U.S.[1] The Surgeon General has estimated that 15.2% of Medicaid costs in 2010 were attributable to smoking.[2] And although smoking has decreased significantly in the U.S. as a whole, the decrease among Medicaid beneficiaries has been comparatively slow.[3] In fact, a recent analysis of National Health Information Survey data from 1997 to 2013 shows that the drop in the Medicaid smoking rate was statistically negligible.[4] With enrollment rising and Medicaid smokers quitting at a slower rate, the proportion of U.S. smokers in Medicaid more than doubled from 8.0% in 1997 to 17.1% in 2013. The proportion of U.S. smokers in Medicaid increased further under the Affordable Care Act, which funded a major expansion of Medicaid beginning in 2014.[5,6] The growing concentration of smokers in Medicaid highlights the need for more effective policies to reduce tobacco use in this population.[4,7,8]

One promising but understudied approach is to offer smokers in Medicaid a financial incentive to quit. It has reasonably been proposed that such incentives may have the greatest impact in populations with the least purchasing power.[9—11] Offering an incentive can motivate low-income smokers to call a tobacco quitline.[12,13] However, to date there has been only limited research on the impact of incentives on smoking-cessation outcomes in Medicaid or other low-income populations. Several clinical trials have found that incentives can boost long-term quitting rates in non-Medicaid settings.[14,15] They have proven effective in corporate workplaces[16—18] and in rural villages.[19] They have helped pregnant smokers quit and remain abstinent postpartum.[20—23] Two recent trials found that incentives can be effective specifically with low-income smokers.[24,25] Notably, the trials demonstrating efficacy to date have offered incentives that are fairly large—ranging from $190 to $1,650—and contingent on particular outcomes.[24,25]

The present study attempts to fill some gaps in the literature. It examines whether offering more modest incentives, up to $60 total, solely to support program participation and that are non-contingent on outcomes can increase cessation. It also examines whether removing a treatment barrier by sending cessation medications directly to participants can boost quitting. Finally, the study examines whether these strategies are effective in a Medicaid population.

METHODS

Study Sample

This randomized trial was embedded in the ongoing service of the California Smokers' Helpline, a tobacco quitline. Participants (N=3,816) were treatment-seeking daily smokers who called the quitline between July 2012 and May 2013, completed an intake interview in which they met inclusion criteria for the study, and provided consent to participate (Figure 1). To be eligible, participants had to speak English or Spanish, be aged ≥ 18 years, be a daily smoker, be enrolled in Medi-Cal (the Medicaid program in California) under Title XIX,[26] and provide sufficient contact information. Callers were excluded if they were eligible for free nicotine patches through a separate quitline campaign or if they completed intake with staff not trained to consent study participants. Smokers with uncontrolled high blood pressure, arrhythmia or angina, a history of heart attack or stroke within the previous 6 months, severe allergy to adhesive, or current pregnancy required medical approval to participate. In these cases, the quitline faxed a form to their doctor explaining the apparent contraindication(s) and requesting signed approval. There was no racial or sex bias in the selection of participants.

All participants provided oral consent for participation and were sent a detailed written consent form in the mail. The study, including the oral consent procedure, was approved by the Human Research Protections Program of the University of California, San Diego (No. 120216). The trial was registered December 2011 (NCT01502306).

Participants were consented and randomized at intake unless they required medical approval, in which case they were randomized when approval was obtained.

At the time of the study there was a separate campaign, not part of the trial, to encourage Medi-Cal smokers to call the quitline and receive a $20 gift card for completing a first counseling session. These callers were not excluded from the study because in real-world quitline operations, it is common to employ a broad range of promotional strategies to drive demand. To determine whether this campaign influenced outcomes, participants were stratified by whether they had called in response to the gift card offer.

Participants were then randomly assigned by computer to one of three groups: usual care (UC); nicotine patches (NP); or nicotine patches + financial incentives (NP+FI). Group assignment was in the ratio of 1.0 to 1.4 to 1.4, respectively, with a block size of 19 within each stratum. Greater proportions were assigned to NP and NP+FI so that more participants would receive free patches. The main hypotheses for the study were that outcomes would be significantly better for NP than for UC, and significantly better for NP+FI than for NP.

Measures

Telephone counseling. Participants in all three groups received quitline counseling[27] following protocols proven effective in previous trials.[28,29] Counseling included a pre-quit call of $\cong 30$ minutes, in which counselors used Motivational Interviewing to enhance participants' motivation to quit, attempted to boost their self-efficacy, and helped them develop a solid quitting plan. Counseling also included four sessions of 5—10 minutes each during the first month of quitting to help participants implement their plans, adjusting as needed. These sessions were front-
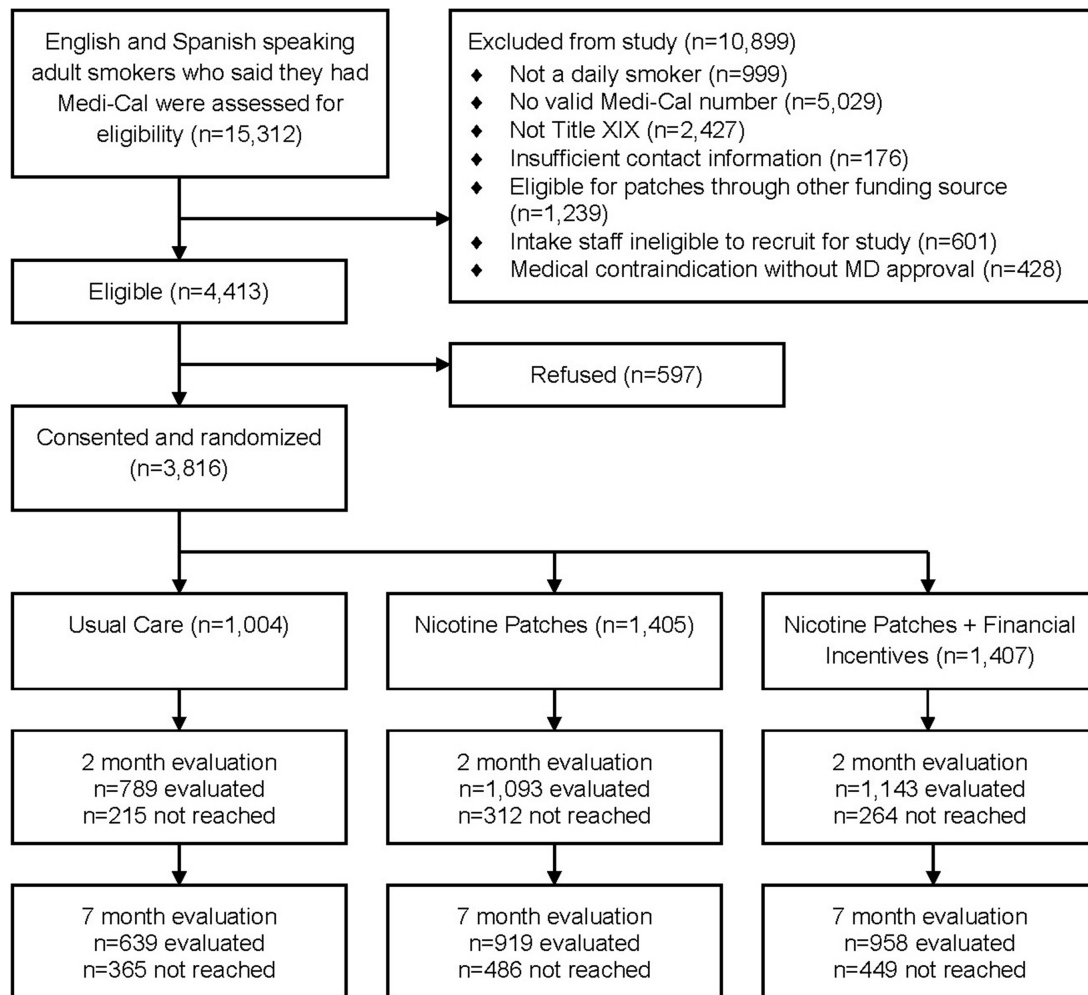
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┌─────────────────────────────┐        ┌────────────────────────────────────────────────┐
│ English and Spanish speaking│        │ Excluded from study (n=10,899)                   │
│ adult smokers who said they │        │  ♦ Not a daily smoker (n=999)                    │
│ had Medi-Cal were assessed  │        │  ♦ No valid Medi-Cal number (n=5,029)            │
│ for eligibility (n=15,312)  │        │  ♦ Not Title XIX (n=2,427)                       │
└─────────────────────────────┘        │  ♦ Insufficient contact information (n=176)      │
              │                         │  ♦ Eligible for patches through other funding    │
              │────────────────────────▶    source (n=1,239)                              │
              │                         │  ♦ Intake staff ineligible to recruit for study  │
              ▼                         │    (n=601)                                       │
┌─────────────────────────────┐        │  ♦ Medical contraindication without MD approval  │
│ Eligible (n=4,413)          │        │    (n=428)                                       │
└─────────────────────────────┘        └────────────────────────────────────────────────┘
              │
              │────────────────────────▶  ┌──────────────────────┐
              │                            │ Refused (n=597)      │
              ▼                            └──────────────────────┘
┌─────────────────────────────┐
│ Consented and randomized    │
│ (n=3,816)                   │
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Usual Care (n=1,004)	Nicotine Patches (n=1,405)	Nicotine Patches + Financial Incentives (n=1,407)
2 month evaluation n=789 evaluated n=215 not reached	2 month evaluation n=1,093 evaluated n=312 not reached	2 month evaluation n=1,143 evaluated n=264 not reached
7 month evaluation n=639 evaluated n=365 not reached	7 month evaluation n=919 evaluated n=486 not reached	7 month evaluation n=958 evaluated n=449 not reached

Figure 1. Flow of participants in the RCT.

loaded during the critical first weeks of quitting when the probability of relapse is highest.[30] In the event of slips or relapse, participants were urged to keep trying. Over time they were encouraged to adopt the self-image of a nonsmoker, as a hedge against relapse.[27]

Nicotine patches. The three groups differed in how participants accessed quitting aids. UC followed the standard Medi-Cal procedure, in which smokers first had to obtain a doctor's prescription and proof of enrollment in counseling before they could access free quitting aids at their local pharmacy. They could obtain nicotine replacement therapy, bupropion, or varenicline. Medi-Cal covered 28 weeks of treatment annually, in 4-week increments.

In NP and NP+FI, the quitline sent over-the-counter patches directly to participants via express mail, eliminating the need for a prescription and trip to the pharmacy. They received 4 weeks of patches at a time, with unlimited refills as long as they were engaged in counseling and actively quitting. Participants in all groups who wanted to use other quitting aids could use the standard Medi-Cal procedure to obtain them, as proof of enrollment was sent to all participants.

Financial incentives. Participants in NP+FI received a $20 gift card for completing a pre-quit counseling call and a second card based on the number of follow-up counseling calls they completed ($10 per call, up to a maximum of $40). The first card was sent immediately after the initial counseling call, to reward participants for taking the first step and to incentivize them to continue. The second card was sent 6 weeks after enrollment, by which time most participants had finished the program. Participants could continue receiving counseling after 6 weeks, but there was no financial incentive for these additional sessions.

Evaluation staff contacted participants 2 and 7 months after enrollment. A computer-assisted telephone interview was used to assess smoking status, quit attempts, and use of quitting aids. Information about slips and relapses was anchored to specific dates to allow analysis of multiple outcome measures. These included the quit attempt rate and rates of abstinence for various lengths of time. Quit attempt rate was defined as the percentage of participants who quit smoking for ≥24 hours since enrollment. Seven- and 30-day abstinence rates were calculated at both 2- and 7-month evaluations. Seven-day abstinence was defined as not having smoked, even a puff, for ≥7 days at the

time of evaluation. Thirty-day abstinence was defined as not having smoked for 30 days at the time of evaluation, allowing for slips of one day or less.[28,31] Six-month prolonged abstinence was calculated at the 7-month evaluation, and was defined as not smoking for ≥180 days, again allowing for slips of 1 day or less. The primary outcome measure was intention-to-treat (ITT) 6-month prolonged abstinence. Participants in NP and NP+FI were asked if they had used the patches sent by the quitline and all participants were asked if they had used other patches or quitting aids, such as nicotine gum, nicotine lozenges, bupropion, or varenicline. Because of this variation in the protocol, evaluation staff could not be blinded to participants' treatment assignment.

Statistical Analysis

Descriptive analytics were used to examine differences among study groups on demographic characteristics and tobacco consumption. The groups were also compared on patches received, counseling received, and quitting aids used, with 95% CIs presented in tables.[32] The main hypotheses were evaluated using Fisher's exact test.[32] An additional analysis was conducted to examine if the separate campaign of offering $20 gift cards for calling the quitline, which led to a portion of participants requesting the gift card at the time of their first contact with the quitline, moderated the intervention effect. Outcomes were analyzed using both complete-case analysis, including only those reached for evaluation, and ITT analysis, including all participants and counting those lost to follow-up as smokers who made no attempt to quit. Analyses were conducted in 2017 using SAS, version 9.4.

RESULTS

Baseline characteristics of participants (N=3,816) are presented in Table 1. There was equivalence of conditions at baseline on all key demographics and on cigarettes per day. About two thirds of participants were female. The mean age was about 46 years. Approximately 40% were of ethnic minority or multiracial backgrounds. About 60% had a high school education or less. Mean daily cigarette consumption was 17.

Table 2 shows the percentages of participants sent nicotine patches and the percentages who reported using quitting aids. As shown in the first row, no participants in UC and nearly all (>99%) individuals in the NP and NP+FI groups were sent patches, per study protocol.

Quitting aid utilization rates were based on the self-report of participants reached for evaluation at 2 or 7 months. In all groups, the quitting aid most commonly used was patches. In UC, 51.8% had used them by the 7-month evaluation. Both patch groups were considerably more likely to use them: 86.5% of NP and 89.4% of NP+FI participants had used patches by the 7-month evaluation.

Varenicline was the second most commonly used product, again in all groups. But the pattern seen with patches was reversed: the UC group was significantly more likely to use varenicline than either patch group. Rates at 7 months were 15.8% for UC compared with 10.8% for NP and 10.0% for NP+FI.

Table 3 shows utilization of behavioral interventions, including telephone counseling and financial incentives. Although all groups had high rates of completing a first counseling call, the NP group had a statistically lower rate, 89.9%, compared with 93.2% for the UC group and 95.5% for the NP+FI group.

As mentioned earlier, at the time of the study there was a separate campaign to encourage Medi-Cal smokers to call the quitline and receive a $20 gift card for completing a counseling call. About one fifth of participants in the UC and NP groups did so and received this incentive. By contrast, 95.5% of participants in the NP+FI group received a $20 gift card, as everyone assigned to this group received the incentive if they completed the first call.

Among participants who completed a first call, the NP+FI group utilized more counseling than the other two groups. They were significantly less likely to drop out after the first session (9.0% vs 18.0% for UC and 14.9% for NP) and significantly more likely to complete four or more follow-up calls (65.8% vs 41.7% for UC and 45.1% for NP). They completed one more call on average than participants in the other two groups (median=5 vs 4).

Among participants in the three groups, only those in the NP+FI group received a second gift card for completing additional calls, per study protocol. As Table 3 shows, more than half (58.0%) of NP+FI participants who completed a first counseling call received a $40 gift card for completing all four follow-up calls ($10 per call) within the initial 6-week counseling period. Another 31.4% received gift cards ranging in value from $10 to $30 for completing one to three follow-up calls.

Table 4 shows quitting outcomes by treatment group at 2 and 7 months, using both complete-case and ITT analyses. The complete-case analysis is based on participants who completed either the 2- or 7-month evaluation interview. The ITT analysis includes all randomized participants, counting those not reached for evaluation at 2 or 7 months as smoking at the respective time point.

The complete-case analysis shows that at 2 months, NP+FI group participants were more likely to have made a quit attempt (84.2%) than NP (77.5%) group participants, who in turn were more likely than UC (69.2%, both $p<0.001$) group participants. The NP+FI group had significantly higher 7- and 30-day abstinence rates (44.4% and 36.9%, respectively) than either NP (33.1% and 25.7%) or UC (32.5% and 24.1%, all $p<0.001$). A similar pattern was observed at 7 months. Moreover, the NP+FI group had a higher 6-month prolonged abstinence rate

Table 1. Baseline Characteristics of Participants

Characteristics	Usual care, % (95% CI) (*n*=1,004)	Nicotine patches, % (95% CI) (*n*=1,405)	Nicotine patches + Financial incentives, % (95% CI) (*n*=1,407)
Gender			
Female	67.2 (64.3, 70.1)	68.0 (65.5, 70.4)	67.7 (65.2, 70.1)
Male	32.8 (29.9, 35.7)	32.0 (29.6, 34.5)	32.3 (29.9, 34.8)
Age, years			
18−24	5.3 (3.9, 6.7)	4.8 (3.6, 6.0)	4.5 (3.4, 5.6)
25−44	35.4 (32.4, 38.4)	36.6 (34.1, 39.1)	35.5 (33.0, 38.0)
45−64	54.8 (52.7, 57.9)	52.9 (50.3, 55.5)	54.1 (51.5, 56.7)
≥ 65	4.6 (3.3, 5.9)	5.7 (4.5, 6.9)	6.0 (4.7, 7.3)
Mean age, years	46.1 (45.3, 46.9)	46.0 (45.3, 46.7)	46.5 (45.8, 47.2)
Race/ethnicity			
White	61.3 (58.3, 64.3)	58.4 (55.8, 61.0)	58.2 (55.6, 60.8)
Black	15.8 (13.5, 18.1)	19.6 (17.5, 21.7)	20.1 (18.0, 22.3)
Hispanic	9.1 (7.3, 10.9)	10.1 (8.5, 11.7)	9.8 (8.2, 11.4)
Asian/Pacific Islander	1.9 (1.0, 2.8)	1.7 (1.0, 2.4)	1.1 (0.5, 1.7)
American Indian	1.9 (1.0, 2.8)	2.7 (1.0, 3.6)	2.2 (1.4, 3.0)
Multi-racial	9.8 (7.9, 11.7)	7.3 (5.9, 8.7)	8.1 (6.7, 9.5)
Other	0.1 (0, 0.30)	0.3 (0, 0.6)	0.4 (0, 0.8)
Education, years			
≤ 12	58.8 (55.7, 61.9)	60.1 (57.5, 62.7)	58.5 (55.9, 61.1)
> 12	41.2 (38.3, 44.1)	39.9 (37.3, 42.5)	41.5 (39.0, 44.0)
Cigarettes per day (mean)	17.7 (17.0, 18.4)	17.4 (16.9, 17.9)	17.1 (16.6, 17.6)

Table 2. Patch Provision and Use of Quitting Aids

Measure	Usual care, % (95% CI)	Nicotine patches, % (95% CI)	Nicotine patches + Financial incentives, % (95% CI)
Patches sent to participant	*n*=1,004	*n*=1,405	*n*=1,407
	0	99.4 (99.0, 99.8)	99.7 (99.4, 100.0)
Used quitting aid within 2 months[a]	*n*=789	*n*=1,093	*n*=1,143
Patches	41.8 (38.4, 45.3)	82.2 (79.9, 84.4)	85.7 (83.7, 87.8)
Gum	4.7 (3.2, 6.2)	4.3 (3.1, 5.5)	4.1 (3.0, 5.3)
Lozenge	1.3 (0.5, 2.0)	0.6 (0.2, 1.1)	1.7 (0.9, 2.4)
Bupropion	3.2 (1.9, 4.4)	2.7 (1.8, 3.7)	3.9 (2.8, 5.1)
Varenicline	12.7 (10.4, 15.0)	8.0 (6.4, 9.6)	6.7 (5.1, 8.0)
Any quitting aid	60.1 (56.7, 63.5)	87.3 (85.3, 89.3)	90.4 (88.7, 92.1)
Used quitting aid within 7 months[b]	*n*=639	*n*=919	*n*=958
Patches	51.8 (47.9, 55.7)	86.5 (84.3, 88.7)	89.4 (87.4, 91.3)
Gum	6.3 (4.4, 8.1)	6.3 (4.7, 7.9)	7.1 (5.5, 8.7)
Lozenge	2.7 (1.4, 3.9)	1.2 (0.5, 1.9)	1.8 (0.9, 2.6)
Bupropion	4.5 (2.9, 6.2)	3.7 (2.5, 4.9)	4.9 (3.5, 6.3)
Varenicline	15.8 (13.0, 18.6)	10.8 (8.8, 12.8)	10.0 (8.1, 11.9)
Any quitting aid	72.1 (68.7, 75.6)	92.0 (90.2, 93.7)	93.6 (92.1, 95.2)

[a]Rates are based on participants reached for evaluation at 2 months.
[b]Rates are based on participants reached for evaluation at 7 months.

Table 3. Use of Behavioral Interventions

Measure	Usual care, % (95% CI)	Nicotine patches, % (95% CI)	Nicotine patches + Financial incentives, % (95% CI)
		Treatment group	
First counseling call	*n*=1,004	*n*=1,405	*n*=1,407
	93.2 (91.7, 94.8)	89.9 (88.3, 91.5)	95.5 (94.4, 96.5)
$20 incentive for first call	*n*=1,004	*n*=1,405	*n*=1,407
	19.7 (17.3, 22.2)	21.3 (19.1, 23.4)	95.5 (94.4, 96.5)
Follow-up counseling calls[a]	*n*=936	*n*=1,263	*n*=1,343
0 calls	18.0 (15.5, 20.4)	14.9 (13.0, 16.9)	9.0 (7.5, 10.5)
1 call	12.9 (10.8, 15.1)	13.3 (11.4, 15.2)	6.5 (5.2, 7.8)
2 calls	12.3 (10.2, 14.4)	13.0 (11.1, 14.8)	8.9 (7.4, 10.5)
3 calls	15.2 (12.9, 17.5)	13.7 (11.8, 15.6)	9.8 (8.2, 11.3)
≥4 calls	41.7 (38.5, 44.8)	45.1 (42.4, 47.9)	65.8 (63.3, 68.4)
Incentives for follow-up calls[a,b]	*n*=936	*n*=1,263	*n*=1,343
$0	0	0	10.6 (8.9, 12.2)
$10	0	0	7.4 (6.0, 8.9)
$20	0	0	9.7 (8.1, 11.3)
$30	0	0	14.3 (12.4, 16.2)
$40	0	0	58.0 (55.4, 60.6)
No. of follow-up calls[a]	*n*=936	*n*=1,263	*n*=1,343
Mean	5.0 (4.6, 5.2)	5.1 (4.8, 5.3)	6.2 (5.9, 6.4)
Median	4	4	5

[a]Based on participants who completed a first counseling call.
[b]Participants in Nicotine patches+Financial incentives received $10 for each follow-up counseling call completed within 6 weeks of intake. Differences between the percentages completing follow-up counseling calls and the percentages receiving incentives were due to calls completed after the 6-week eligibility period.
No., number.

(19.3%) than either NP or UC groups (15.8% and 14.1%, respectively, both *p* < 0.05). Except for quit attempt rates, the NP group was not significantly different from the UC group on any of these measures.

The ITT analysis yielded lower rates across the board, as those who could not be reached for evaluation were assumed to be smoking, but the pattern was the same. NP+FI participants were more likely to make a quit attempt (68.4%) than NP participants (60.2%, *p* < 0.001), and NP participants were more likely to make an attempt than UC participants (54.3%, *p*=0.004). The NP+FI group had significantly higher 7- and 30-day abstinence rates (36.1% and 30.0%, respectively) than either NP (25.8% and 20.0%) or UC groups (25.5% and 18.9%, all *p* < 0.001). The NP group did not differ from the UC group on either measure.

Similarly, at 7 months, the NP+FI group had a higher 7-day abstinence rate (21.2%) than NP (16.4%, *p*=0.002) and UC (16.1%, *p*=0.001) groups; a higher 30-day abstinence rate (21.5%) than NP (16.9%, *p*=0.004) and UC (16.7%, *p*=0.002) groups; and a higher 6-month prolonged abstinence rate (13.2%) than NP (10.3%, *p*=0.001) and UC groups (9.0%, *p*=0.02). ITT 6-month prolonged abstinence was the most rigorous measure used, and the

primary outcome measure for the study. Again, NP did not differ from UC on any of these measures.

The relative risk (RR) for ITT 6-month prolonged abstinence was 1.15 (95% CI=0.90, 1.48) for NP versus UC; 1.27 (95% CI=1.04, 1.66) for NP+FI versus NP; and 1.47 (95% CI=1.16,1.86) for NP+FI versus UC (numbers not shown). The number needed to treat, again using 6-month prolonged abstinence in an ITT analysis, was 34 for NP+FI versus NP and 24 for NP+FI versus UC (numbers not shown).

Additional analysis was conducted to assess whether the intervention effect differed between those who called the quitline for a $20 gift card as offered by a separate campaign and those who did not. A logistic regression was conducted for ITT 6-month prolonged abstinence. There was no significant interaction between the treatment condition X calling in response to the offer. More specifically, there was no significant difference in quitting outcome between those who did and those who did not call in response to the offer (*p*=0.54), and there was no significant interaction between treatment condition X calling in response to the offer, either for the comparison between NP and UC groups (*p*=0.21) or for the comparison between NP+FI and UC groups (*p*=0.42). The

Table 4. Quitting Outcomes of Three Treatment Groups

Measure	Usual care, %	Nicotine patches, %	Nicotine patches + Financial incentives, %	NP vs UC, *p*-value	NP+FI vs NP, *p*-value	NP+FI vs UC, *p*-value
Complete-case[a]						
2 month evaluation	*n*=789	*n*=1,093	*n*=1,143			
Made quit attempt	69.2	77.5	84.2	**< 0.0001**	**< 0.0001**	**< 0.0001**
≥ 7 days abstinent	32.5	33.1	44.4	0.75	**< 0.0001**	**< 0.0001**
≥ 30 days abstinent	24.1	25.7	36.9	0.42	**< 0.0001**	**< 0.0001**
7 month evaluation	*n*=639	*n*=919	*n*=958			
≥ 7 days abstinent	25.4	25.1	31.1	0.92	**0.004**	**0.012**
≥ 30 days abstinent	26.3	25.8	31.5	0.05	**0.006**	**0.02**
≥ 6 months abstinent	14.1	15.8	19.3	0.36	**0.04**	**0.007**
Intention-to-treat[b]						
2 month evaluation	*n*=1,004	*n*=1,405	*n*=1,407			
Made quit attempt	54.3	60.2	68.4	**0.004**	**< 0.0001**	**< 0.0001**
≥ 7 days abstinent	25.5	25.8	36.1	0.88	**< 0.0001**	**< 0.0001**
≥ 30 days abstinent	18.9	20.0	30.0	0.51	**< 0.0001**	**< 0.0001**
7 month evaluation	*n*=1,004	*n*=1,405	*n*=1,407			
≥ 7 days abstinent	16.1	16.4	21.2	0.84	**0.001**	**0.002**
≥ 30 days abstinent	16.7	16.9	21.5	0.93	**0.002**	**0.004**
≥ 6 months abstinent	9.0	10.3	13.2	0.27	**0.02**	**0.001**

Note: Boldface indicates statistical significance (*p* < 0.05).
[a]Complete case rates are based on participants reached for evaluation at the stated intervals.
[b]ITT rates are based on all participants randomly assigned, counting those not reached for evaluation as smokers.
FI, financial incentives; NP, nicotine patches; UC, usual care.

differences between three treatment conditions remained the same as in the main analysis.

DISCUSSION

This large randomized trial evaluated different strategies for helping Medicaid beneficiaries quit smoking through a statewide quitline. Specifically, it assessed whether sending either nicotine patches alone or patches plus financial incentives improves participants' outcomes, relative to a usual care condition of proactive, multisession telephone counseling. The counseling was previously shown to increase quit attempts and double quit rates.[28,29]

Participants in the NP group (i.e., those who received patches only but no financial incentives) received patches sent directly by the quitline. This removed what was hypothesized to be a key barrier to treatment, because participants would otherwise need to get a doctor's prescription and have it filled at a pharmacy to obtain medication. The study showed that sending patches directly to participants did increase the use of cessation medications. More than nine in ten participants in the NP group reported using some form of medication. However, use of medications was also high in the UC group, with more than seven in ten using them. Sending patches also led to a slight increase in quit attempts (significant in both complete-case and ITT

analyses) although the NP group used less counseling than the UC group (perhaps because their improved access to quitting aids made them feel they needed less behavioral support). But sending patches did not have a significant effect on abstinence. The lack of effect probably says little about nicotine patches, whose efficacy as a cessation aid is well established.[33] Rather, it is likely due to robust treatment utilization in the UC group. Not only did more than 70% in the UC group obtain a quitting aid on their own but more than 90% completed an initial counseling session (slightly higher than in the NP group), with the median completing four follow-up calls (the same as in the NP group). Given the high rates of treatment utilization in both groups, a 20-percentage-point difference in medication use was insufficient to produce a statistically meaningful difference in outcomes for the patch comparison.

By contrast, the NP+FI group clearly did better than the NP group. The NP+FI group could receive the same counseling and patches as NP, plus incentives of $20 for completing a first counseling session and $10 for each of four follow-up counseling sessions, for a total possible incentive of $60. On process measures, they were more likely to complete a first counseling call, completed more follow-up counseling calls, and used cessation medications at similarly high rates. On outcome measures, they were more likely to make a quit

attempt, more likely to be abstinent for 7 or 30 days at both 2 and 7 months, and more likely to achieve 6-month prolonged abstinence. The NP+FI group also compared favorably to the UC group, on most process measures and all outcomes.

Although previous trials of incentives have achieved significant effects, this study is unique in demonstrating that even modest incentives can have a statistically meaningful impact on smoking cessation outcomes. One successful trial, conducted in Switzerland, provided total rewards of up to $1,650 per participant.[24] Two others in U.S. corporate settings provided incentives of $750 to $800.[16,17] Three trials with pregnant smokers provided incentives worth up to several hundred dollars.[20−23] A study in Thailand provided only $50 (in addition to participants' own deposits), but in context this amount is also large, as it represented 20% of average monthly income in the rural villages where the study took place.[19] More recently, a trial conducted with Medicaid beneficiaries through the Wisconsin Smokers' Quit Line achieved a significant effect on outcomes with treatment incentives of up to $190,[25] a historically modest figure yet more than three times greater than the $60 provided in the present study. The magnitude of these incentives is consistent with a finding from the wider evidence base that large incentives are more influential than small ones with respect to health behavior change.[34] Accordingly, some experts have warned against designing incentive programs with rewards that are too small.[35−39] However, others have observed that incentives proven effective in trials may never be implemented in real-world practice if decision makers see them as being too large.[14] The results of this study show that incentives can be both modest and effective, making them potentially more acceptable to implement in real-world practice.

This study is also the first in which the incentives proven effective were non-contingent on outcomes. Participants were told upfront that their incentives would be based on the number of counseling calls they completed, not on whether they successfully quit smoking. The incentives were tied to process measures to facilitate translation to practice if they proved effective. In real-world quitline practice, only a random sample of participants is followed up for outcomes evaluation, so it is more practical to base the incentives on process measures that are routinely collected for all participants. But it was also important to determine whether non-contingent incentives were even effective.[40] The results show that non-contingent incentives can indeed lead to better quitting outcomes, apparently by increasing engagement with other evidence-based treatment. NP+FI participants received one more counseling session on average than either the UC or NP groups. But given that

counseling utilization was nearly as high in those groups —five sessions total for UC and NP groups versus six for the NP+FI group—the incentives may have had a broader effect on engagement than simply increasing the number of sessions completed. How exactly such incentives enhance treatment engagement and the quitting process deserves further study.

Finally, this study validates the use of financial incentives with Medicaid beneficiaries, a population for whom the evidence on incentives for tobacco cessation is limited (but see Fraser et al.[25]). Most progress to date in reducing the prevalence of tobacco use in the U.S. has occurred outside Medicaid, and as Medicaid has expanded to cover more individuals of low SES, it has "collected" an increasing share of the nation's smokers.[4] Medicaid programs, therefore, need effective, scalable strategies to help the large numbers of smokers they cover.[4,7,8] By layering modest incentives and mailed patches onto an existing, accessible, evidence-based quitline service, this study expands the menu of effective interventions. All states in the U.S. have a quitline providing telephone counseling and could easily offer these adjunctive services to their Medicaid callers, given adequate funding. Promoting free patches and incentives may even help to drive quitline demand, reducing the cost of advertising.[13] Medicaid programs currently spend less than 1% of the cost of treating tobacco-related disease on tobacco-cessation treatments,[1] suggesting that they can afford to fund all evidence-based approaches, including incentives.

Limitations

This study has limitations. First, the incentives tested were adjuncts to a program of telephone counseling, which was itself highly effective.[28,29] Therefore, the results do not address the value of incentives as interventions in their own right, absent other treatment (see Etter and Schmid[24] for a successful trial in which incentives were the only intervention provided). Second, the three-group design employed in this study makes it impossible to determine whether the incentives would have been effective without patches. Third, as a study conducted under real-world conditions in which multiple promotional strategies are used to drive demand, approximately one fifth of participants in the three groups requested and received an advertised $20 gift card for calling the quitline, thus reducing the study's power to detect a difference in the incentives comparison. Fourth, the fact that more than 70% of UC participants obtained quitting aids on their own (with some help from the quitline) reduced the ability to detect an effect of the patch intervention. Fifth, evaluation staff could not be blinded to group assignment because they

needed to ask participants in the NP and NP+FI groups about the patches they received; this may have introduced some bias into the evaluation. Sixth, outcomes were not biochemically validated, although self-reported abstinence is commonly accepted in large community-based trials.[41] Finally, study participants were recruited in California, and it is unknown to what extent the results are generalizable to the rest of the Medicaid population, or indeed to low-income smokers worldwide.

CONCLUSIONS

In this study, financial incentives were shown to increase engagement with an existing, evidence-based treatment program, and to increase both short- and long-term smoking-cessation rates. The incentives were effective despite being modest. The maximum incentive per participant was only $60. Moreover, the incentives were effective even though they were non-contingent on outcomes, making them easier to implement in real-world operations where assessing long-term outcomes for all participants may be impractical.

This study also adds to the small but growing evidence that financial incentives can be an effective smoking cessation intervention for a low-income population. Tested in a real-world setting, such as currently exists in all U.S. states and many other countries, these modest incentives represent an effective, scalable intervention that could feasibly be integrated into existing quitline services.

SUPPLEMENT NOTE

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