

Effectiveness of a Combined Prenatal and Postpartum Smoking Cessation Program

Anne Gadomski · Laurie Adams · Nancy Tallman ·
Nicole Krupa · Paul Jenkins

Published online: 21 January 2010
© Springer Science+Business Media, LLC 2010

Abstract Women frequently quit smoking during pregnancy but then relapse postpartum. The BABY & ME—Tobacco Free program combines prenatal and postpartum smoking cessation counseling and biomarker feedback with monthly postpartum incentives. The settings included 22 sites (WIC offices and prenatal clinics) in upstate New York. A quasi-experimental design was used to evaluate this intervention, that included four face-to-face prenatal sessions with a counselor who did smoking cessation counseling, carbon monoxide testing and random saliva cotinine testing. For 1 year postpartum, mothers were biochemically tested every 3–4 weeks and, if negative, were issued a voucher for diapers. Three implementation models were studied: multi-tasking counselors at fixed sites (Models 1 and 2) versus itinerant smoking cessation specialists (Model 3). Outcomes included biochemically validated abstinence rates during pregnancy and postpartum. Logistic regression was used to identify predictors of postpartum abstinence and program dropout. Proportional hazards regression was used to compare implementation models. Of the 777 pregnant women who enrolled in the program, 588 were eligible for the postpartum program. The intention to treat pregnancy quit rate was 60%. Postpartum, Model 3 showed consistently better quit outcomes than the other models. Predictors of abstinence at 6 months postpartum are: older age (OR = 1.07, 95% C.I. 1.02–1.12), lower baseline carbon monoxide level (OR = 0.69,

95% C.I. 0.49–0.97), Model 3 (OR = 4.60, 95% C.I. 2.80–7.57) and attending more prenatal sessions (OR = 3.52; 95% C.I. 2.19–5.65). The BABY & ME—Tobacco Free program is an effective smoking cessation program for pregnant and parenting women.

Keywords Smoking cessation · Prenatal counseling · Postpartum quit rates · Cessation specialists · Postpartum incentives

Introduction

Smoking during and after pregnancy poses serious health risks to the child and the mother [1]. Pregnancy is an optimal time for smoking cessation interventions because many women stop smoking during pregnancy [2]. Women who are pregnant are 1.8 times more likely to be abstinent than when not pregnant [3, 4]. Therefore, pregnancy is viewed as a window of opportunity for initiating and sustaining smoking cessation.

Maintaining quit status through the postpartum period confers benefit to the next pregnancy as well as increasing the woman's likelihood of abstinence. However, the postpartum period presents a challenge due to a high rate of relapse to smoking after the baby is born; i.e. 60% of postpartum women relapse by 6 months and 80% by 12 months [5]. There are no known effective interventions for preventing postpartum relapse [6–8], however, few studies have focused on postpartum smoking relapse prevention [1]. In addition, the effectiveness of linking prenatal smoking cessation with postpartum relapse prevention is not known.

Incentive-based programs produce higher smoking cessation rates among pregnant women than other interventions [9–11]. For example, a randomized trial of a \$50

A. Gadomski (✉) · N. Tallman · N. Krupa · P. Jenkins
Bassett Healthcare Research Institute, One Atwell Road,
Cooperstown, NY 13326, USA
e-mail: anne.gadomski@bassett.org

L. Adams
TriCounty Tobacco Control Program of Chautauqua, Cattaraugus,
Allegany, Jamestown, NY 14701, USA

incentive per month for saliva thiocyanate confirmed negative test demonstrated quit rates of 32% at 8 months gestation and 21% at 2 months postpartum among WIC participants [12].

The purpose of this study is to measure the effectiveness of a combined prenatal and postpartum counseling and incentive-based smoking cessation intervention, called the BABY & ME—Tobacco Free program. The goal of the program was to help pregnant women quit smoking during pregnancy and maintain abstinence for 1 year postpartum. The program targeted a high risk group in real world settings, i.e. low income pregnant and early parenting women who smoke. The program is based on a multi-pronged intervention that includes prenatal and postpartum cessation counseling, biomarker feedback (carbon monoxide and saliva cotinine testing) and a monthly postpartum incentive (vouchers for diapers).

Materials and Methods

Intervention and Implementation Protocol

The BABY & ME—Tobacco Free program enrolled pregnant smokers through collaborations with local Women, Infants and Children program (WIC), obstetric and prenatal clinics, Prenatal Care Assistance Program (PCAP), and by physician referral. Smoking status was verified in the referral process. Women were eligible for the program if they were regular or occasional smokers or if they quit 1 month before or during pregnancy. Program participants were required to sign an agreement that they would: (1) commit to quit, (2) attend at least four smoking cessation individual sessions during pregnancy and submit to carbon monoxide (CO) breath tests at each session and (3) be tested monthly postpartum in order to qualify for diaper vouchers. The prenatal cessation counseling sessions addressed the following: first, receipt of the self help materials and how to make a quit attempt; second, effects of secondhand smoke, partners who smoke and establishing smoke-free homes and cars; third, stress management and the benefits of not smoking; and fourth, relapse prevention and the postpartum incentive program.

In addition to prenatal smoking cessation, the goal of the BABY & ME—Tobacco Free program was to provide an incentive to women not to smoke after they deliver. Postpartum, women were eligible to receive a voucher worth \$20 towards the purchase of diapers every 3–4 weeks for up to 1 year as long as they continue to have negative CO breath tests. Participants reported their smoking status and performed CO breath test during the postpartum period to verify smoking status. Measured using *SmokeCheck*TM

monitors (Micro Direct Inc.), CO breath tests of 0–6 qualified women to receive a diaper voucher.

Relapse prevention measures in BABY & ME—Tobacco Free program included monthly testing, incentives (diaper vouchers) and counseling. Counseling during the postpartum visit followed the 2000 US DHHS Clinical Practice Guidelines. This included reminding women about the impact of smoking on the woman's health as well as the baby's health, maintaining the support network for cessation, reinforcing success and counseling on stress management. Each visit was approximately 10 min that included CO breath testing and issuing the voucher. If the woman had smoked, the counselor also provided written materials as well as a referral to the NYS Smoker's Quitline. The program print materials are written for a 3rd grade reading level thus tailoring the educational materials to the needs of a low literacy population.

Based on focus group findings preceding the formulation of the BABY & ME—Tobacco Free program, program originators learned that diapers were what low income women wanted, not gas cards, cell phones or food items. This was an item low income women could not obtain through other programs. The program utilizes "non-traditional" partners like chain supermarkets to be part of the cycle of success for the incentive as these superstores are often conveniently located on major bus lines and are the retailers most often used by low income populations.

Three implementation models were utilized. Model 1 utilized on site BABY & ME—Tobacco Free counselors at WIC and PCAP sites where the BABY & ME—Tobacco Free program was first implemented in western NY in 2001. Model 2 was implemented on a much smaller scale by a public health department in a contiguous county and employed social workers at two prenatal clinic sites as well as outreach community health workers. Following the same protocol, Model 1 and 2 counselors enrolled participants on site and then provided counseling, testing and voucher disbursement at those sites in addition to providing WIC services or prenatal care.

Model 3 employed two itinerant smoking cessation specialists based in Syracuse, NY. These two certified tobacco cessation specialists visited several recruitment sites in a five county area to counsel, test and disburse vouchers to women enrolled in the program. For Model 3, postpartum visits were slightly longer, i.e. 15 min, during which the specialist reviewed progress and barriers. The specialist and mother talked briefly about how proud she should be if she is smoke free or, if she is not smoke free, discuss cravings, cues, the baby's health and healthy ways to handle stress. The main difference between Model 3 and the other two models is that the specialist is dedicated to smoking cessation alone and had more cessation counseling training while WIC and clinic staff in the other models

had competing responsibilities. In addition, in Model 3, the same counselor met the client each time for slightly longer sessions; this was not necessarily the case in the other models. Whereas Model 1 had already implemented BABY & ME—Tobacco Free program since its inception in 2001, Models 2 and 3 just started implementation at the beginning of this evaluation.

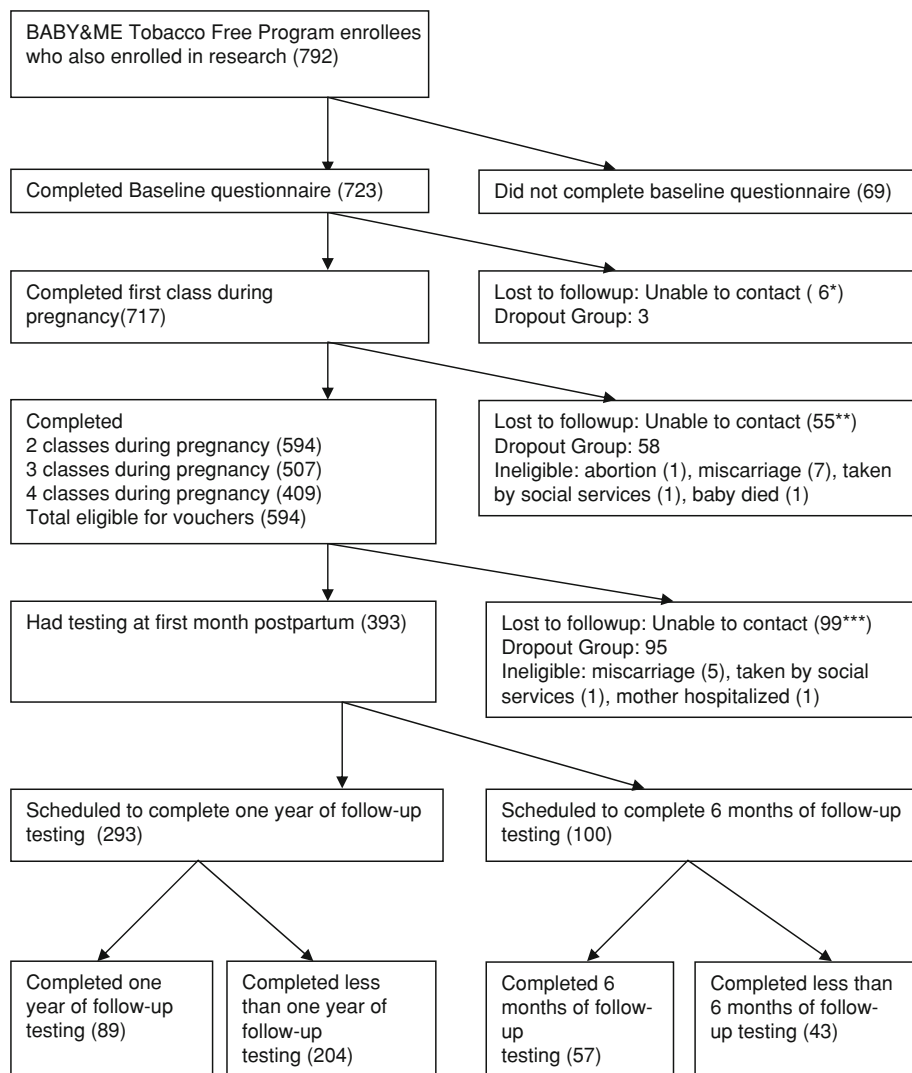
Study Design

The study design is a quasi-experimental evaluation of the BABY & ME—Tobacco Free program compared to a group of women receiving usual care. After the women signed up for the BABY & ME—Tobacco Free program, they were informed about the evaluation and offered the choice to participate in the study. Of the total number of women who registered for the BABY & ME—Tobacco Free program, 65% (792/1214) agreed to also participate in

the research study and signed informed consent (see Fig. 1). Enrollment into research evaluation closely followed the curve for program enrollment (data not shown). Research assistants contacted these women after they enrolled in order to review informed consent forms and study procedures, and complete a baseline questionnaire. Women were then contacted 12 months postpartum to complete a follow up questionnaire by phone interview to assess their current smoking status and cessation experience.

While CO testing was part of the BABY & ME—Tobacco Free program, we also used CO test results to document quit status in our evaluation of this program. In addition, we randomly selected 10% of negative CO tests to verify using a saliva cotinine assay (*NicAlert*TM, Nymox Corp.), a rapid test that requires no special training to complete and yields semi-quantitative results of the primary metabolite of nicotine.

Fig. 1 BABY & ME—tobacco free program: research participant flow diagram



Study Groups

The three implementation models for the BABY & ME—Tobacco Free program were evaluated concurrently along with a comparison group and a drop-out group.

Given the nature of this incentive program, randomization was not feasible because women randomized to a control group were likely to opt out. Therefore, a non-randomized comparison group was selected contextually to be as similar as possible to the intervention sites while not having exposure to the intervention. The comparison group included one WIC site and an obstetric clinic that offered standard care and/or referral to telephonic cessation counseling but not the BABY & ME—Tobacco Free program. The sites that recruited the comparison group were in geographically separate counties in central NY that had similar socioeconomic profiles.

One month after delivery, women who dropped out of the BABY & ME—Tobacco Free program, were contacted by the research staff to assess if they wish to continue in the research arm of this program and complete the 12 month exit interview. These women may or may not have completed the BABY & ME—Tobacco Free program during pregnancy so they may have been completely or partially exposed to the prenatal intervention. Some were eligible to receive the postpartum incentive, but none of the women in the drop-out group had postpartum testing or received vouchers.

Data Analysis

To evaluate possible differences between mothers participating in the program and those who dropped out, baseline characteristics of these two groups were compared using Pearson's Chi square test for categorical data and the Mann–Whitney *U* test for continuous non-parametric data. Statistical significance was defined by a two sided alpha level of .05.

Copies of registration, prenatal session attendance and test results, postpartum vouchers, CO and saliva cotinine test results were sent from the BABY & ME—Tobacco Free program sites to the evaluation center. The main analysis was performed on an intention-to-treat (ITT) basis, whereby all program participants who were lost to follow-up were considered to be smokers. These data were entered and analyzed to calculate the following outcomes.

The pregnancy quit rate was defined as the proportion of women who test CO negative and/or saliva cotinine negative at the 4th prenatal counseling session. Using ITT analysis, the denominator for the pregnancy quit rate is the number of women who were tested at the 1st prenatal session. Using implementation analysis, the denominator is the number of women tested at the 4th session. Because

women enroll in the program at different times during their pregnancy, the time of the 4th session occurred about 8–10 weeks prior to delivery.

The postpartum quit rate was defined as the proportion of subjects who had at least 3, 6 or 12 consecutive CO or saliva cotinine tests that were negative. Using ITT analysis, the denominator for this proportion includes those participants who dropped out or were lost to follow-up because the conservative assumption is that they relapsed and continue to smoke. The percent of negative tests postpartum is defined as the percent of all postpartum follow-ups in which the subject's CO or saliva cotinine tests are negative. Finally, the mean number of consecutive months with negative tests was defined as the longest period in months of consecutive negative tests.

Another outcome measure was time to first failed test during the postpartum period. A proportional hazards regression model was developed to identify predictors of time to first failed test that could represent either a lapse or relapse. The initial at risk group for this model were those mothers who quit smoking prenatally and were attempting to maintain quit status postpartum.

Other studies have shown that several factors predict the success of cessation during pregnancy, namely maternal age, age when mother started smoking, baseline CO level, number of cigarettes consumed per day when smoking regularly, stage of change (action or maintenance vs other) at enrollment, and whether spouse or partner smoke [13, 14]. Based on the transtheoretical model [15], stage of change was self-assessed based on endorsement of one of the following choices describing the participant's current smoking status: Precontemplative: "I do not think smoking is a problem. I am not ready to quit. I do not want to stop smoking."; Contemplative: "I am thinking about quitting smoking. I know that smoking is bad for my health. I want to learn what ways there are to quit smoking."; Preparation: "I am ready to quit smoking. I have planned a quit date. I have the support of my family and friends. I have begun to reduce smoking"; Action: "I will not smoke cigarettes or use other tobacco products. I am attending a smoking cessation group program."; Maintenance: "I am becoming more comfortable as a non-smoker. My cravings for cigarettes are not as strong as they used to be. I feel healthier. I will continue to live as a non-smoker"; Relapse: "How do I start over? I can't believe I had a cigarette. I do not think I can quit again. I disappointed myself and others. I am too weak to stay smoke free. I need more help".

Covariates were tested for univariate association with the outcome of quit status at 6 months postpartum before being entered into a regression model. Interventional factors such as number of sessions attended prenatally (as a proxy for dose of intervention), number of gestational

weeks at session 4 (how close was the last prenatal counseling session to delivery) and implementation model (Models 1, 2 or 3) were also tested. Those independent variables with a significant bivariate association were included in a logistic regression model predicting 6 month quit status (CO and saliva cotinine verified). This multivariate model was used to estimate the odds ratio of quitting with adjustment for significant covariates.

Power calculations were based on the following estimates. Based on previously published studies, the quit rate in the comparison group was not expected to exceed 0.30. A quit rate in the intervention group of at least 0.45 would therefore be considered to be a clinically relevant improvement. Assuming a two-tailed alpha of .05, the combined sample of 400 intervention and 200 control subjects would provide a power of .96 for detecting this minimally relevant difference. This sample size supports regression models anticipating that the regression models would contain at most six or seven covariates and using the rule of thumb of ten subjects per parameter estimated, or even the more stringent rule of ten endpoints per parameter.

Human Subjects

Two Institutional Review Boards approved and monitored this study. This research was conducted in accord with prevailing ethical principles.

Results

Baseline Comparison of the Study Groups

Baseline characteristics of the study groups are presented in Table 1. One-third of the mothers enrolled were less than 21 years of age. Almost half (49%) of the participants were light smokers based on a cut-off of ≤ 10 cig per day. As might be expected from a quasi-experimental design, there were significant differences at baseline among the study groups. The drop-out group had higher level of addiction factors that, in part, may explain why they dropped out of the BABY & ME—Tobacco Free program. The intervention groups had higher mean minutes before smoking in the morning, lower baseline CO levels and a

Table 1 Baseline characteristics of the BABY & ME—tobacco free study groups

	Model 1 <i>n</i> = 378	Model 2 <i>n</i> = 22	Model 3 <i>n</i> = 152	Comparison <i>n</i> = 66	Dropout ^a <i>n</i> = 155	<i>P</i> value*
Age (mean)	23.0	23.1	23.6	24.9	23.5	0.053
# Years smoking (mean)	7.35	6.91	8.20	8.6	8.15	0.055
# Cig per day (mean) ^b	13.3	9.7	15.5	11.6	16.4	0.0001
% Heavy smoker ^b	46.9	27.3	56.9	47.0	58.4	0.01
# Minutes before smoking in morning (mean)	81	169	113	70	73	0.063
# Prior quit attempts (mean)	3.3	4.6	3.2	3.0	2.8	0.499
% Quit at time of program registration	56.1	45.0	51.3	43.9	21.3	0.0001
Baseline CO level (mean)	1.69	1.4	1.62	1.75	2.45	0.0001
# Years of school (mean)	12.1	11.6	12.0	12.3	11.8	0.175
# of children (mean)	0.70	0.50	0.68	1.01	0.86	0.067
% with spouse or partner who smokes	61%	73%	64%	54%	67%	0.01
% Caucasian	90%	91%	89%	95%	93%	0.35
% Medicaid	62%	73%	70%	38%	68%	0.0001
% Prenatal care assistance program	20%	9%	16%	41%	23%	0.0006
% Preparatory SOC	23%	32%	27%	11%	39%	0.0001
% Maintenance SOC	49%	54%	45%	42%	19%	0.0001
% Rural residence	67%	95%	46%	92%	65%	0.0001

SOC stage of change

* *P* value applies to the comparison of all five study groups presented

^a Women who dropped out of the program but agreed to be interviewed postpartum

^b Based on how many cigarettes the mother reported smoking per day when she was a daily smoker at the time of program enrollment or when she found out she was pregnant. Heavy smoker is defined as mother who smoked ≥ 11 cigarettes per day when she was a daily smoker or when she found out she was pregnant

higher percentage of women who had quit at the time of program registration, factors that imply a lower level of nicotine addiction. The comparison group differed by insurance, rural residence and were less likely to have a partner who smokes.

Prenatal and Postpartum Participant Retention

Retention between research enrollment and the 1st BABY & ME—Tobacco Free prenatal session was 93% (708 – 659 = 49) (see Fig. 1). Between the 1st and 4th prenatal session, it was 60% (659 – 393 = 270). Retention into the postpartum period was better, i.e. 89% (393 – 352 = 41). Total drop-out includes 159 women lost to follow-up plus 154 (154/777 = 20%) women who dropped out of the program but agreed to be followed for a total of 312 (312/708 = 44%). The drop out rates did not vary significantly by intervention model, i.e. 30% for Model 1, 23% for Model 2 and 26% for Model 3. There were no women lost to follow-up in the comparison group. Postpartum follow-up for 100 women was limited to 6 months because the grant ended before 12 month follow-up could be completed.

At baseline, 83% of program participants had their smoking status verified by their obstetric provider. Prenatally, 58% (410/708) of women received all four sessions of the intervention. In addition, 20 women completed their 4th session at the first postpartum visit and also received vouchers at this visit. The mean gestational age (in weeks) at the 4th prenatal session in Model 3 was significantly later, at 35 weeks, compared to 32 weeks in Model 1, 28 weeks Model 2, and 31 weeks for drop-outs ($P = 0.0001$). Therefore, the 4th session in Model 3 was given closer to the time of the baby’s delivery.

Deception Rates

To verify negative CO tests, 10% of negative CO tests were randomly verified with a saliva cotinine test. Deception rates (the number of positive saliva cotinine tests divided by negative CO) varied by model in our evaluation, with low values of 6% for Model 3, 13% for Model 1 versus 61% for Model 2.

Outcomes

The pregnancy quit rates for both intention-to-treat (ITT) and implementation (IMP) analysis are presented in Table 2. Because the time of the 4th session varied by group and model, the mean gestational age at the time of the 4th session is shown in Table 2 with each group (ITT) pregnancy quit rate. Model 1 (61%) and Model 3 (60%) had significantly higher ITT pregnancy quit rates compared to Model 2 (50%) and the drop-outs (7.7%, $P < 0.0001$).

Postpartum quit status indicators consistently favored Model 3 (see Table 2). Model 3 has consistently higher quit rates at 3, 6 and 12 months compared to Models 1 and 2. Model 3 has the highest passing rate (97%). Model 3 has a higher mean of 6.0 consecutive months with negative tests compared with 4.8 for Model 1 and 3.3 for Model 2 ($P = 0.03$).

Another measure of cessation success we utilized was time to first failed test (carbon monoxide or saliva cotinine) as measured from the baby’s date of birth (DOB) (see Fig. 2). This survival model has both the 6 month and 12 month participants right censored at 6 and 12 months, respectively. The model includes 319 mothers followed postpartum; 76 participants with missing dates are excluded. Survival curves plotting CO or saliva cotinine confirmed

Table 2 BABY & ME—tobacco free program cessation outcomes by study group

	Model 1	Model 2	Model 3	Dropouts ^a
Pregnancy quit rate ($n = 707$) ITT [§]	61	50	60.5**	7.7
Pregnancy quit rate ($n = 425$) IMP [@]	84@ 32 weeks	69@ 28 weeks	97**@ 35 weeks	32@ 31 weeks
Quit @3 months postpartum ($n = 340$)	52	37.5	77**	–
Quit @6 months postpartum ($n = 340$)	32	25	64**	–
Quit @12 months postpartum ($n = 293$)	9	0	44**	–
Percent of negative tests postpartum ($n = 394$)	90	74	97**	–
Mean consecutive postpartum months with negative tests ($n = 552$)	4.6	3.3	6.0*	–

Prenatal and postpartum quit rate percentages, percent of negative postpartum tests and the mean number of consecutive postpartum months with negative tests are based on carbon monoxide breath tests and a random sample of saliva cotinine tests. The comparison group was not tested biochemically after baseline and therefore is not included in this table

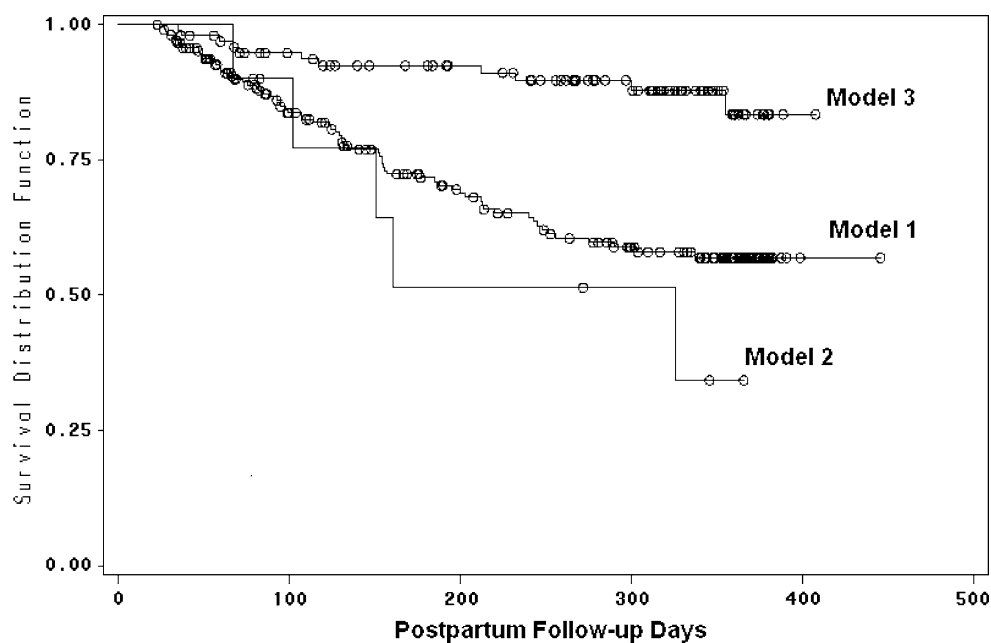
* $P = 0.005$, ** $P = 0.0001$

[§] ITT Intention to treat; [@]IMP Implementation analysis

[#] Sample sizes for outcomes vary due to length of follow-up completed

^a Women who dropped out of the program, but agreed to be followed, did not participate in postpartum testing

Fig. 2 BABY & ME—tobacco free program survival curves: time to first failed postpartum test. Participant time to first failed postpartum test, either carbon monoxide or saliva cotinine, was measured from the baby's date of birth (DOB). This survival model has both the 6 month and 12 month mothers right censored at 6 and 12 months, respectively. $N = 319$ (74 participants with missing data are excluded)



monthly point prevalence abstinence rates, show large differences for the three models tested. In a proportional hazards model, the hazard ratios for Model 1 ($HR = 3.75$) and Model 2 ($HR = 5.71$) are both significantly higher than for Model 3 (the reference group) ($P = 0.0001$), which had the highest likelihood of mothers passing their CO and saliva cotinine tests postpartum.

Self-reported outcomes were ascertained at the 12 month postpartum interview. Overall, the response rate was 74.3% and did not vary significantly by study group (highest was for Model 2 (85.7%) and lowest for the drop-out group (69.4%). At 12 months postpartum, a large percentage of Model 3 participants (65.6%) rated the BABY & ME—Tobacco Free program as “very helpful” compared to Models 1 (53.2%) and 2 (45.4%), and the drop-out group (14.3%, $P = 0.002$). The comparison group did not participate in the program so they were not asked this question. Among women who continued to smoke postpartum, change in mean daily cigarette consumption was measured from registration to 12 month postpartum interview. Women who were still smoking in Model 3 reported significantly higher reduction in the mean number of cigarettes smoked per day (15.0) compared to Model 1 (10.6, $P = 0.0008$) and Model 2 (6.6, $P = 0.006$). Model 3 also had a higher reduction in mean number of cigarettes smoked per day cigarettes than the comparison group (6.9, $P < 0.0001$) and the drop-out group (8.4, $P = 0.0001$).

In univariate comparisons, quit status at 6 months postpartum was significantly associated with whether the spouse or partner smoked ($P = 0.048$), whether the women had quit at the time of registration ($P < 0.0001$) and the number of years of school completed ($P = 0.0009$). Quit status at 6 months postpartum was not associated with rural

residence ($P = 0.26$), Medicaid insurance ($P = 0.66$) or number of cigarettes smoked at time of program registration or when the women found out she was pregnant ($P = 0.44$).

Predictors of abstinence at 6 months postpartum as well as predictors of dropping out of the BABY & ME—Tobacco Free program postpartum in the logistic regression model are summarized in Table 3. Model 3 is associated with significantly increased odds for quitting smoking postpartum. In addition, for each prenatal class attended, the odds are tripled for quitting smoking postpartum. Older women and women with lower baseline carbon monoxide levels also had a higher odds of quitting. Years of school completed, having a partner or spouse who smoked and quit status at the time of program registration were not independent predictors of quit status at 6 months postpartum.

Factors that were associated with an increased odds of dropping out were being insured by Medicaid, having higher levels of nicotine dependence, i.e. baseline CO level, the number of cigarettes smoked when smoking regularly and still smoking at the time of program registration. Protective factors include endorsing a higher stage of change at the time of registration and being enrolled in Model 3.

Discussion

Based on strength of evidence equivalent to the A rating, the 2008 update of DHHS Clinical Practice Guidelines recommend that pregnant smokers should be offered self help materials and 10 min face-to-face psychosocial

Table 3 Predictors of postpartum abstinence at 6 months, and of program drop out by logistic regression

	OR	95% C.I.
<i>Predictors of abstinence @ 6 months postpartum</i>		
Age	1.07	1.02–1.12
Baseline carbon monoxide level	0.69	0.49–0.97
Stage of change ^a	1.34	0.96–1.87
Model 3	4.60	2.80–7.57
# of prenatal sessions	3.52	2.19–5.65
Spouse or partner smokes	1.15	0.82–1.63
Not quit at time of program registration	0.84	0.42–1.70
# Years of school	1.08	0.95–1.21
<i>Predictors of dropping out of the BABY & ME tobacco free program</i>		
Medicaid	1.58	1.05–2.28
Baseline carbon monoxide level	1.57	1.28–1.94
# of cigarettes smoked when smoking regularly	1.02	1.001–1.05
Stage of change ^a	0.71	0.53–0.94
Model 3	0.42	0.26–0.68
Spouse or partner smokes	1.10	0.74–1.62
Not quit at the time of program registration	1.79	1.01–3.17
# of children	0.97	0.83–1.15
# Years of school	0.98	0.89–1.07

OR odds ratio; 95% C.I. 95% confidence interval for the odds ratio

^a Stages of Change were defined as:
 1 = Pre-contemplative;
 2 = Contemplative;
 3 = Preparation;
 4 = Action;
 5 = Maintenance

intervention to exceed brief quit advice [16]. The BABY & ME—Tobacco Free program exceeds these recommendations by combining prenatal and postpartum smoking cessation counseling and biomarker feedback with a monthly postpartum incentive program. This study documents several encouraging outcomes attributable to the BABY & ME—Tobacco Free program. Using intention to treat analysis, the prenatal quit rate was 60% while the postpartum quit rates varied by model from 32 to 64% at 6 months.

The itinerant counselor model (Model 3) demonstrated consistently better outcomes than the other models. In addition to well known factors that predict quit status, participation in Model 3 and the number of prenatal sessions attended were also predictive of quit status at 6 months postpartum. The number of sessions that a pregnant woman attended prenatally was independently associated with abstinence at 6 months postpartum, even when controlling for stage of change. Thus, each prenatal session added a significant increment to the odds of quitting at 6 months postpartum. The significance of these program components as predictors of quit status underscore the effectiveness of this program.

Apart from rural/urban residence, there are no baseline differences among the intervention groups that may explain the differential success of Model 3. Rural/urban residence was not associated with abstinence at 6 months postpartum at the univariate level so it was not included in the multivariate model. However, Model 3 is an independent

predictor of abstinence at 6 months in the logistic regression model. The program components that may explain the better outcomes achieved in Model 3 include: itinerant counselors who are dedicated to smoking cessation (as opposed to also performing other functions i.e. WIC, prenatal care), specific tobacco cessation specialist training and longer postpartum counseling (15 min per session).

Financial incentives for smoking cessation program enrollment or successful smoking cessation could be an important mechanism to increase smoking cessation rates by increasing utilization of effective programs [17]. WIC program participants may be more receptive to monetary incentives due to their lower socioeconomic status [9, 12], thus making WIC sites ideal for recruitment and implementation of the BABY & ME—Tobacco Free program. Because fewer low SES women benefit from brief intervention, due to greater stress, family conflict, and depression [18, 19], more frequent cessation service sessions, offered separately from prenatal care, may be more effective in increasing cessation rates [20]. The BABY & ME—Tobacco Free program was integrated into the areas, locations, and “comfort level” services that low income population already utilize, such as WIC, prenatal clinics and public health department offices. In addition, the program is highly portable given the ease of testing with the portable carbon monoxide monitors or saliva test strips. This enabled BABY & ME—Tobacco Free itinerant counselors to do home visits, or meet with working women at rest stops or convenience stores on their lunch hour.

This study addresses the effectiveness rather than the efficacy of this intervention. This study is subject to the limitations of quasi-experimental design and the possibility of selection bias for both the intervention and comparison groups. At baseline, the intervention groups had slightly lower levels of addiction and thus may be biased toward increased success in quitting relative to the other groups. The most significant differences between the drop-out group versus the intervention groups are in addiction indicators whereas the comparison group differs from the intervention groups by insurance coverage and residence. While we were able to adjust for these differences in our analysis, there may be unmeasured differences due to the fact that the women were not randomized to the study groups. The comparison group, though not exposed to the BABY & ME—Tobacco Free Program, received the current standard of care in NY, and cannot be considered a control group.

Inclusion of the dropout group informs us of the outcomes of women who the program did not serve well, i.e. heavier smokers. The addition of smoking cessation pharmacotherapy postpartum could improve the quit rates for this group. Nicotine replacement therapy combined with cognitive-behavioural therapy may be effective in augmenting smoking cessation rates during pregnancy [21], although this approach is controversial [22]. Because of the uncertainty surrounding the use of medications for pregnant or breastfeeding women who smoke, smoking cessation pharmacotherapy was not a formal part of this program. Few women used medication, therefore we cannot assess the incremental effects that medication use might have on quit rates. Another study limitation is monthly, rather than more frequent, carbon monoxide breath testing or salivary cotinine testing; however, it was not feasible to test women more often.

Because most of our participants were low income, white and had a mean of 12 years of education (see Table 1), our data cannot address differences in outcome by income, ethnicity or higher education. Thus, further studies are needed to test the effectiveness of this program in more diverse populations.

The BABY & ME—Tobacco Free program is a novel individual-level treatment approach designed to improve smoking cessation effectiveness because it includes evidence based components, provides continuity and counseling long-term, appeals to low income women and is feasible in real world settings. This evaluation of the BABY & ME—Tobacco Free program has yielded encouraging results that merit further study.

Acknowledgments This study was funded by the Promising Interventions Grant from Tobacco Use Prevention and Control Program, at the New York State Department of Health. We are grateful to the

many BABY & ME Tobacco Free program sites in Chautauqua, Cattaraugus, Allegany and Livingston counties in New York State. We also acknowledge REACH CNY in Syracuse, NY for implementation of the itinerant BABY & ME Tobacco Free program model. We also acknowledge the Women's Health Clinic at Bassett Healthcare in Cooperstown, NY and the Schoharie county WIC program for recruiting the comparison group. This study was presented at the 2007 and 2009 National Conference on Tobacco or Health and at the 2007 and 2008 American Evaluation Association meetings.

References

- Barker, D., Orleans, T., Halpin, H., & Barry, M. (2004). So near, yet so far: Tobacco dependence treatment for pregnant women. *Nicotine & Tobacco Research*, 6(2), S259–S267.
- Lumley, J., Oliver, S. S., Chamberlain, C., & Oakley, L. (2004). Interventions for promoting smoking cessation during pregnancy. *Cochrane Database System Review*, 18(4), CD001055.
- Ortendahl, M., & Näsman, P. (2007). Use of coping techniques as a predictor of lapse when quitting smoking among pregnant and non-pregnant women. *The American Journal on Addictions*, 16(3), 238–243.
- Crittenden, K. S., Manfredi, C., Cho, Y. I., & Dolecek, T. A. (2007). Smoking cessation processes in low-SES women: The impact of time varying pregnancy status, health care messages, stress and health concerns. *Addictive Behaviors*, 32, 1347–1366.
- Ma, Y., Goinis, K. V., Pbert, L., & Ockene, J. K. (2005). Predictors of smoking cessation in pregnancy and maintenance postpartum in low income women. *Maternal and Child Health Journal*, 9(4), 393–402.
- Van't Hof, S. M., Wall, M. A., Dowler, D. W., & Stark, M. J. (2000). Randomised controlled trial of a postpartum relapse prevention intervention. *Tobacco Control*, 9(suppl), iii64–iii66.
- Roske, K., Schumann, A., Hannover, W., Grempler, J., et al. (2008). Postpartum smoking cessation and relapse prevention intervention: A structural equation modeling application to behavioral and non-behavioral outcomes of a randomized clinical trial. *Journal of Health Psychology*, 13(4), 556–568.
- Levitt, C., Shaw, E., Wong, S., Kaczorowski, J., et al. (2007). Systematic review of the literature on postpartum care: Effectiveness of interventions for smoking relapse prevention, cessation, and reduction in postpartum women. *Birth*, 34(4), 341–347.
- Donatelle, R. J., Hudson, D., Dobie, S., Goodall, A., Hunsberger, M., & Oswald, K. (2004). Incentives in smoking cessation: Status of the field and implications for research and practice with pregnant smokers. *Nicotine & Tobacco Research*, 6(2), S163–S179.
- Gulliver, S., Colby, S., Hayes, K., & Raffa, S. (2004). Tobacco cessation treatment for pregnant smokers: Incorporating partners and incentives. *Medicine and Health, Rhode Island*, 87(1), 9–12.
- Higgins, S. T., Heil, S. H., Solomon, L. J., et al. (2004). A pilot study on voucher-based incentives to promote abstinence from cigarette smoking during pregnancy and postpartum. *Nicotine & Tobacco Research*, 6(6), 1015–1020.
- Donatelle, R. J., Prows, S. L., Champeau, D., & Hudson, D. (2000). Randomised controlled trial using social support and financial incentives for high risk pregnant smokers: Significant other supported (SOS) program. *Tobacco Control*, 9(SIII), iii67–iii69.
- Lu, Y., Tong, S., & Oldenburg, B. (2001). Determinants of smoking and cessation during and after pregnancy. *Health Promotion International*, 16(4), 355–365.
- Chen, X., Stanton, B., Shankaran, S., & Li, X. (2006). Age of smoking onset as a predictor of smoking cessation during pregnancy. *American Journal of Health Behavior*, 30(3), 247–258.

15. Prochaska, J. O., & Velicer, W. F. (1997). The transtheoretical model of health behavior change. *American Journal of Health Promotion, 12*(1), 38–48.
16. Department of Health and Human Services (DHHS). (2009). *Clinical practice guideline for treating tobacco use and dependence: 2008 update*. Accessed 6 Mar 6, 2009, from <http://www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=hstat2.table.29637>.
17. French, G. M., Groner, J. A., Wewers, M. E., & Ahijevych, K. (2007). Staying smoke free: An intervention to prevent postpartum relapse. *Nicotine & Tobacco Research, 9*(6), 663–670.
18. Melvin, C. L., & Gaffney, C. A. (2004). Treating use and dependence of pregnant and parenting smokers: An update. *Nicotine & Tobacco Research, 6*(S2), S107–S124.
19. Adams, E. K., Melvin, C. L., & Raskind-Hood, C. L. (2008). Sociodemographic, insurance, and risk profiles of maternal smokers post the 1990's: How can we reach them. *Nicotine & Tobacco Research, 10*(7), 1121–1129.
20. Stotts, A. L., DeLaune, K. A., Schmitz, J. M., & Grabowski, J. (2004). Impact of a motivational intervention on mechanisms of change in low-income pregnant smokers. *Addictive Behaviors, 29*(8), 1649–1657.
21. Osadchy, A., Kazmin, A., & Koren, G. (2009). Nicotine replacement therapy during pregnancy: Recommended or not recommended? *Obstetrics and Gynaecology Canada, 31*(8), 744–747.
22. Dempsey, D. A., & Benowitz, N. L. (2001). Risks and benefits of nicotine to aid smoking cessation in pregnancy. *Drug Safety, 24*(4), 277–322.