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Wisconsin Striving to Quit—
First Breath Incentive Program
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Abstract

Importance: Smoking during pregnancy is the leading preventable cause of severe negative health consequences to both the mother and infant, with some of the harms to the infant being lifelong. There is an urgent need to improve prenatal and postpartum cessation treatment for pregnant smokers.

Objective: To evaluate the effectiveness of a monetary incentive for increasing engagement in postpartum cessation treatment, improve abstinence, and sustain abstinence at six-month follow-up.

Design, Setting, and Participants: Two-group randomized quality improvement study recruiting Wisconsin Medicaid-enrolled pregnant smokers receiving smoking cessation counseling through the *First Breath* program of the Wisconsin Women's Health Foundation.

Interventions: Participants were randomized to either an Incentive Group (n = 505) or a Control Group (n = 509). All participants received $40 at enrollment for a baseline assessment and were offered prenatal cessation counseling.

Incentive Group participants received $25 for each of six prenatal provider visits completed. In the postpartum period, Incentive Group participants could receive compensation for four home visits ($40 each for the one-week postpartum visit and the six-month postpartum visit; $25 each for the two-month postpartum visit and the four-month postpartum visit) and five postpartum counseling calls ($20 per call). Incentive Group participants also received an additional $40 for biochemically verified abstinence at both the one-week and six-month visits. Control Group participants were compensated only for the one-week and six-month postpartum visits ($40 each).

Main Outcomes: The primary outcome was biochemically confirmed seven-day point prevalence abstinence at the six-month follow-up visit. Secondary outcomes included: greater number of postpartum home visits and phone calls taken, biochemically confirmed abstinence at the postpartum one-week visit, and increased self-reporting of smoking status at the two- and four-month visits.

Results: Incentive Group participants had significantly higher smoking abstinence rates at the six-month postpartum visit than did Control Group participants (14.7% vs. 9.2%, respectively: $p < 0.01$). This effect was mediated by Incentive Group participants' greater acceptance of postpartum home visits and counseling calls.

Conclusions and Relevance: This study shows that fairly moderate levels of incentive payments (total possible treatment and contact incentive payment of $500) increased Medicaid-enrolled pregnant smokers' engagement and success in postpartum smoking cessation treatment.

Background

Smoking during pregnancy exacts tremendous human and economic costs resulting from multiple severe negative health consequences to both the mother and infant, with some of the harms to the infant being lifelong.[1 2 3 4 5] In addition, postpartum smoking also has a great toll on both the mother's and child's health.[6] It is vital to identify intervention strategies that reduce smoking during and after pregnancy and help women maintain abstinence.

Many of the smoking cessation interventions used with pregnant smokers have yielded modest or inconsistent effects.[7 8] At the same time, the use of incentives to reinforce smoking abstinence has produced relatively promising outcomes.[9 10 11 12] Importantly, incentive programs have been shown to increase abstinence among low-income pregnant women,[13] who are especially likely to be smokers.[14 15] However, important questions remain concerning the use and effectiveness of incentive programs targeting pregnant women.

First, while there is considerable evidence that incentive programs increase abstinence rates during pregnancy,[16] there is less evidence that these programs produce abstinence that continues well beyond the initial postpartum period.[17] For example, a recent Cochrane meta-analysis examined the effects of incentives on postpartum abstinence.[18] This analysis showed a significant beneficial effect on postpartum abstinence, but only four trials assessed abstinence at six months postpartum. Three of the four trials were relatively small, with sizable incentives and highly intense and frequent monitoring of smoking. Little is known about the persistence of postpartum abstinence among low-income women in response to an incentive program that is feasible for real-world delivery. Research indicates that more than half of the women who quit smoking during pregnancy resume smoking after delivery (relapse) by six months postpartum.[19 20] Studies also confirm that low-income women are more likely to relapse than their more economically secure peers.[21]

A second issue focuses on the structure of the incentives and the interventions. For example, some interventions involve frequent contact between treatment personnel and patients, use relatively large incentive payments, and require frequent biochemical ascertainment of smoking status at increased costs, all of which may discourage utilization and reduce potential impacts.[22 23 24 25 26 27 28 29] These and similar issues also raise concerns about dissemination and replication potential.

There is evidence of incentive-based interventions for pregnant women who smoke being successfully implemented in real-world conditions. Tappin et al added an incentive component to a treatment-as-usual smoking intervention for pregnant women.[30] This program involved a maximal incentive payment of moderate size (≈$600) and produced long-term increases in smoking abstinence (albeit not biochemically confirmed). The payment magnitude is notable

since many applications of incentive interventions use maximal payments of $1,000 or more.[31] In addition, Ierfino and colleagues demonstrated that an incentive intervention for smoking during pregnancy could be implemented in an obstetric clinic. However, this study generated no effectiveness data, and it is, thus, unknown whether the incentive treatment actually "worked."[32] While incentive interventions have been used successfully in real-world applications with male and female smokers, there is limited evidence that such smoker incentive programs have ever been targeted to enhance postpartum abstinence.[33] [34]

In September 2011, the Wisconsin Department of Health Services (DHS) was one of 10 states awarded a Medicaid Incentives for the Prevention of Chronic Diseases (MIPCD) grant from the Centers for Medicare and Medicaid Services (CMS). The initiative, called Striving to Quit, was designed to test the effects of incentives on smoking cessation services by adult Medicaid members who smoke. The Wisconsin study included two arms. One focused on linking non-pregnant adult Medicaid members who smoked to the Wisconsin Tobacco Quit Line, and a second focused on linking pregnant Medicaid members who smoked to in-person and telephone smoking cessation counseling. This report focuses on the second study arm.

As the designated grantee, DHS assumed the leadership role for the Striving to Quit initiative, with the Office of Policy Initiatives and Budget providing project management services, including facilitating collaboration among both internal and external partners. Within DHS, the Division of Health Care Access and Accountability (DHCAA–Medicaid) provided executive oversight and coordination with contracted health maintenance organizations (HMOs); it also managed the state data exchange with CMS and the national evaluator. The DHS Division of Public Health (DPH) served as the lead for marketing strategies, including social media and TV ad buys, and for development of materials (posters, brochures, postcards, etc.). The HMOs assisted in marketing and outreach to individual smokers in their health plans and in recruiting obstetric clinics to participate by agreeing to provide brief smoking cessation counseling to potentially eligible members and making referrals to First Breath, the prenatal component of the intervention.

Additionally, the Wisconsin Women's Health Foundation, a nonprofit entity focused on promoting women's health, served three primary roles:

1. To develop, implement, and manage the smoking cessation for pregnant women arm of the initiative, including outreach activities to obstetric clinics and pregnant smokers enrolled in Medicaid, and hiring and training the Striving to Quit health educators to deliver postpartum services.
2. To participate in the research design and implementation.
3. To contribute to the comprehensive program evaluation, including data collection. The evaluation was conducted by the University of Wisconsin (UW)-Madison School of Medicine and Public Health's Center for Tobacco Research and Intervention (UW-CTRI).

The current study explores the effectiveness of an incentive-based intervention for pregnant smokers enrolled in Wisconsin Medicaid, with a primary focus on postpartum abstinence and treatment engagement. Much of the treatment occurred postpartum, with the primary outcome being biochemically confirmed abstinence at 26 weeks (six months) postpartum. Further, most of the incentive payments were contingent upon participation in postpartum visits and phone calls rather than abstinence per se. This made the incentive payment process more feasible since participants could earn reinforcement without visiting a treatment facility and without biochemical ascertainment (e.g., participants could be mailed gift cards for participating in phone counseling). Third, the total amount of contingent payment available was moderate in magnitude ($460 total possible payment post study enrollment). Finally, the incentive intervention was made available as an adjuvant to an existing state-supported smoking cessation program targeting low-income pregnant women, First Breath. This statewide program provides one-on-one counseling and goal setting via a variety of specially trained maternal and child health care providers as a component of regular prenatal and postpartum care. The incentive program—Striving to Quit-First Breath—was designed to complement and enhance this successful program by providing more intensive counseling for up to six months following delivery.

The study design compared two groups:

1. The Incentive Group received compensation for participating in treatment contacts (via their obstetric provider or a Striving to Quit health educator), enrolling, and being abstinent at a six-month follow-up visit (total possible incentives = $500).
2. The Control Group received compensation only for enrolling and being abstinent at the six-month follow-up visit (total possible incentives = $120).

All women were randomized following consent to either the Incentive or Control Group based on tables prepared by UW-CTRI. Separate tables were created based on race (i.e., white/non-white) and county of residence. All women in both groups had access to the same services.

Methods

Methods Refinement: Adapting to Challenges

The First Breath component of Striving to Quit was originally designed to work with existing First Breath providers, with women who were participating in the program being referred to Wisconsin Women's Health Foundation staff for additional screening to determine their eligibility for the study. Unfortunately, this approach was not successful due to a number of issues.

The Striving to Quit-First Breath team, composed of Wisconsin Women's Health Foundation staff and the lead health educator, screened all First Breath participants for basic Striving to Quit study eligibility:

- Participant had to be 18 years of age or older.
- Participant had to be enrolled in Medicaid.
- Participant had to be enrolled in a participating HMO (HMOs could elect not to participate).
- Participant had to have lived in a county with high birth disparity rates and accessible First Breath providers.
- Participant had to have an estimated delivery date in range (baby would be born within the study period).

Over the course of the Striving to Quit-First Breath study, 30-40% of the women who met these basic eligibility requirements were deemed ineligible. The most common reasons included that they were not in a participating HMO or they were no longer pregnant. Of the remaining potential participants, a significant percentage had missing, incorrect, or disconnected phone numbers in their First Breath files and could not be contacted. This issue was addressed by retraining a majority of the First Breath prenatal sites on the importance of obtaining complete and accurate information and timely submission to the Striving to Quit-First Breath team. In addition, DHS and the Wisconsin Women's Health Foundation agreed to request UW Health Sciences Institutional Review Board (IRB) approval to allow the team to send invitational letters to participants, expand eligibility for Striving to Quit-First Breath to non-HMO Medicaid enrollees, and expand the intervention to additional counties.

A second challenge occurred in April 2014 following a change in Medicaid eligibility criteria, which impacted the ability of approximately 10-12% of Striving to Quit-First Breath participants to retain coverage beyond the traditional 60 days postpartum. Because these women were no longer enrolled in Medicaid, they could no longer be included in the study. To retain this group of women in the study, DHS received CMS approval to continue their Medicaid coverage through the full six-month postpartum study period using only state (non-grant) funds.

A third major challenge experienced by both arms of Wisconsin's Striving to Quit initiative was recruiting and enrolling eligible individuals. For the Striving to Quit-First Breath study, the pool of potentially eligible women was much smaller than was anticipated during the planning period due to the challenges highlighted above and the unexpected amount of time needed to recruit and train/retrain obstetric clinics for First Breath and verify eligibility for the study. As a result, the enrollment goal was reduced from 3,000 to 1,250 early in the project. Even with the reduction, the Striving to Quit-First Breath team did not reach the enrollment goal.

A number of strategies were implemented over the course of the study (August 2012 through December 2015) to increase enrollment (enrollment ended June 2015). Among these were the following:

- Established enrollment goals for each existing First Breath site and provided additional on-site and online training as well as onsite technical assistance. Each clinic received regular updates on its progress. This effort resulted in record high enrollment in First Breath and, subsequently, more potentially eligible women for the study.
- Recruited and trained 76 new First Breath clinics, many in previously unserved areas.
- Expanded the Striving to Quit-First Breath service area to an additional 30 counties across Wisconsin.
- Developed First Breath interest forms to facilitate community-based outreach, including community baby showers, back-to-school health fairs, and nutrition programs. Women completing the forms were connected with a First Breath site and then screened for Striving to Quit-First Breath.
- Developed a partnership with Jump at the Sun Consultants, a minority-owned firm focused on improving health outcomes for black women in southeast Wisconsin. A Jump at the Sun Consultants team, composed of 10 young black outreach workers, identified pregnant smokers at community events and through street outreach (e.g., at grocery and convenience stores and neighborhood pharmacies) in Milwaukee and Racine. Interest forms were completed and submitted to the Striving to Quit-First Breath team. This strategy was very effective in reaching women who otherwise would not have been identified, but it required a significant amount of time to conduct follow-up and study screening.
- Worked with the Striving to Quit media team to produce and run a TV ad featuring a pregnant smoker and promoting Striving to Quit-First Breath in the Madison, Milwaukee, Green Bay, La Crosse, and Wausau markets. The ad generated a few calls, but many were screened out due to gender, pregnancy status, or insurance status.
- Modified the postpartum intervention from the original 12 months to six months to allow additional time for enrollment.

Participant Recruitment

Participants were recruited into the study through the existing First Breath program (see Figure 1 for the Consort diagram). Pregnant women at risk for smoking enrolled in First Breath through agencies affiliated with the Wisconsin Women's Health Foundation. These agencies included public health departments and private and community health clinics that provided prenatal and postpartum health care services to women throughout Wisconsin. After delivery, Wisconsin Women's Health Foundation Striving to Quit-First Breath health educators provided additional support and smoking cessation counseling for up to six months postpartum.

Originally designed to work with agencies from five target counties, recruitment was gradually expanded to 127 agencies in 35 counties to increase enrollment. The Wisconsin Women's Health Foundation used First Breath-affiliated agencies (e.g., clinics with high prenatal populations) in these target counties to recruit study participants. Further, the Wisconsin

Women's Health Foundation worked with First Breath program agencies, offering staff training, technical assistance, and recruitment goal setting. The Wisconsin Women's Health Foundation also recruited women into the study via direct community outreach (e.g., community baby showers and health fairs). Thus, study entry came through either agency referral or via direct contact by an interested woman. Wisconsin Women's Health Foundation staff described the study to all potentially eligible participants and screened all referrals for study eligibility by phone.

The study eligibility criteria were as follows:

- Participant had to be female.
- Participant had to be 18 years of age or older.
- Participant had to be pregnant.
- Participant could not be involved in another stop smoking research study.
- If participant had not already quit, participant had to be willing to quit or cut down on smoking in the next 30 days, or if participant had already quit, participant had to want to stay abstinent after the birth.
- Participant had to be a daily smoker (at least one cigarette each day for at least one week) at some point within the last six months.
- Participant had to be enrolled in Medicaid.
- Participant had to be willing to engage in the study procedures.

Individuals could enroll at any point during their pregnancy. Women meeting these criteria were verbally consented over the phone to participate in the study; copies of the consent and other study information were mailed to each participant following verbal consent.

Treatment and Assessment Contacts

Prenatal Treatment Contacts

Striving to Quit-First Breath smoking cessation treatment began from the point of consent, which occurred at some point during pregnancy. All prenatal study cessation treatment was based on the 2008 U.S. Public Health Service-sponsored Clinical Practice Guideline[35] and was considered standard of care treatment. Regular prenatal treatment delivered during prenatal provider visits was provided to all participants. Incentive Group participants received $25 per prenatal provider visit while Control Group participants did not. Counselors were prenatal health care providers at the First Breath-affiliated agencies and were trained by Wisconsin Women's Health Foundation First Breath staff to provide smoking cessation interventions. First Breath-affiliated providers included nurses, medical assistants, and health educators. These providers transmitted standard data on the dates and length of tobacco cessation counseling sessions to the Striving to Quit-First Breath team. The number of prenatal contacts provided reflected the length of time remaining in the pregnancy at enrollment and on the treatment regimens of the different prenatal clinics and providers.

Postpartum Treatment Contacts

Striving to Quit-First Breath health educators employed by the Wisconsin Women's Health Foundation delivered all postpartum smoking treatment in the participant's home and over the phone (see Figure 2). The first postpartum visit was scheduled to occur one to three weeks postpartum. Striving to Quit-First Breath health educators had at least a Bachelor of Science degree and were trained by the Wisconsin Women's Health Foundation in smoking cessation intervention and in the study protocol. There were four home visits (30-60 minutes each) and five counseling calls (10-20 minutes each) scheduled over the first six-month postpartum period (see Figure 1), with all contact involving the standard First Breath smoking cessation counseling protocol. Wherever possible, a participant had the same Striving to Quit-First Breath health educator for all visits and phone contacts.

The original study design called for treatment to entail a total of 11 contacts over 12 months. However, to maximize enrollment during the study period, the duration of treatment was shortened from 12 to six months early in the trial. This involved eliminating one phone call and one home visit, both of which were scheduled to occur after the first six-month postpartum visit. Thus, treatment consisted of nine treatment contacts over six months (Figure 1). The type and timing of Striving to Quit-First Breath contacts over the first six months postpartum were unaffected by this protocol change. Fidelity to evidence-based smoking cessation counseling was supported by initial training, use of a detailed counseling manual, quarterly file reviews, and supervised home visits.

Incentive Treatment

Figure 2 shows the schedule of incentive payments. The study compensated all participants $40 for study registration and enrollment and $40 per visit for attendance at postpartum visits one and four (at week 26). Participants attending visits one and four completed expired air carbon monoxide testing to biochemically verify self-reports of abstinence from smoking; participants with expired-air carbon monoxide test values of less than 7 parts per million (ppm) were considered to be abstinent.

Control Group participants could receive up to $120 in total incentive payments.

Incentive Group participants also received:

- $25 per visit for each of the six prenatal visits they completed.
- $25 per visit for attendance at postpartum visits two and three.
- $20 per call for completion of each of five postpartum counseling calls.
- An additional $40 per visit for demonstration of abstinence at postpartum visits one and four (demonstrated by an expired-air carbon monoxide test value of less than 7 ppm).

Thus, Incentive Group participants could receive up to a total of $500 for enrolling and participating in all scheduled home visits and calls. In order to receive the incentives for the

treatment contacts, a minimum duration of 10 minutes for calls and 20 minutes for visits was established. Multiple attempts were made to schedule all calls and visits, with the same protocol being used for both treatment groups.

Incentive payments were distributed either by mail (for prenatal visits and postpartum calls) or in person at visits. More specifically, at enrollment, participants were given the choice between four types of gift cards: Visa, Wal-Mart, Target, or Walgreens. Gift cards were mailed to participants following prenatal visits and phone calls and given in person at visits and for completed expired-air carbon monoxide tests.

Assessments

Assessments were administered at baseline (enrollment) and at all Striving to Quit-First Breath program contacts (both phone and in-person). At baseline Striving to Quit-First Breath registration, assessments captured the following measures that were transmitted to the UW-CTRI via secure file transfer protocol for those women who consented to enroll:

- Sociodemographic variables.
- Smoking history.
- Medicaid ID.
- Motivation and confidence to quit or reduced smoking.
- Barriers to cessation.
- Past quit attempts.
- General health information.
- Goals.

A UW-CTRI baseline assessment also captured initial levels of relevant constructs:

- Current depressive symptoms (Center for Epidemiologic Studies Depression Scale Revised [CESD-R-10]).[36]
- The intent of the woman to breastfeed (on a 1-10 confidence scale).
- Perceived social support (via the Wisconsin Social Support Scale).[37]

These same assessments were tracked across the postpartum visits (with the CESD-R-10 only administered at baseline and six months postpartum). An expired-air carbon monoxide test was administered at both the first postpartum contact and the six-month visit. Self-reported smoking status was assessed at all Striving to Quit-First Breath program contacts, including reminder calls.

Postpartum assessments included:

- The Wisconsin Smoking Withdrawal Scale (WSWS).[38]
- Smoking variables (e.g., maximum cigarettes per day in the past week).
- Motivation to quit.

- Confidence in their ability to quit.
- Extratreatment support for quitting.
- Intratreatment support for quitting.
- Mood and anxiety items.

All assessment data gathered by Striving to Quit-First Breath staff were uploaded electronically to UW-CTRI researchers through secure web-based data collection and transmission.

Outcomes

The primary outcome was biochemically confirmed seven-day point prevalence abstinence at the six-month follow-up visit. Secondary outcomes included: greater number of postpartum home visits and phone calls completed, biochemically confirmed abstinence at the postpartum one-week visit, and increased self-reporting of smoking status at the two-month and four-month visits.

Analytic Methods

Treatment groups were compared on demographic and smoking history characteristics via $\chi 2$ tests (for categorical variables) and independent groups t-tests (for continuous variables). Treatment group differences in binary abstinence outcomes were tested via logistic regression models, which yielded odds ratios and 95% confidence intervals. Risk differences (i.e., differences between the Control Group and Incentive Group abstinence rates) and 95% confidence intervals for risk differences were calculated using Proc Freq (SAS Institute Inc.) via the RISKDIFF option and are reported for abstinence outcomes. Group differences in treatment engagement (e.g., number of postpartum visits and counseling calls) were tested using Proc GLM (SAS Institute, Inc.). Mediation analyses were computed via the SAS PROCESS macro.[39]

The original grant proposal estimated power based on a total sample size of 3,100 participants (n = 3100). The sample size of 3,100 afforded power to detect a treatment effect of clinical significance (e.g., 15% in the Control Group vs. 25% in the Incentive Group; power > 0.90). However, recruitment of participants was slower than anticipated, and the ultimate sample size was 1,014. Recalculation of power based on a sample size of 1,014 for a potential effect size of 15% vs. 25% yielded power greater than 0.95.

Results

Baseline Sample Characteristics

Table 1 shows the characteristics of the participants randomized to the two experimental groups. As the table reveals, participants, on average, entered the study at the 14th week of gestation, were young (mid-20s), about 50% were racial minorities, and the majority had at least a high school education. An examination of smoking-related variables at baseline (Table 1) shows that nearly 60% smoked more than 10 cigarettes per day, more than half smoked within

30 minutes of waking, and about 50% lived with a smoker. The two groups did not differ significantly on any of the variables listed in Table 1.

Smoking Outcomes

Table 2 presents key smoking outcomes for the two groups.

Postpartum Visit Four (26 weeks)

The primary smoking outcome was biochemically confirmed seven-day point prevalence abstinence at 26 weeks postpartum. Results show that the Incentive Group achieved significantly higher point-prevalence abstinence at this follow-up postpartum visit than did the Control Group: 14.7% vs. 9.2%, respectively (risk difference = -5.42, confidence interval = -9.40 to -1.44, $p < 0.01$). When self-reported outcomes were analyzed (with no biochemical confirmation), the abstinence rates for the Incentive and Control Group participants were 16.0% and 10.6%, respectively (risk difference = -5.3, confidence interval = -9.60 to -1.26, $p < 0.02$).

Because there was a meaningful range of self-reported smoking at baseline (enrollment), with some participants not actively smoking just prior to study induction, abstinence at 26 weeks postpartum was examined as a function of smoking status at baseline (prenatally). Among those *abstinent* at baseline (n = 199: 100/505 of Incentive Group participants and 99/509 of Control Group participants), biochemically confirmed seven-day point prevalence abstinence rates at 26 weeks were 32.0% and 24.2% for the Incentive and Control groups, respectively (risk difference = -7.76, confidence interval = -20.20 to 4.70, $p = 0.2237$). Among those *smoking* at baseline (n = 815), the seven-day biochemically confirmed abstinence rates at 26 weeks for the Incentive and Control Group participants were 10.4% and 5.6%, respectively (risk difference = -4.76, confidence interval = -8.47 to -1.05, $p < 0.02$).

Ideally, visit four was scheduled to occur at about 26 weeks postpartum. The Incentive and Control Group participants attended this visit a mean of 204 (SD = 23.8) and 205 (SD = 26.3) days postpartum, respectively ($F = 0.27$, $df = 1,674$, $p > 0.05$).

Postpartum Visit One (one to three weeks)

Incentive Group participants attained a slightly higher seven-day biochemically confirmed abstinence rate at postpartum visit one than did the Control Group participants: 17.0% vs. 13.4%, respectively, but this difference was not significant (risk difference = -3.67, confidence interval = -8.08 to 0.74, $p = 0.1035$).

Postpartum Visit Two (eight weeks) and Visit Three (16 weeks)

Table 2 shows that the Incentive Group participants reported higher seven-day point prevalence abstinence rates at visits two and three, both of which were statistically significant.

These results could not be confirmed against biochemical testing since that testing was not done at these visits.

Other Abstinence Data

This study used the historical "gold standard" definition for non-smoking in smoking cessation research as its primary outcome: seven-day point prevalence, biochemically confirmed abstinence (in this case documented with an expired-air carbon monoxide test value of less than 7 ppm). This gold standard also applies "intent-to-treat" criteria, with all participants who were lost to follow-up or unable to be contacted considered to be smokers in the analysis. As a result, this approach is the most conservative way to analyze the data. Self-reporting, external measurement, and applying intent-to-treat criteria are considered the most valid measures for confirming smoking status and are recommended in tobacco control literature.[40]

Additional analyses found higher quit rates when not requiring a dual abstinence measure—both biochemical confirmation and self-reported seven-day point prevalence abstinence confirmation. In large part, this finding resulted from the considerable self-reporting of smoking within the past seven days among the 271 women who had a "non-smoking" expired-air carbon monoxide test result at the 26-week visit. More specifically, 46% (126/271) of the women with an expired-air carbon monoxide test value of less than 7 ppm (designated in the study protocol as non-smoking) showed some smoking in the week prior. The amount of smoking among these 126 women ranged from 1 to 30 cigarettes on the day that each woman smoked the heaviest within the prior week. This large rate of self-reported smoking greatly reduced the number of women who could be considered as non-smoking. Further, examining only women reporting some smoking in the previous seven days, almost 80% (115/146) reported that their maximum number of cigarettes smoked on any of these days was five or less. Smoking at these low levels often yields expired-air carbon monoxide test values of less than 7 ppm, the value used to determine "smoker" status for this study. These specific expired-air carbon monoxide test values and self-reported findings, as well as related methodology questions, are further analyzed in the discussion section of this report.

We have provided a supplemental table (Table 4) to show how the study would look if other criteria were applied to the determination of smoking status. In this table, intent-to-treat and responder-only (using only those who came to the visit) criteria are applied with the abstinence criteria of self-reported smoking being eliminated (i.e., exclusively using the biochemical test result, CO < 7 ppm). Both of these supplemental analyses yielded findings that concurred with the main study outcomes using the primary study outcome criteria: in all analyses, the Incentive Group produced a statistically significant higher quit rate than the Control Group. Specifically, in the first additional analysis shown in Table 4, using intent-to-treat and abstinence-based-only criteria on expired-air carbon monoxide test results, the quit rates were significantly higher in the Incentive Group than in the Control Group (34.7% in the Incentive Group vs. 14.7% in the Control Group; $p < 0.001$). The second additional analysis shown in Table 4 provided data that

included responders only—that is, only the 671 (of 1,014) participants who provided biochemically confirmed abstinence. In this responder-only analysis, 48.6% of Incentive Group participants were confirmed abstinent, while only 29.1% of Control Group participants were abstinent ($p < 0.001$).

Finally, additional analyses were done to examine the relative effects of incentives on those smoking or not smoking at the baseline visit:

- Sixty-five women self-reported *smoking* at baseline but were confirmed as abstinent at the six-month test. In the Control Group, 5.6% (23/410) of the women who self-reported smoking at baseline were abstinent at six months, while in the Incentive Group, 10.4% (42/405) of the women who self-reported smoking at baseline were abstinent at six months.
- Fifty-six women self-reported *no smoking* at baseline *and* were confirmed as abstinent at the six-month test. In the Control Group, 24.2% (24/99) of the women who self-reported no smoking at baseline were abstinent at six months, while in the Incentive Group, 32% (42/405) of the women who self-reported smoking at baseline were abstinent at six months.

These results suggest an association between incentives and helping women quit—if they were not successful at quitting during their pregnancy at the time of the baseline contact—as well as an association between incentives and helping those who were not smoking at that time to stay abstinent. Because of the lower numbers in these subanalyses, neither result reached statistical significance.

Other Visit-Based Outcomes

At all four postpartum visits, participants reported the maximum number of cigarettes smoked on a single day in the previous week (Max CPD) and the number of days in the previous week that they had smoked (Days Smoked). With regard to Max CPD, the Incentive Group participants reported smoking fewer cigarettes across all four postpartum visits than did the Control Group participants: the means for visits one through four for the two groups were, respectively:

- Visit one = 5.29 vs. 6.00 (n = 739).
- Visit two = 4.97 vs. 6.04 (n = 641).
- Visit three = 5.00 vs. 6.00 (n = 585).
- Visit four = 4.83 vs. 6.32 (n = 673).

Differences were significant across visits two and three (F's = 3.96 -20.8, p's = 0.047 - 0.0001). With regard to Days Smoked in the last week, Incentive Group participants smoked significantly

fewer days across all four visits than did Control Group participants: the means for visits one through four for the two groups were, respectively:

- Visit one = 4.06 vs. 4.53 (n = 742).
- Visit two = 4.17 vs. 4.95 (n = 641).
- Visit three = 4.11 vs. 5.00 (n = 585).
- Visit four = 3.91 vs. 4.96 (n= 673) (F's = 4.96 - 23.40, p's = 0.026 - 0.0001).

A detailed listing of all calls and visit attendance, as well as incentives paid, is in Table 5.

The observed reductions in maximum smoking and in number of days of smoking in the past week raise questions about whether these effects merely reflect the influence of treatment or abstinence per se. That is, did the incentive intervention affect smoking heaviness or number of days of smoking independent of its effects on abstinence itself? To address this, the effects of the incentive intervention were examined in relation to the visit four (six-month) data among those who did *not* claim abstinence at that visit. Results show that among these participants, the Incentive Group treatment produced a lower mean Max CPD than did the Control Group treatment at visit four: means = 6.08 (SD = 5.1) vs. 8.01 (SD = 6.11), respectively; F = 16.31 (1, 552), $p < 0.0001$. Results also indicate that the Incentive Group treatment reduced the number of days non-abstaining participants reported smoking in the past week: means = 4.93 (SD = 2.25) vs. 5.82 (SD = 2.0), respectively; F = 25.54, $p < 0.0001$.

Participants rated both their motivation to quit and their confidence in their ability to quit at each visit. The Incentive Group participants tended to report higher motivation to quit smoking and greater confidence in their ability to quit than did Control Group participants across all four postpartum visits. These differences were not consistently significant but were significant at visit four. For motivation to quit smoking, the visit four ratings for the Incentive Group and Control Group participants were 4.41 vs. 4.20 (n = 674) (F = 7.82, p = 0.005). For confidence in ability to quit, the visit four ratings for the two groups, respectively, were 4.18 vs. 3.97 (n = 670) (F = 20.16, $p < 0.01$). The two groups did not differ on other measures gathered at visits, including perceived extratreatment support for quitting; intratreatment support for quitting; CESD-R-10 depression (total score); the Wisconsin Smoking Withdrawal Scale (total score); having felt worried, tense, or anxious in the past 30 days; or having felt sad, blue, or depressed.

Treatment Engagement

Prenatal Treatment Engagement

Incentive Group participants completed a mean of 1.2 (SD = 1.4, n = 509) prenatal visits where smoking cessation counseling was documented, while Control Group participants completed a mean of 0.9 such visits (SD = 1.6, n = 505); medians for the two groups were 1 and 0, respectively, a difference that was significant with the Kruskal-Wallis test ($\chi^2 = 5.6$, p = 0.018).

Postpartum Treatment Contacts

Incentive Group participants completed a greater mean number of postpartum home visits than did Control Group participants (3.0 [SD = 1.4] vs. 2.3 [SD =1.5], respectively; F = 57.1, df = 1,1012, p = 0.0001). Table 3 depicts the maximum number of visits participants made in the two groups. This table shows that a considerably greater percentage of Incentive Group participants attended the four planned visits than did the Control Group participants; the difference in distribution of group participants across the number of scheduled visits was significant (χ^2 = 68.6, p < 0.0001).

The results show that attendance varied across the four scheduled visits; attendance rates for the Incentive and Control groups were, respectively:

- Visit one = 76.4% vs. 70.5%.
- Visit two = 75.6% vs. 51.3%.
- Visit three = 72.5% vs. 43.4%.
- Visit four = 71.3% vs. 62.1%.

While attendance was significantly different for all four visits (p's < 0.04), the data show that differences in attendance between the two groups were smaller in magnitude for those visits where Control Group participants received compensation for visit attendance (as Figure 2 shows, Control Group participants received $40 compensation for attendance for taking an expired-air carbon monoxide test at visits one and four).

Table 3 also depicts the number of postpartum phone calls taken by participants of the two groups. This table reveals that of the five postpartum phone calls scheduled, about 62% of Incentive Group participants took either four or five calls, while only about 30% of Control Group participants did so. The difference in distribution of group participants across the maximum numbers of calls taken was significant (χ2 = 128.7, p < 0.0001). The mean numbers of calls taken by participants of the two groups were 3.5 (SD = 1.8, n = 505) for the Incentive Group and 2.4 (SD = 1.7, n = 509) for the Control Group (F = 102.2, df = 1,1012, p < 0.0001).

Incentive Payments

All participants received an initial $40 incentive payment for enrolling. The initial incentive payment is not included in the following analyses. Thus, the maximum *post-enrollment* incentive payments were $460 for Incentive Group participants and $80 for Control Group participants.

In terms of actual incentive payments delivered, Incentive Group participants received an average of $29.16 for attendance at prenatal visits. For postpartum contacts, the Incentive Group participants received a mean of $69.45 for postpartum calls, $88.99 for postpartum visits (not including incentives for biochemically confirmed abstinence), and $26.21 for biochemically confirmed abstinence at visits one and four. In all, Incentive Group participants received a mean

of $184.67 for *postpartum visit* attendance, call attendance, and biochemically confirmed abstinence. Control Group participants received a mean of $53.05 for attendance at postpartum visits one and four. Total mean payments made to participants in the two groups across both prenatal and postpartum periods (excluding the initial $40 incentive payment) were $213.83 for Incentive Group participants and $53.05 for Control Group participants.

Mediation

Mediation analyses used biochemically determined abstinence at six months (n = 1,014) as the outcome and the total number of postpartum home visits and counseling calls as the mediator. Analyses focused on whether the increase in visits and calls taken by Incentive vs. Control Group participants could account statistically for the former group's higher abstinence rate (14.7 vs. 9.2%, respectively). A simple logistic regression (non-mediational) model revealed that treatment group affected six-month abstinence ($c = -0.52$, $p < 0.01$). When number of visits was entered in the full mediational model (see Figure 3), the path (unstandardized regression coefficient) from treatment group to number of visits (a) was significant ($a = 1.80$, $p < 0.0001$), as was the path from the number of visits to six-month abstinence ($b = -0.32$, $p < 0.0001$). However, the direct path from treatment group to outcome (c') was no longer significant in the full model ($c' = -0.02$, $p = 0.9070$). The indirect mediated effect of number of calls (the product of paths a and b) was significant ($ab = -0.57$, $p < 0.0001$).

Project Costs

The primary analyses of costs for the pregnant women arm of Striving to Quit (Striving to Quit-First Breath) focused on first identifying the costs of all project activities that would be required to implement the incentive program on an ongoing basis. Costs of planning the project, grant administration, and research within the project are not included in the analysis. Further, these analyses make the assumption that the postpartum smoking cessation program is being added onto an existing prenatal smoking cessation program (First Breath), thus reducing the specific direct costs and other support costs required to *add that program onto* the existing program. The costs of developing a new "freestanding" smoking cessation program where no previous program existed would be considerably higher.

Project costs were allocated into three categories:

1. Service costs, including billed staff time for counseling and testing, as well as all incidentals connected with services.
2. Incentives.
3. Service-related administrative costs, including promotion/marketing and staff time for administering the intervention.

Costs have all been calculated on a per-participant basis for the 1,014 enrolled in this project. Total project costs for these women were $658,256, an average of $649 per participant. All costs have been adjusted to reflect actual expense of the project in the field; no budgeted costs

have been used. Table 6 summarizes the costs for this project for the three categories and overall; it further breaks down the costs for those in the Incentive and Control groups. In general, replication of the project would probably use either the incentive or non-incentive approach, not a mixture. This makes the cost data for the two separate groups more relevant for replication as compared with the overall cost for the full 1,014 participants.

As Table 6 shows, the cost of implementing Striving to Quit-First Breath with the full set of incentives in this protocol was $181 greater per participant than an implementation that includes only incentives for attending the biochemical confirmation visits. Specifically, the cost of the program was $559 per participant in the Control Group and $740 per participant in the Incentive Group.

Cost per Quit per Participant

The project then examined the cost per quit per participant for the two different study groups to provide a more specific analysis of whether the additional expense of incentives (which averaged approximately $181 more for Incentive Group participants) produced a more (or less) expensive primary outcome. The analysis of cost per quit per group found that Control Group participants had an average cost per quit of $6,056, and Incentive Group participants averaged $5,049 per quit. Thus, the demonstrated effect of incentives on treatment participation and quitting behavior shown in this study outweighed the differentially higher cost of providing the incentives, yielding a $1,007 lower cost per quit.

Discussion

This research evaluated the effects of an incentive program that was used as an adjuvant to an ongoing, real-world smoking intervention program for low-income (Medicaid-enrolled) pregnant smokers (First Breath)—with enhanced counseling treatment support into the postpartum period, which is when pregnant women who smoke typically relapse to tobacco use. Incentive Group participants achieved significantly higher rates of biochemically confirmed, seven-day point prevalence abstinence at six months postpartum than did Control Group participants (14.7% vs. 9.2%, respectively: $p < 0.01$). Incentive Group participants were also more likely to self-report seven-day point prevalence abstinence at months two and four than were Control Group participants. The data on abstinence among subgroups reported above suggest that participation in the Incentive Group significantly increased quitting among those who were smoking prenatally; there was also some evidence that it successfully maintained abstinence among those who had already quit in the prenatal period (although the number for this comparison was small and the difference did not achieve statistical significance).

While Striving to Quit-First Breath incentivized both treatment engagement and biochemically confirmed abstinence, the bulk of potential incentives were contingent upon the former. The addition of the Striving to Quit incentive program to the existing First Breath program for pregnant women who smoke was intended to promote and maintain cigarette abstinence during the postpartum period when relapse back to smoking is common.[41] [42] [43] Striving to Quit-First Breath was designed so that it would possess external validity and dissemination potential. Therefore, it did not require frequent meetings to secure biochemical evidence of abstinence, it used incentives of relatively modest magnitude (i.e., total possible incentive payments of $460 after study enrollment and an actual average payment of $213.83 per participant), and it was delivered by research-certified clinical staff.

Incentive Group participants achieved higher rates of biochemically confirmed, seven-day point prevalence abstinence at six months postpartum than did Control Group participants. Incentive Group participants were also more likely to self-report seven-day point prevalence abstinence at months two and four than were Control Group participants. The data on abstinence among subgroups reported above suggest that participation in the Incentive Group significantly increased *quitting* among those who were smoking prenatally; there was also some evidence that it successfully maintained abstinence among those who had already quit in the prenatal period (although the number for this comparison was small and the difference did not achieve statistical significance).

Incentive Group participants also reported less heavy smoking during the postpartum period, smoking fewer cigarettes per day on their peak smoking days over the past week and smoking on fewer days over the past week. These effects were found at the six-month postpartum visit

in the total sample and in those who did not claim abstinence at that time. Thus, the incentive intervention not only increased abstinence rates, but also decreased self-reported smoking and heaviness of smoking even among those who were continuing to smoke.

The incentives were intended to increase treatment engagement. Indeed, as shown in Table 3, Incentive Group participants attended more prenatal and postpartum treatment visits and took more postpartum phone calls than did the Control Group participants. They also withdrew from the program at a lower rate than Control Group participants (Figure 1). A mediational model showed significant mediational paths from treatment group to number of postpartum visits and calls, and from postpartum visits and calls to six-month abstinence. The product of these mediational paths was significant, indicating that these paths were jointly significantly determinant of smoking outcome. This analysis, therefore, supports the hypothesis that incentivizing smoking treatment engagement can enhance smoking cessation success.

While the incentive intervention significantly increased six-month abstinence rates, the effects were fairly modest. The biochemically confirmed seven-day point prevalence abstinence rates at six months postpartum were 14.7% vs. 9.2% for the Incentive and Control groups, respectively. A 5% increase in abstinence rates could greatly benefit public health when an intervention is of low intensity and cost. However, the Striving to Quit-First Breath smoking intervention program is fairly intensive, involving up to four postpartum visits and five postpartum phone calls. Thus, it would be important to identify ways to increase the effectiveness of the incentive program. Focusing the incentives more on treatment engagement in the *postpartum* period might enhance outcomes; after all, participants had little exposure to the prenatal incentives (participants often enrolled in the program shortly before their deliveries, reducing the opportunity for multiple prenatal treatment visits). It is also the case that treatment contacts and incentive payments could be front-loaded so that they occur earlier in the postpartum period since that is a time of great relapse risk.[44] Finally, even though the effect of the incentive intervention was modest, it is important to bear in mind that it is vitally important to assist this population; these smokers are fairly young (age 26 on average), have infants and children in their homes, and face numerous other risk factors for smoking-related disease and disability.

The modest levels of abstinence observed in this study reflect the difficulty in boosting abstinence in this population due to the numerous challenges they face, such as:

- High levels of stress due to poverty.
- Difficulty coping with the challenges of a newborn.
- High levels of smoking in their social networks, including in their homes.
- Their relative youth (often associated with decreased likelihood of successful cessation[45]).
- Dysfunctional beliefs about smoking.[46]

The challenges faced by this population are reflected in their demographics (Table 1). For example, over half lived with a smoker, less than 10% were married, and only about a third were employed. Such factors should be considered when evaluating treatment effects obtained with this population.

It is important to note that the Control Group participants received meaningful incentives for attending postpartum visits one and four where biochemical ascertainment of smoking status occurred ($40 for each visit). Since Incentive Group participants could earn only an additional $25 per visit for attending the other two postpartum visits, it is clear that the amount of incentives for postpartum *visit* attendance did not differ greatly across the two groups. It is possible that the effects of incentives on abstinence would have been larger if the Control Group participants had received smaller (or no) incentives for treatment visit attendance.

This research has several limitations. One relates to the manner of testing used to determine smoking status. This limitation is a potential factor in the discordance between participant self-reporting of smoking and the "non-smoking" expired-air carbon monoxide test value recorded at the six-month visit. While any smoking is detrimental to health, the study is not able to answer the question of what proportion of the large group of women who reported smoking but had an expired-air carbon monoxide test value of less than 7 ppm might be able to maintain this low level of smoking over time and what, if any, other health benefits would accrue from that. In most longitudinal studies, low levels of smoking do progress back toward everyday smoking. In this study, the amount of low-level smoking among those who were biochemically confirmed as abstinent at visit one was 10% less at the initial home visit (45%, 122/276), which also suggests a possible pattern of greater amounts of low-level smoking over time. Substantial data also indicate that low-income smokers do smoke at lower rates and in inconsistent patterns based on their ability to afford cigarettes. It is also possible that some participants quit or reduced their smoking just prior to the six-month visit. A number of more recent articles on the use of the expired-air carbon monoxide test have indicated that at least in some populations where smoking is at lower levels, an expired-air carbon monoxide test value of 4 ppm would be a more appropriate value to determine nonsmoking.[47 48] Due to the expired-air carbon monoxide test instrument used, the study is not able to re-analyze the data using this lower value. Further research could explore setting a lower value for biochemical confirmation. Another alternative for biochemical testing, serum cotinine, might have been more sensitive in detecting temporally remote smoking.[49 50 51]

A number of other limitations should be mentioned. The limited reported exposure to prenatal smoking cessation intervention (averaging barely over one reported counseling contact per person) may have suppressed abstinence rates. Also, while we know that about half of the Medicaid smokers enrolled in the study participated in at least half of the visits and calls, it is quite possible that the intensity and perceived burden of the intervention might have discouraged participation by targeted smokers. Characteristics of this real-world target

population (high levels of transience, comorbidities, trauma, incarceration, and other social and health needs) may have affected the ability of many enrollees to effectively participate in the interventions being offered. Finally, the mediational analysis did not control for smoking during the period of postpartum visit attendance. Therefore, home visit attendance might have been affected by smoking success rather than visit attendance affecting smoking status. In essence, the outcomes of the mediational analysis are inconclusive regarding the direction of causal influence.

The economic analysis (see Table 6) is subject to limitations. Full-scale implementation of such a program may vary in size, and it would be anticipated that economies of scale would play a role. Per-participant expenses, such as testing costs, could be lowered with more people participating (or be raised with fewer participants). This project enrolled a little under 500 people per year. Second, ongoing implementation of a program (rather than a research study) may result in fewer barriers to enrollment, reducing some of those costs on a per-participant basis. Third, as stated in the opening paragraph of the cost analysis, the analysis is entirely based on the premise that an existing smoking cessation program targeting pregnant women is available and can add a postpartum component. Finally, the cost structure of this project is related to a specific public/private partnership among a state agency, a university, private and public health care clinics, and a private, nonprofit community organization. Other arrangements would likely produce different cost structures.

In conclusion, this research shows that incentives for treatment engagement and abstinence significantly, but modestly, increased biochemically confirmed abstinence among Medicaid-enrolled women who smoked for six months after they had given birth. The incentives also increased treatment engagement, and this effect appeared to account statistically for the effects of incentives on long-term abstinence. Finally, the incentive program was designed to permit ready dissemination: the potential incentive payments were relatively modest, the program did not require frequent monitoring of smoking status, and it was used as an adjunct to a real-world, ongoing health program for low-income pregnant women.

Figure 1: Consort Diagram

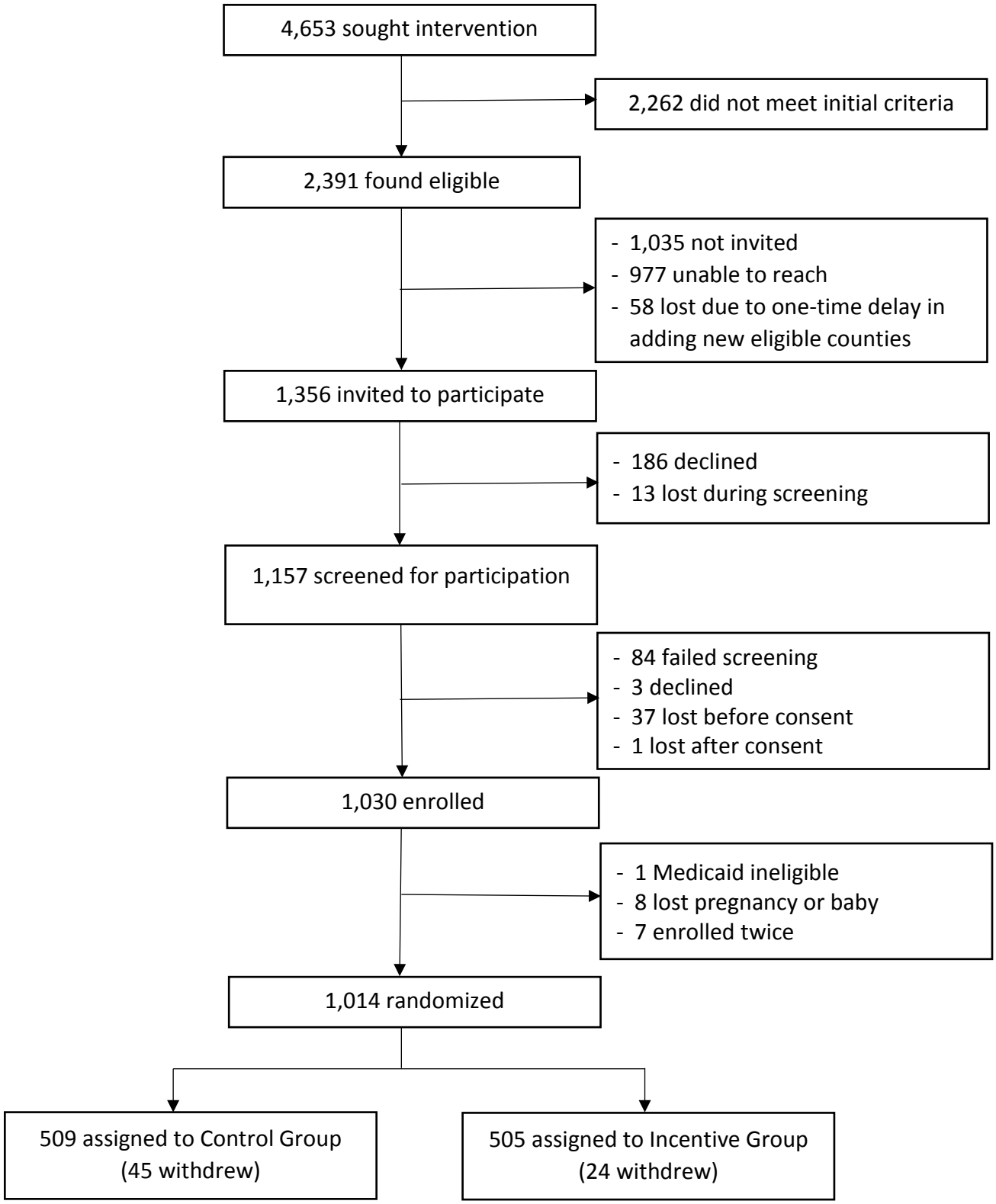


Figure 2: Treatment Contacts and Payments

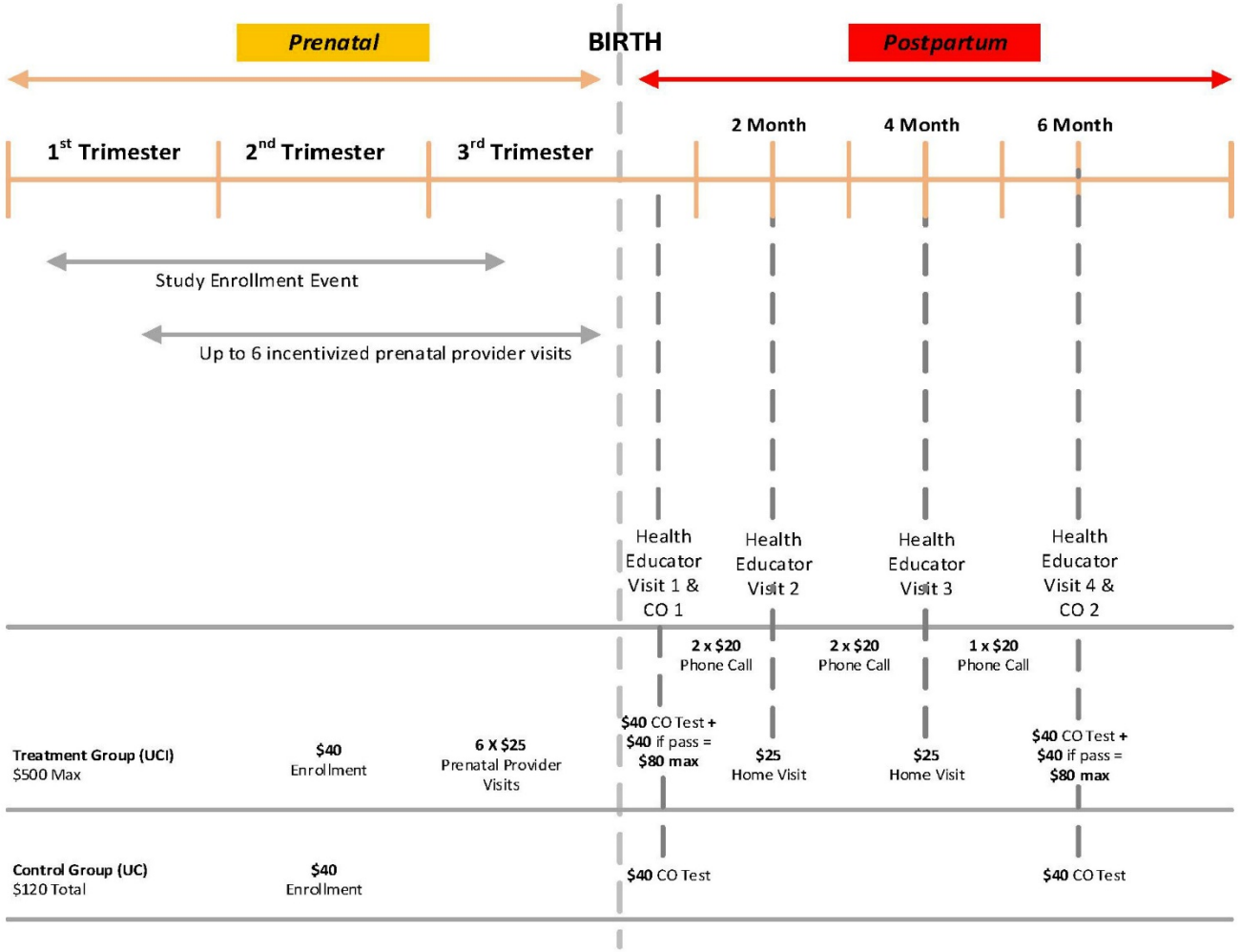
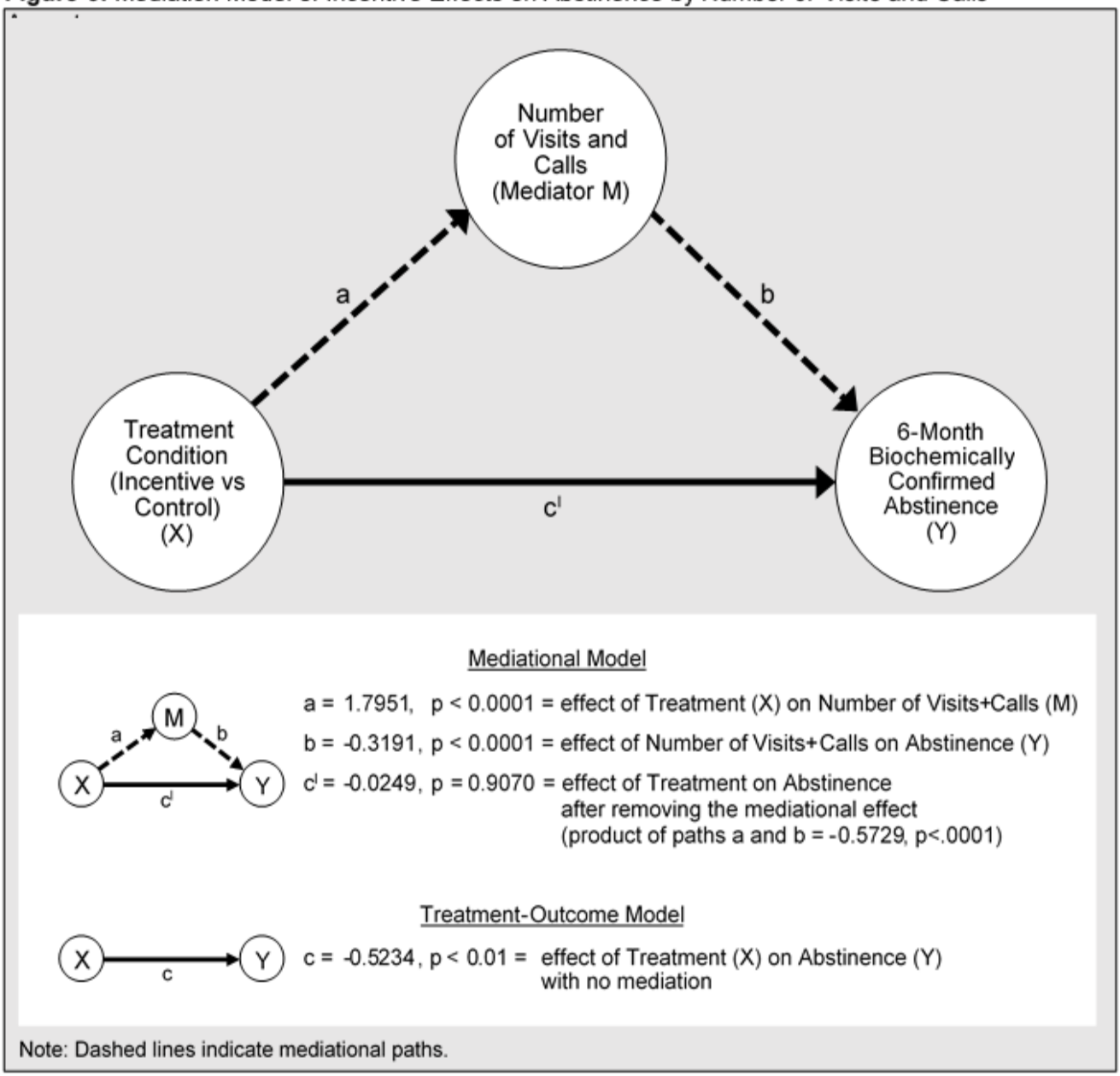


Figure 3: Mediation Model of Incentive Effects on Abstinence by Number of Visits and Calls



Note: a, b, and c = unstandardized regression coefficients. The path c′ = direct effect of X on Y; c′ estimates the difference between group means holding M constant (adjusted mean difference in ANCOVA terms). M = total number of postpartum visits and calls completed.

Table 1: Baseline Sociodemographic and Smoking-Related Variables by Treatment Group

Variable		Treatment Group		P-Value
		Control (n = 509)	Incentive (n = 505)	
Week of Gestation at Entry into the Study	Mean (SD)	14.7 (8.3)	14.7 (8.2)	0.9706
Age	Mean (SD)	26.1 (5.1)	26.7 (5.4)	0.0600
Race	**%** White	47.2%	45.4%	0.1655
	% Black or African American	36.9%	39.8%	
	% Asian	0.8%	0.2%	
	% American Indian/Alaska Native	2.0%	1.0%	
	% Other	2.8%	1.0%	
	% Refused/Do Not know/Missing	7.5%	8.5%	
Ethnicity	% Hispanic	5.3%	4.8%	0.9042
	% Non-Hispanic	81.7%	81.8%	
	% Refused to Answer/Missing	13.0%	13.5%	
Education	% Less Than High School	3.7%	4.2%	0.4056
	% Some High School	20.6%	20.6%	
	% High School or GED	34.2%	34.3%	
	% Some College or Two-Year Degree	25.55	22.0%	
	% College Degree	3.0%	5.4%	
	% Refused to Answer/Missing	13.0%	13.7%	
Marital Status	% Single	31.8%	32.3%	0.6767
	% in a Relationship	27.9%	26.7%	
	% Living with a Partner	16.1%	14.7%	
	% Married	7.9%	8.5%	
	% Widowed/Divorced/Other	1.8%	3.4%	
	% Refused to Answer/Missing	14.5%	14.55	
Baseline Heaviest Cigarettes per Day	% 1-10 Cigs	39.3%	38.4%	0.5916
	% 11-20 Cigs	39.1%	39.4%	
	% > 20 Cigs	17.5%	19.4%	
	% Refused to Answer/Missing	4.1%	2.8%	
Age First Started Smoking Daily	Mean (SD)	16.4 (3.3)	16.3 (3.4)	0.5962
FTCD[1] Item 1	% Smoking Within 30 Min	58.4%	54.7%	0.1586
	% Smoking After 30 Min	24.8%	30.1%	
	% Refused to Answer/Missing	16.9%	15.3%	
Living with a Smoker	% Yes	52.1%	50.1%	0.7461

Variable		Treatment Group		P-Value
		Control (n = 509)	Incentive (n = 505)	
Prior Use of Nicotine Replacement Therapy	**%** Yes	13.6%	12.1%	0.6622
Prior Use of Varenicline	**%** Yes	2.6%	2.6%	0.8713
Prior Use of Bupropion	**%** Yes	1.2%	1.4%	0.8371
Tried to Quit on Own	**%** Yes	15.9%	12.3%	0.2034
Tried Reduction in Smoking	% Yes	23.2%	26.1%	0.5052
Confidence in Quitting[2]	Mean (SD)	4.0 (1.1)	4.1 (1.1)	0.2608
Motivation to Quit[3]	Mean (SD)	4.3 (1.0)	4.3 (1.1)	0.8531

[1]FTCD = Fagerstrom Test of Cigarette Dependence (Fagerstrom, 2012; Heatherton et al, 1991).
[2]Confidence in Quitting was rated on a 1 to 5 scale (1 = not at all; 5 = extremely confident about quitting).
[3]Prior Motivation to Quit was rated on a 1 to 5 scale (1 = not at all; 5 = extremely motivated to quit smoking).

Table 2: Postpartum Seven-Day Point Prevalence Abstinence Outcomes by Treatment Group

Postpartum Endpoint	Abstinence Rates, N Abstinent/Total (%)		Abstinence Risk Difference (95% CI), P-Value[b]	Unadjusted Odds Ratio (95% CI)[c]
	Control	Incentive	Control vs. Incentive	Control vs. Incentive
Home Visit 1—One Week Postpartum CO-Confirmed[a] Seven-Day Point Prevalence Abstinence Rates	68/509 (13.36%)	86/505 (17.03%)	-3.67 (-8.08 to 0.74) P = .1035	0.75 (0.53 to 1.06)
Home Visit 2—Eight Weeks Postpartum Self-Reported Seven-Day Point Prevalence Abstinence Rates	44/509 (8.64%)	87/505 (17.23%)	-8.58 (-12.68 to -4.48) P < .0001	0.45 (0.31 to 0.67)
Home Visit 3—Four Months Postpartum Self-Reported Seven-Day Point Prevalence Abstinence Rates	40/509 (7.86%)	85/505 (16.83%)	-8.97 (-12.99 to -4.96) P < .0001	0.42 (0.28 to 0.63)
Home Visit 4—Six Months Postpartum CO-Confirmed[a] Seven-Day Point Prevalence Abstinence Rates	47/509 (9.23%)	74/505 (14.65%)	-5.42 (-9.40 to -1.44) P < .01	0.59 (0.40 to 0.87)

[a]Biochemical test of abstinence based on expired-air carbon monoxide test (passing based on expired-air carbon monoxide test value of less than 7 ppm).

[b]Pairwise comparisons of abstinence risk differences were tested via Proc Freq (SAS Institute, Inc.) by specifying the RISKDIFF option which provides standard Wald asymptotic confidence limits for the risks.

[c]Unadjusted odds ratios based on logistic regression analysis.

Table 3: Number of Postpartum Visits and Counseling Calls Attended by Participants in the Incentive and Control Groups

Number of Postpartum Visits or Calls [a]	Postpartum Visits Attended n (%)[b]		Postpartum Counseling Calls Taken n (%)[c]	
	Control (n = 509)	Incentive (n = 505)	Control (n = 509)	Incentive (n = 505)
0	90 (17.7%)	57 (11.3%)	112 (22.0%)	66 (13.1%)
1	87 (17.1%)	39 (7.7%)	67 (13.2%)	31 (6.1%)
2	81 (15.9%)	45 (8.9%)	79 (15.5%)	26 (5.2%)
3	96 (18.9%)	91 (18.0%)	97 (19.1%)	67 (13.3%)
4	155 (30.5%)	273 (54.1%)	83 (16.3%)	105 (20.8%)
5	-	-	71 (14.0%)	210 (41.6%)

[a]There were a maximum of four postpartum visits and a maximum of five counseling calls.

[b] $\chi^2 = 68.6$, $p < .0001$.

[c] $\chi^2 = 128.7$, $p < .0001$.

Table 4: Outcomes by Treatment Group Based Only on Biochemical Test Results

Postpartum Endpoint	Abstinence Rates, Number Abstinent/Total (%)		Abstinence Risk Difference (95% CI), P-Value[b]	Unadjusted Odds Ratio (95% CI)[c]
	Control	Incentive	Control vs. Incentive	Control vs. Incentive
Home Visit 4—Six Months Postpartum CO-Confirmed Abstinence Rates[a] Intent-to-Treat Analysis	92/509 (18.07%)	175/505 (34.65%)	-16.58 (-21.91 to -11.25) P < 0.0001	0.42 (0.31 to 0.56)
Home Visit 4—Six Months Postpartum CO-Confirmed Abstinence Rates[a] Responder-Only Analysis	92/316 (29.11%)	175/360 (48.61%)	-19.50 (-26.61 to -12.30) P < 0.0001	0.43 (0.32 to 0.60)

[a]Abstinence based only on expired-air carbon monoxide test results (passing based on expired-air carbon monoxide test value of less than 7 parts per million); self-reported smoking status was not used in the determination of abstinence for these analyses.

[b]Pairwise comparisons of abstinence risk differences were tested via Proc Freq (SAS Institute Inc.) by specifying the RISKDIFF option, which provides standard Wald asymptotic confidence limits for the risks.

[c]Unadjusted odds ratios based on logistic regression analysis.

Table 5: Visit and Call Attendance and Payments

Visit or Call	Attendance Rates Number Attending Visit or Call (%)		Incentive Paid	
	Control Group (n = 509)	Incentive Group (n = 505)	Control Group	Incentive Group
Registration	509 (100%)	505 (100%)	$20,360	$20,200
Prenatal Visit 1	225 (44.2%)	255 (50.5%)	$0	$6,375
Prenatal Visit 2	105 (20.6%)	130 (25.7%)	$0	$3,250
Prenatal Visit 3	68 (13.4%)	86 (17.0%)	$0	$2,150
Prenatal Visit 4	37 (7.3%)	57 (11.3%)	$0	$1,425
Prenatal Visit 5	23 (4.5%)	41 (8.1%)	$0	$1,025
Prenatal Visit 6	13 (2.6%)	20 (4.0%)	$0	$500
Postpartum Visit 1	359 (70.5%)	386 (76.4%)	$14,360	$21,680
Postpartum Visit 2	261 (51.3%)	382 (75.6%)	$0	$9,550
Postpartum Visit 3	221 (43.4%)	366 (72.5%)	$0	$9,150
Postpartum Visit 4	316 (62.1%)	360 (71.3%)	$12,640	$21,400

Visit or Call	Attendance Rates Number Attending Visit or Call (%)		Incentive Paid	
	Control Group (n = 509)	Incentive Group (n = 505)	Control Group	Incentive Group
Postpartum Call 1	253 (49.7%)	343 (67.9%)	$0	$6,860
Postpartum Call 2	268 (52.7%)	348 (68.9%)	$0	$6,960
Postpartum Call 3	224 (44.0%)	362 (71.7%)	$0	$7,240
Postpartum Call 4	230 (45.2%)	346 (68.5%)	$0	$6,920
Postpartum Call 5	228 (44.8%)	355 (70.3%)	$0	$7,100
Total Payments			$47,360	$131,785

Table 6: Per-Participant Cost of Striving to Quit-First Breath Incentive Program

	Control Group (n = 509)	Incentive Group (n = 505)	Overall Cost (n = 1014)
Service cost	$57	$68	$62
Incentive cost	109	279	194
Service administration	393	393	393
Total cost	559	740	649
Total cost for all participants	$284,633	$373,622	$658,256
Participants who were abstinent at six months postpartum based on seven-day point prevalence confirmed by biochemical test	47	74	---
Cost per quit	$6,056	$5,049	NA

Notes:

- Due to rounding errors, the total cost of all participants may not exactly equal the total cost (per participant) times the number of participants.
- Service costs include staff costs for provision of smoking cessation counseling and testing services by Striving to Quit-First Breath health educators, as per study protocol.
- Incentive costs are the cost of the incentives.
- Service administration costs include promotion/marketing costs plus travel costs for Striving to Quit-First Breath staff to get to home visits, materials and supplies for testing, letters, and other service-related materials, such as printing flyers; costs of staff training and supervision; and the cost of administering the incentives.

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