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## Impact of an Incentive-based Prenatal Smoking Cessation Program for Low-income Women in Colorado

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### Abstract

**Objective:** To assess birth outcomes and cost-savings of an incentive-based prenatal smoking cessation program targeting low-income women in Colorado.

**Design:** Prospective observational cohort with nonequivalent population control groups.

**Sample:** Program participants (n=2,231) linked to the birth certificate to ascertain birth outcomes compared to two reference populations from Pregnancy Risk Assessment Monitoring System (PRAMS) and Colorado live births based on the birth certificate.

**Measurements:** Tobacco cessation metrics in the third trimester of pregnancy, neonatal low birth weight (<2,500 grams), preterm birth (birth at < 37 weeks gestation), neonatal intensive care

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DECLARATION OF INTERESTS:

unit (NICU) admission and maternal gestational hypertension. Cost-savings and return on investment (ROI) were projected using average Medicaid reimbursement.

**Results:** Infants of mothers enrolled in the program had a lower risk of low birthweight (RR=0.86; 95% CI= 0.75, 0.97), preterm birth (PTB) (RR=0.76; 95% CI= 0.65, 0.88) and neonatal intensive care unit (NICU) admission (RR=0.76; 95% CI= 0.66, 0.88) compared to the birth certificate population, corresponding to a ROI of \$7.73 and an individual cost savings of \$6,040. Compared to PRAMS, infants of enrolled mothers had a lower risk of PTB (RR=0.72; 95% CI= 0.53, 0.99) and NICU admission (RR=0.45; 95% CI= 0.32, 0.62), corresponding to an ROI of \$2.79 and an individual cost savings of \$2,182.

**Conclusions:** We found a reduction of adverse birth outcomes, and cost savings.

### Keywords

tobacco use cessation; prenatal care; pregnancy; birth weight; premature birth; vulnerable populations

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## BACKGROUND

Smoking during pregnancy is the most substantial modifiable risk factor for infant low birth weight (LBW), preterm birth (PTB) and perinatal mortality in the United States (Dietz et al., 2010; Horta, Victora, Menezes, Halpern, & Barros, 1997). Moderate reductions in the prevalence of prenatal smoking were seen in the U.S. from 2000 to 2010 (from 13.3% to 12.3%), with larger reductions in Colorado (from 10.2% to 7.8%) (Tong, Dietz, Morrow, et al., 2013). However, the link between social disadvantage and prenatal smoking, along with a lower likelihood of a successful cessation, is well recognized (Reid, Hammond, Boudreau, Fong, & Siahpush, 2010).

Cessation of tobacco use by the third trimester of pregnancy has been shown to eliminate much of the reduction in birthweight (England et al., 2001; Harrod et al., 2014; MacArthur & Knox, 1988) and the risk of PTB (Wallace, Aland, Blatt, Moore, & DeFranco, 2017) caused by prenatal smoking. While cessation of tobacco use before pregnancy is ideal, quitting before the third trimester has been shown to prevent adverse birth outcomes (England et al., 2001; Lieberman, Gremy, Lang, & Cohen, 1994; Ohmi, Hirooka, & Mochizuki, 2002). Between 41% and 53% of women who smoked before pregnancy “spontaneously quit” before their first prenatal visit (Colman & Joyce, 2003; Quinn, Mullen, & Ershoff, 1991; Tong, Dietz, Morrow, et al., 2013); however prenatal quit rates are substantially lower among low-income smokers (Hayes et al., 2016; Tong, Dietz, Morrow, et al., 2013), suggesting a need for focused interventions adapted to the needs of these populations. A 2017 Cochrane review of psychosocial interventions for prenatal smoking identified specific model components associated with high quality evidence of effectiveness, particularly for low-income populations, including financial incentives (Boyd, Briggs, Bauld, Sinclair, & Tappin, 2016), biomonitoring feedback (Cope, Nayyar, & Holder, 2003), and support that is more intensive than brief health education provided in routine prenatal care (Chamberlain et al., 2017). Research from widespread, community-level

implementation of models for smoking cessation among vulnerable populations is particularly sparse.

The aim of this study was to examine birth outcomes and project cost savings at the individual and state level associated with participation in a prenatal smoking cessation intervention, known as the Baby & Me Tobacco Free (BMTF) program. Cessation metrics and risk estimates of adverse birth outcomes among women enrolled in the BMTF program are compared to two reference populations of low-income women.

## METHODS

### Design and Sample

For the current study, we used prospective data on  $n=2,431$  women who enrolled in the BMTF program between January 1, 2014 and March 31, 2017. We linked individual data to the birth certificate registry at the Colorado Department of Public Health and Environment (CDPHE) to obtain birth outcomes of enrollees in the BMTF program during this 39 month period. Data were unavailable to identify and link women who had refused or were not offered the program during the study period. Two reference populations of low-income women who smoked in the 3 months prior to or during pregnancy were obtained. One was selected from the Colorado birth certificate registry for the same time period (excluding women who participated in BMTF), and the second was derived from Colorado PRAMS from 2014–2015 (unable to exclude women who participated in BMTF). A description of the smoking cessation program and the two reference populations are provided in the subsequent paragraphs. The study was approved by the Institutional Review Board.

The Colorado BMTF program is based on the original implementation of the BMTF program in New York (Gadomski, Adams, Tallman, Krupa, & Jenkins, 2011), and has been implemented in 21 states. In Colorado, BMTF has been implemented widely since 2014 in 55 local sites across 52 counties. The program was delivered in the mothers' communities at medical centers or local public health agency clinics with existing health services such as prenatal care and Women Infants and Children (WIC) clinics. Recruitment into the program was ongoing, and women were referred by a provider, self-referred or informed about the program while receiving care at one of the participating clinics or centers. Women were eligible to enroll in BMTF if they were currently pregnant, resided in a participating county, and self-reported smoking at least 3 months prior to becoming pregnant. There were no exclusions on age, income or insurance status; a majority of these women utilized Medicaid or had annual household income of less than \$25,000.

The program included four in-person prenatal counseling sessions led by public health nurses and health educators utilizing motivational interviewing techniques. At each of the four prenatal counseling session, a carbon monoxide breath test was performed to validate smoking cessation status (Micro<sup>+baby</sup> Smokerlyzer, Covita) and provide feedback to the mother. Participants received a diaper voucher incentive at the third and fourth prenatal session if the carbon monoxide breath monitoring result was <6 parts per million (ppm). The diaper vouchers were redeemable for any brand or size of diapers or wipes, and could be used in-store only within the mothers' community. In total, the available incentive was \$50

in diaper vouchers, provided in two equal increments at prenatal sessions contingent on biomonitoring confirmation of abstinence. Diaper vouchers were chosen as the incentive because the public health agencies administering the intervention have restrictions on providing cash and diaper-related expenses pose a significant financial challenge for low-income parents. Facilitators from each participating agency administered standardized data collection instruments to gather information on socio-demographic characteristics, smoking history, secondhand smoke exposure, and smoking cessation. All data were entered into a web-based, HIPAA-compliant database.

For the birth certificate reference population, inclusion criteria included women who delivered a live-born infant in Colorado between January 1, 2014 and March 31, 2017, were residents of Colorado, and at the time of delivery self-reported smoking in the three months prior to or during pregnancy. Additional inclusion criteria included a total household income <\$25,000/year and/or Medicaid insurance status. Exclusion criteria included women who participated in the BMTF program during the study period. All birth certificates utilized the 2003 version of the U.S. Standard Certificate for Live Births with maternal smoking characterized as the average number of cigarettes smoked per day in the three months prior to pregnancy and in each pregnancy trimester.

The Colorado PRAMS reference population included aggregate data from the 2014–15 PRAMS survey, a cross-sectional, population-based survey conducted by the Centers for Disease Control and Prevention in collaboration with CDPHE on a stratified random sample of women who delivered a live-born infant between January 1, 2014 and December 31, 2015. PRAMS questionnaires were self-administered in English and Spanish via postal mail to women at approximately 2–4 months postpartum and telephone follow-up was conducted for non-respondents. The following national-level questions were administered to all PRAMS respondents: “Have you smoked any cigarettes in the past 2 years?” Respondents who answered “yes” were asked how many cigarettes they smoked on an average day in the 3 months before they got pregnant and in the last three months of their pregnancy. Respondents who answered anything other than “I didn’t smoke then” for both time periods were included in the reference group. The PRAMS reference population was further limited to women who reported a total household income of \$26,000 per year and/or who used Medicaid as the primary source of insurance for prenatal care.

## Measures

Adverse reproductive outcomes for each study population were abstracted from the birth certificate, including: LBW (<2,500 grams), PTB (birth at <37 weeks gestation), admission to the neonatal intensive care unit (NICU) and maternal gestational hypertension. Additional data abstracted from the birth certificate included: the average number of cigarettes smoked per day in the three months prior to pregnancy and in each subsequent trimester; maternal age at delivery; maternal race/ethnicity (non-Hispanic white, any Hispanic, non-Hispanic black and non-Hispanic other race); highest level of maternal educational attainment (< high school or high school); source of insurance at time of delivery (Medicaid, private or other); marital status (married or not married); parity (none, 1–2, 3); and geographic area of residence classified as urban, rural or frontier based on Colorado Rural Health Center

designations, where rural counties are not designated as parts of metropolitan areas and frontier counties have population densities of 6 or fewer persons per square mile (CRHC, 2016).

Carbon monoxide breath tests determining smoking status were collected prospectively in the BMTF program (i.e., before birth outcomes had occurred). Prenatal smoking cessation measures in the BMTF study population were calculated using an implementation quit proportion defined as the number of women with carbon monoxide-validated cessation at the last BMTF visit attended in the third trimester of pregnancy divided by the number of women who attended a BMTF visit in the third trimester of pregnancy. An intention-to-treat (ITT) cessation measure was calculated as the number of women with carbon monoxide validated cessation at the last BMTF visit in the third trimester of pregnancy divided by the number of women who enrolled in the BMTF program and attended at least one prenatal visit. The ITT cessation measure assumes all mothers who were lost to follow-up before their 3<sup>rd</sup> trimester of pregnancy, had relapsed to using tobacco after their last carbon monoxide-validated smoke-free BMTF visit.

Smoking status during pregnancy was determined by maternal self-report at time of delivery or 2–4 months postpartum in the birth certificate and PRAMS populations, respectively (i.e. after knowing birth outcomes). Cessation in the reference populations was calculated based on maternal self-report of tobacco use as the number of women who reported smoking 0 cigarettes in the third trimester of pregnancy (for the birth certificate) or last 3 months of pregnancy (for PRAMS) divided by the number of women who reported smoking at least 1 cigarette in the 3 months prior to or during pregnancy.

### **Analytic Strategy**

The total and per-person cost analysis of BMTF included relevant costs associated with implementing the program over the study period. These included staff time to deliver the intervention and costs of training, administration (including carbon monoxide monitoring), and incentives (diaper vouchers). The reference populations were assumed to have received no additional prenatal smoking cessation care above and beyond usual prenatal care, and it was assumed that the BMTF population would have also received usual care; as such, the cost of usual prenatal care and its related smoking cessation is valued at \$0 for the purpose of this analysis (Drummond, Sculpher, Torrance, O'Brien, & Stoddart, 2005). Costs for each adverse maternal delivery and birth outcome were based on the average Medicaid reimbursement for a delivery complicated with the outcome, minus the average reimbursement for an uncomplicated delivery (Rohde, 2012; U.S. Department of Labor, 2017). Medicaid reimbursement costs were obtained from the 2010 and 2014 Medicaid reimbursement payments for the state of Colorado, accessed through the Healthcare Cost and Utilization Project (HCUPnet) (U.S. Department of Health and Human Services). Each cost was time-adjusted and discounted for the relevant years using the Medical Care Price Index (U.S. Department of Labor, 2017).

The per-person cost savings were determined by multiplying the cost for each outcome by the risk difference between the intervention group and reference groups. Total annual cost savings were derived by multiplying the total per-person cost savings by the per-person cost

of BMTF divided by 3.25 years (the length of the study period). The hypothetical cost savings to the state of Colorado of providing the BMTF intervention to all low-income, Medicaid recipients who smoked in the three months prior to or during pregnancy, was extrapolated from the total cost savings multiplied by the eligible population based on 2015 PRAMS. The return on investment (ROI) was calculated by dividing the per person cost savings by the per person cost of BMTF. A sensitivity analysis for the cost saving estimates were performed by only including risk differences for outcomes that were significant at a  $p < 0.05$  between the BMTF study group and the reference groups.

Pearson chi-square tests ( $\alpha = 0.05$ ) were used to compare sociodemographic characteristics between the BMTF study population and the two reference populations. The PRAMS reference population was weighted for sampling probabilities, non-response and non-coverage to allow for generalization to all Colorado resident births among women who match reference population eligibility criteria. Comparisons between PRAMS and the BMTF population were conducted by assigning a weight of one to each BMTF participant and using Taylor-series linearization for variance estimates. Separate complete case multivariable log-binomial regression models were used to estimate cumulative incidence, risk ratios (RR) and 95% confidence intervals (CIs) for each outcome, adjusted for confounding covariates. Covariates were selected for each model based on the operational criteria for confounding or a previously demonstrated clinical or biologic rationale. For the comparison between BMTF and the birth certificate reference, the LBW model was adjusted for maternal age, race/ethnicity, income, insurance, area of residence and number of prenatal visits; the models for PTB, NICU, and gestational hypertension were adjusted for maternal age, race/ethnicity, income and insurance. For the comparison between BMTF and the PRAMS reference population, the LBW and PTB models were adjusted for maternal age, race/ethnicity and area of residence; the NICU model was adjusted for maternal age and race/ethnicity; and the gestational hypertension model was adjusted for maternal age. Statistical analyses were performed using SAS 9.4 and SAS-callable SUDAAN 11.0.1 in SAS 9.4 (SAS Institute Inc., Cary, NC).

## RESULTS

A total of 2,231 participants (91.8%) were linked to a live birth in the birth certificate registry at CDPHE. The birth certificate reference population includes 16,739 women and the PRAMS reference population consists of 501 respondents, reflecting a weighted response of 16,351 women.

The characteristics of women enrolled in the BMTF study population relative to the reference populations and smoking characteristics are presented in Table 1. Compared to the birth certificate reference population, participants in BMTF were more likely to be <20 years of age ( $p < 0.0001$ ), non-Hispanic black ( $p = 0.03$ ), have a high school education ( $p = 0.004$ ), insured by Medicaid during pregnancy ( $p < 0.0001$ ), unmarried ( $p = 0.0003$ ), primiparous ( $p < 0.0001$ ) or reside in a frontier county ( $p < 0.0001$ ). Compared to the PRAMS reference population, participants in BMTF were more likely to be non-Hispanic white or non-Hispanic black ( $p < 0.0001$ ), unmarried ( $p < 0.0001$ ), primiparous ( $p = 0.01$ ) or reside in a frontier county ( $p < 0.0001$ ).

Regarding smoking history prior to pregnancy presented in Table 1, BMTF participants consumed a higher quantity of cigarettes than the PRAMS and birth certificate reference populations; 14.0% compared to 4.4% and 3.0% of participants reported smoking 20+ cigarettes/day in BMTF, PRAMS and birth certificate, respectively. Regarding cessation, the implementation quit proportion in the 3<sup>rd</sup> trimester of pregnancy in BMTF was 83.1% and the ITT quit proportion was 62.3%, both higher than the self-reported quit proportion in the birth certificate reference population of 29.5% ( $p<0.0001$ ). Compared to self-reported cessation by the last 3 months pregnancy in PRAMS (60.4%), only the implementation quit proportion was higher in BMTF ( $p<0.0001$ ).

A majority of BMTF participants enrolled in their second trimester (52.2%), averaged 3.11 prenatal sessions out of the possible 4 visits, and utilization of the Colorado QuitLine was low between visits (8%–17%). At enrollment in the BMTF program, participants reported an average of 8.5 years of tobacco use and about 5 previous quit attempts. A majority of BMTF participants had a significant other who smoked (59.4%) but did not allow anyone to smoke inside their home (79.2%). About 98% of BMTF participants self-reported smoking 3 months prior to pregnancy. At the time of enrollment into BMTF, 58.63% were validated as not smoking by the carbon monoxide breath test. Table 2 displays the smoking characteristics of BMTF participants at enrollment as well as program participation measures.

### Infant and maternal outcomes

The cumulative incidence of maternal and neonatal delivery outcomes is presented in Figure 1. The incidence of LBW was 12.0% (95%CI=10.6, 13.3%), 15.5% (95%CI=15.0, 16.1%) and 12.5% (95%CI=11.9, 13.0%) in the BMTF, birth certificate and PRAMS reference populations, respectively. The incidence of PTB was 9.0% (95%CI= 7.8, 10.2%), 12.4% (95%CI= 11.9, 12.9%), and 11.4% (95%CI= 8.2, 14.7%) in the BMTF, birth certificate and PRAMS reference populations, respectively. NICU admissions occurred among 9.6% (95%CI= 8.4, 10.9%), 13.1% (95%CI= 12.6, 13.6%) and 19.3% (95%CI= 14.3, 24.3%) of neonates in the BMTF, birth certificate and PRAMS reference populations, respectively. Finally, gestational hypertension occurred in 5.4% (95%CI= 4.4, 6.3%), 4.6% (95%CI= 4.2, 4.9%) and 6.0% (95%CI= 2.7, 9.3%) of women in the BMTF, birth certificate and PRAMS reference populations, respectively.

The adjusted RRs for each adverse neonatal and maternal delivery complication in the BMTF program relative to the reference populations are shown in Figure 2. Participants in BMTF had a 14% lower risk of LBW (RR=0.86; 95%CI= 0.75, 0.97), a 24% lower risk of PTB (RR=0.76; 95%CI= 0.65, 0.88) and a 24% lower risk of NICU admission (RR=0.76; 95%CI= 0.66, 0.88) compared to women in the birth certificate reference group. Compared to the PRAMS reference group, participants in BMTF had a 28% (RR=0.72; 95%CI= 0.53, 0.99) lower risk of PTB and a 55% (RR=0.45; 95%CI= 0.32, 0.62) lower risk of NICU admission. Enrollment in BMTF was not associated with a differential risk of gestational hypertension in comparison to either reference population.

### Cost savings estimates

Findings from the cost savings analysis are presented in Table 3. The average yearly cost of implementing the BMTF program over the 39 month study period was \$536,189, a per-person cost of \$781. Total per-person cost savings of BMTF compared to the birth certificate and PRAMS reference populations was \$6,040 and \$2,182, respectively. Total annual cost savings associated with the BMTF intervention was \$4,144,118 and \$1,497,299 compared to the birth certificate and PRAMS reference populations, respectively. If the BMTF program covered all Colorado Medicaid recipients who smoke in the three months prior to or during pregnancy (estimated N=8,986 from 2015 PRAMS), we extrapolate that the state of Colorado would save between \$16.8 and \$6.0 million dollars annually on healthcare costs associated with adverse smoking-related birth outcomes, based on the birth certificate and PRAMS comparisons respectively. Of note, these extrapolations do not include the additional cost to expand BMTF to all Colorado Medicaid smoking pregnant women and assume that health outcomes will be similar in this larger population. The ROI of BMTF compared to the birth certificate and PRAMS reference groups, respectively, was \$7.73 and \$2.79. Results of the sensitivity analysis are displayed in Supplemental Table 1 which considers only risk difference estimates that were significant at  $p < 0.05$ . The per-person cost savings of BMTF compared to the birth certificate and PRAMS reference populations was \$6,088 and \$1,538, respectively. The total annual cost savings, ROI and extrapolated potential annual cost savings was \$4,177,605, ROI=\$7.79 and \$16,834,061 (for the BMTF compared to the birth certificate reference); and \$1,055,013, ROI=\$1.97 and \$4,251,278 (for the BMTF compared to the PRAMS reference).

### DISCUSSION

Our results provide insight into an incentive-based smoking cessation program targeted at low-income women that was implemented widely across the state of Colorado. Participants who enrolled in BMTF between January 1, 2014 and March 31, 2017 tend to be young (less than 20 years of age), first time mothers residing in rural or frontier parts of the state. In comparison to two population-based reference groups, BMTF participants had a 24–28% reduction in the risk of preterm birth and a 24–55% reduction in the risk of NICU admissions. For an intervention that costs on average, \$781 per-enrollee, we estimate that implementation of BMTF resulted in a yearly cost savings to the state of \$1.4 to \$4.1 million dollars. This is the first study we are aware of to compare an incentive-based prenatal smoking cessation model against a PRAMS reference group. This is important because previous literature has shown that PRAMS captures a higher proportion of women who smoked during pregnancy compared to the birth certificate, making PRAMS a strong reference population (Allen, Dietz, Tong, England, & Prince, 2008; Tong, Dietz, Farr, D'Angelo, & England, 2013).

Previous community-level implementation studies of evidence-based prenatal smoking interventions focusing on low-income populations have shown mixed results. Implementation of an intervention based on an expanded version of the 5A's model (Ask, Advise, Assess, Assist, Arrange) delivered by trained health educators to low income women in rural South-Central Appalachia was associated with increased birthweights and



50% fewer NICU admissions compared to a historical control group (Bailey, 2015). In contrast, a study by Britton et al. reported no impact on birth outcomes associated with implementation of a nurse-managed cessation program based upon the 5A's that was completely integrated into prenatal care (Avidano Britton, Brinthaup, Stehle, & James, 2006; Britton, James, Collier, Sprague, & Brinthaup, 2013). The BMTF program has also been implemented in Tennessee in which a 61% reduction in LBW among 866 BMTF participants with high levels of participation compared to a birth certificate reference population of women of all income levels was observed (Zhang et al., 2017). Explanations for the differential effects of the same intervention implemented in both Colorado and Tennessee populations likely derive from the limited assessment of participants with high levels of participation in BMTF and the choice of a birth certificate reference population that was not limited to low-income women, thus overestimating population-level impact.

The observed reduced risk of adverse birth outcomes in BMTF compared to the two reference populations may in part be explained by factors other than participation in the smoking cessation program. First, women who enrolled in BMTF may have represented a "phenotype" of smoker with higher motivation and/or self-efficacy in their ability to quit. Previous studies, including a study among low-income women, identified both motivation to quit and self-efficacy as important predictors of enrollment in smoking cessation programs (Graham et al., 2008; Kviz, Crittenden, & Warnecke, 1992; Pohl, Martinelli, & Antonakos, 1998; Woods et al., 2002). Data on women who were offered BMTF in their community and refused were not available to evaluate this possibility. Additionally, as part of the BMTF program, public health nurses and health educators received training in motivational interviewing techniques, emphasizing client-centered goal setting during the prenatal counseling sessions. Therefore, whether a woman enrolled with a higher affinity to quit or the woman's motivation to quit was strengthened by the motivational interviewing could not be evaluated in the current study. We also found that the proportion of women who quit smoking by the third trimester of pregnancy was twice as high with the conservative ITT metric in the BMTF study population compared to the birth certificate reference population, but not marginally different than the PRAMS reference population. Therefore, the reduced risk of adverse birth outcomes in BMTF compared to PRAMS may be partly attributed to the reduced reporting bias of cessation status in the BMTF study population in which third trimester cessation was determined via carbon monoxide-testing before knowledge of birth outcomes compared to self-report in PRAMS 2–4 months after the birth (with knowledge of adverse outcomes). Furthermore, the differential methods of smoking ascertainment likely overestimate third trimester cessation in the reference populations, thus hampering direct comparisons of quit metrics between our study population and reference populations.

Our study is subject to several limitations. First, prenatal smoking status in the BMTF population was validated with carbon monoxide testing before birth outcomes occurred, while smoking status in our reference populations was self-reported after birth. Self-reporting bias is likely in the reference populations, which would operate to underestimate any protective effect of the intervention. While prenatal smoking was self-reported in both reference populations, inclusion of the PRAMS reference group is a strength of our study as PRAMS has been shown to capture a higher proportion of light smokers (Tong, Dietz, Farr, et al., 2013) and smokers in the three months prior to and during pregnancy compared to the

birth certificate (Allen et al., 2008). The conservative assumption of the ITT cessation metric, which assumed participants who dropped out of BMTF relapsed to smoking, may have falsely labeled a proportion women lost to follow-up as a failed cessation attempt. Second, we are unable to distinguish effects of the diaper voucher incentive and the motivational interviewing components of the program on birth outcomes and cost-savings; however, our promising findings warrant future research using a more rigorous randomized controlled trial design. Another limitation is the inability to directly compare women who enrolled in BMTF to those who refused as data on non-participants were not collected at time of program implementation. We are also unable to assess the type or intensity of prenatal smoking cessation care received in the reference populations. Further, previous RCTs of the effectiveness of financial incentives were based on either cash payments (Baker et al., 2018) or shopping vouchers for cessation success (Donatelle, Prows, Champeau, & Hudson, 2000; McConnachie, Haig, Sinclair, Bauld, & Tappin, 2017), while BMTF provides diaper vouchers. The diaper voucher adaptation of financial incentives is both sensitive to the restrictions of government agencies unable to distribute cash incentives and the financial needs of low-income mothers. Finally, the risks of prenatal tobacco exposure extend well beyond maternal delivery and neonatal birth complications and were not evaluated in our study nor included in our cost estimates.

Overall, our findings indicate a reduction in preventable smoking related adverse birth outcomes among women who participated in the BMTF program, and suggest health care savings. These findings also have implications for public health nursing as the field continues to evolve in the development, implementation and sustainability of community-based prenatal smoking cessation programs. The strong collaborations between the public health nursing community with tobacco cessation specialists are essential to understand and address the challenges of low income pregnant women. Additional translational studies are needed to understand both the sustainability of long-term integration of BMTF in communities and the replication of the program in different settings. Other assessments of the BMTF program should include a randomized controlled study to test the impacts of the most efficacious components of the program.

## Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Tessa Crume: (1) made a substantial contribution to conception and design of the study, to data acquisition, and interpretation; and (2) revised the article for important intellectual content; and (3) read and approved the final version of the submitted manuscript.

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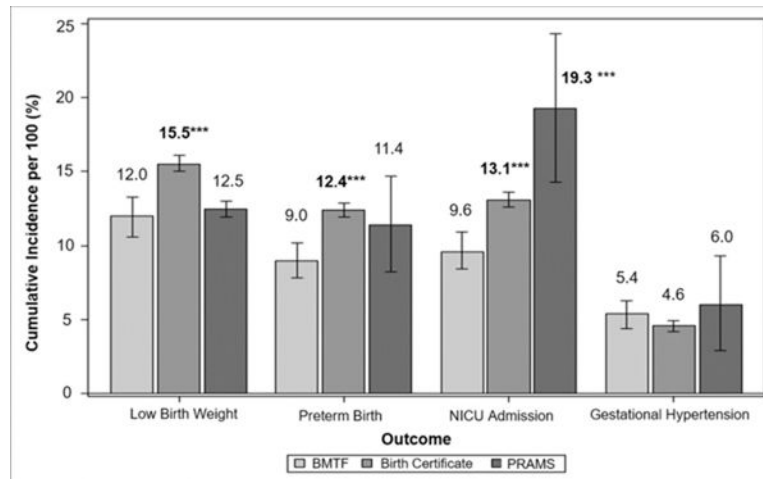
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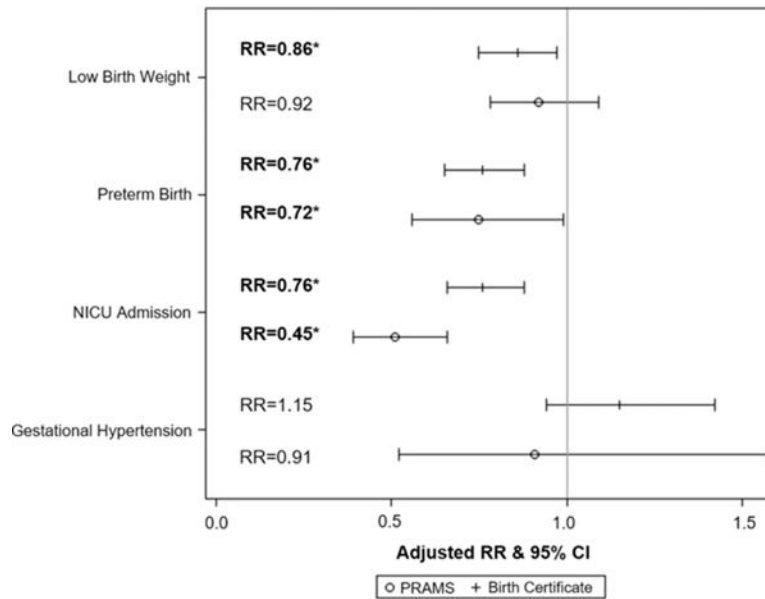
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**Figure 1.**

Adjusted cumulative incidence of adverse birth outcomes in the BMTF study and referent groups: the Colorado Birth Certificate Registry (January 1, 2014–March 31, 2017) and Colorado PRAMS (2014–2015) Abbreviations: BMTF, Baby and Me Tobacco Free; NICU, neonatal intensive care unit; PRAMS, Pregnancy Risk Assessment Monitoring System. Footnotes: Boldface indicates statistical significance (\* $p < 0.05$ , \*\* $p < 0.01$ , \*\*\* $p < 0.001$ ) For the comparison between BMTF and the birth certificate referent group the LBW model was adjusted for maternal age (continuous), race/ethnicity (reference: non-Hispanic white), total household income (reference: \$15,000–\$25,000), insurance (reference: Medicaid), residence (reference: urban) and number of prenatal visits. The PTB, NICU, and gestational hypertension models were adjusted for maternal age, race/ethnicity, total household income and insurance. For comparison between BMTF and the PRAMS referent group the LBW and PTB models were adjusted for maternal age (continuous), race/ethnicity (reference: non-Hispanic white), and residence (reference: urban). The NICU model was adjusted for maternal age and race/ethnicity. The gestational hypertension model was adjusted for maternal age.



**Figure 2.** Risk Ratios of adverse birth outcomes in the BMTF study and referent groups: the Colorado Birth Certificate Registry (January 1, 2014-March 31, 2017) and Colorado PRAMS (2014–2015) Abbreviations: BMTF, Baby and Me Tobacco Free; CI, confidence interval; NICU, neonatal intensive care unit; PRAMS, Pregnancy Risk Assessment Monitoring System; RR, relative risk; Footnotes: Boldface indicates statistical significance (\*p<0.05, \*\*p<0.01, \*\*\*p<0.001) For the comparison between BMTF and the birth certificate referent group the LBW model was adjusted for maternal age (continuous), race/ethnicity (reference: non-Hispanic white), total household income (reference: \$15,000-\$25,000), insurance (reference: Medicaid), residence (reference: urban) and number of prenatal visits. The PTB, NICU, and gestational hypertension models were adjusted for maternal age, race/ethnicity, total household income and insurance. For comparison between BMTF and the PRAMS referent group the LBW and PTB models were adjusted for maternal age (continuous), race/ethnicity (reference: non-Hispanic white), and residence (reference: urban). The NICU model was adjusted for maternal age and race/ethnicity. The gestational hypertension model was adjusted for maternal age.

**Table 1.** Characteristics of the BMTF population and referent groups: Colorado Birth Certificate Registry and Colorado PRAMS

Variable	BMTF Participants (n=2,231) <sup>a</sup>	Referent population from CO Birth Certificate Registry (n=16,739) <sup>d</sup>	BMTF vs. Birth Certificates p-value <sup>b</sup>	Referent population from PRAMS (n=16,351) <sup>c</sup>	BMTF vs. PRAMS p-value <sup>d</sup>
Maternal age, years			<0.0001 <sup>***</sup>		0.3
<20	271 (12.2)	1438 (8.6)		1508 (9.2)	
20–29	1450 (65.0)	10895 (65.1)		10727 (65.6)	
30	510 (22.9)	4397 (26.3)		4117 (25.2)	
Maternal race/ethnicity			0.03 <sup>*</sup>		<0.0001 <sup>***</sup>
Hispanic	545 (25.2)	3724 (22.8)		4119 (25.6)	
NH white	1409 (65.0)	11025 (67.6)		9529 (59.3)	
NH black	159 (7.3)	1089 (6.7)		1071 (6.7)	
Other	54 (2.5)	478 (2.9)		1364 (8.5)	
Education			0.004 <sup>**</sup>		0.8
< High school	468 (21.2)	4030 (24.1)		3542 (21.8)	
High school	1740 (78.8)	12512 (74.8)		12725 (78.2)	
Insurance			<0.0001 <sup>***</sup>		0.5
Medicaid	1951 (87.6)	14005 (83.7)		14,447 (88.9)	
Private	216 (9.7)	1830 (10.9)		1254 (7.7)	
Other	61 (2.7)	855 (5.1)		550 (3.4)	
Marital Status			0.0003 <sup>**</sup>		<0.0001 <sup>***</sup>
Married	828 (37.2)	6863 (41.2)		8374 (51.4)	
Not Married	1398 (62.8)	9794 (58.8)		7934 (48.7)	
Parity			<0.0001 <sup>***</sup>		0.01 <sup>*</sup>
None	1134 (50.8)	5910 (35.3)		6942 (42.5)	
1–2 births	881 (39.5)	7948 (47.5)		7132 (43.6)	
3 births	216 (9.7)	2873 (17.2)		2277 (13.9)	
Residence			<0.0001 <sup>***</sup>		<0.0001 <sup>***</sup>



Variable	BMTF Participants (n=2,231) <sup>d</sup>	Referent population from CO Birth Certificate Registry (n=16,739) <sup>d</sup>	BMTF vs. Birth Certificates p-value <sup>b</sup>	Referent population from PRAMS (n=16,351) <sup>c</sup>	BMTF vs. PRAMS p-value <sup>d</sup>
Frontier	142 (6.4)	553 (3.3)		313 (1.9)	
Rural	361 (16.2)	2517 (15.0)		1706 (10.4)	
Urban	1728 (77.5)	13669 (81.7)		14,332 (87.7)	
Cigarettes/day in the 3 months prior to pregnancy					
None	50 (2.3)	75 (0.4)	<0.0001 <sup>***</sup>	1843 (11.3)	<0.0001 <sup>***</sup>
1 – 5	513 (23.3)	6742 (40.3)	<0.0001 <sup>***</sup>	5032 (30.8)	<0.0001 <sup>***</sup>
6 – 10	659 (29.9)	5885 (35.2)		4733 (29.0)	
11 – 20	673 (30.5)	3502 (20.9)		4025 (24.6)	
21+	310 (14.0)	509 (3.0)		718 (4.4)	
Unknown	26 (1.7)	26 (0.2)		N/A	
Cessation by 3 <sup>rd</sup> trimester	1389 (83.1) <sup>e</sup>	4927 (29.5) <sup>g</sup>	<0.0001 <sup>h***</sup>	9747 (60.3) <sup>g</sup>	<0.0001 <sup>i***</sup>
	ITT=1389 (62.3) <sup>f</sup>		<0.0001 <sup>i***</sup>		0.5699 <sup>k</sup>

Abbreviations: BMTF, Baby and Me Tobacco Free; CO, Colorado; ITT, intention to treat; NH white, non-Hispanic white; NH black, non-Hispanic black; PRAMS, Pregnancy Risk Assessment Monitoring System.

Boldface indicates statistical significance (\*p<0.05, \*\*p<0.01, \*\*\*p<0.001)

<sup>a</sup> All values N(%).

<sup>b</sup> Pearson Chi-square p-values for two-tailed tests of significance.

<sup>c</sup> Weighted Ns and %s

<sup>d</sup> Pearson Chi-square test for two-tailed tests of significance with Taylor linearization for variance estimates in the weighted PRAMS sample.

<sup>e</sup> 3<sup>rd</sup> trimester implementation quit metric calculated as the number of women in BMTF with carbon monoxide validated cessation in 3<sup>rd</sup> trimester of pregnancy (n=1389) out of those who attended a visit in the 3<sup>rd</sup> trimester of pregnancy (n=1671).

<sup>f</sup> Intention-to-treat measure calculated as the number of women in BMTF with carbon monoxide validated cessation in the 3<sup>rd</sup> trimester of pregnancy (n=1389) out of those who enrolled in BMTF and attended 1 prenatal visit (n=2231).

<sup>g</sup> Self-reported cessation by of the last three months of pregnancy among those who self-reported smoking in the 3 months prior to or during pregnancy.

<sup>h</sup> Pearson Chi-square test for two-tailed tests of significance comparing the 3<sup>rd</sup> trimester implementation quit metric in BMTF to self-reported cessation by the 3<sup>rd</sup> trimester on the birth certificate.

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Pearson Chi-square test for two-tailed tests of significance comparing the 3<sup>rd</sup> trimester ITT quit metric in BMTF to self-reported cessation by the 3<sup>rd</sup> trimester on the birth certificate.

Pearson Chi-square test for two-tailed tests of significance comparing the 3<sup>rd</sup> trimester implementation quit metric in BMTF to self-reported cessation by the 3<sup>rd</sup> trimester in PRAMS with Taylor linearization for variance estimates in the weighted PRAMS sample.

Pearson Chi-square test for two-tailed tests of significance comparing the 3<sup>rd</sup> trimester ITT quit metric in BMTF to self-reported cessation by the 3<sup>rd</sup> trimester in PRAMS with Taylor linearization for variance estimates in the weighted PRAMS sample.

**Table 2.**

Smoking characteristics at baseline and program participation measures of BMTF participants

<b>Smoking Characteristics at Enrollment</b>	<b>Mean (SD) or N (%)</b>
Years of tobacco use, mean (SD)	8.55 (5.45)
Previous quit attempts, mean (SD)	5.22 (9.57)
Cigarettes smoked per day at enrollment:	
< 1	193 (8.65)
1 – 5	572 (25.64)
6 – 10	267 (11.97)
11 – 20	115 (5.15)
20+	12 (0.53)
Did not smoke at time of enrollment	1008 (45.18)
Unknown	64 (2.86)
Carbon monoxide test level at enrollment:	
0 – 6	1308 (58.63)
7 – 10	326 (14.61)
11 – 20	384 (17.21)
20+	173 (7.75)
Unknown	40 (1.79)
Significant other who smokes:	
Yes	132 (59.43)
No	692 (31.09)
Unknown	216 (9.48)
Smoking allowed in the house:	
No one is allowed to smoke	1762 (79.19)
Smoking is permitted in the house	446 (20.04)
Unknown	17 (0.76)
Smoking allowed in vehicle:	
No one is allowed to smoke in the car	1050 (47.19)
Smoking is permitted in the car	933 (41.93)
Do not have vehicle/Unknown	440 (10.88)
<b>Program Participation Measures</b>	<b>Mean (SD) or N (%)</b>
Trimester of enrollment in BMTF:	
1 <sup>st</sup>	609 (27.32)
2 <sup>nd</sup>	1163 (52.18)
3 <sup>rd</sup>	457(20.50)
Average number of prenatal BMTF visits, mean (SD)	3.11 (1.18)
Average time between prenatal BMTF visits (weeks), mean (SD)	
Enrollment & Visit 1	1.51 (3.22)
Visit 1 & Visit 2	5.41 (4.29)
Visit 2 & Visit 3	4.61 (3.77)

Smoking Characteristics at Enrollment	Mean (SD) or N (%)
Visit 3 & Visit 4	3.95 (3.47)
Colorado QuitLine use between each prenatal BMTF visit:	
Between enrollment visit and 1 <sup>st</sup> visit	175 (8.09)
Between 1 <sup>st</sup> and 2 <sup>nd</sup> visit	311 (17.32)
Between 2 <sup>nd</sup> and 3 <sup>rd</sup> visit	185 (12.01)
Between 3 <sup>rd</sup> and 4 <sup>th</sup> visit	132 (10.08)

Abbreviations: SD, standard deviation

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**Table 3.**

Estimated cost savings of the Colorado Baby and Me Tobacco Free Program

Outcome	2017 Medicaid Reimbursement <sup>a</sup>	BMTF compared to PRAMS	BMTF compared to Birth Certificate
		Per Person Cost Savings	
Gestational Hypertension	\$ 6,100	\$ 37	\$ (-49)
Low birth weight	\$ 121,597	\$ 608	\$ 4,256
NICU admission	\$ 3,375	\$ 327	\$ 118
Preterm birth	\$ 50,423	\$ 1,210	\$ 1,714
<b>Total Per Person Cost Savings<sup>b</sup></b>		\$ 2,182	\$ 6,040
<b>Total Cost Savings (yearly)</b>			
Total cost savings of BMTF (annual) <sup>c</sup>		\$ 1,497,299	\$ 4,144,118
Extrapolated to the State of Colorado (annual) <sup>d</sup>		\$ 6,033,514	\$ 16,699,126
Return on Investment <sup>e</sup>		\$ 2.79	\$ 7.73

Abbreviations: BMTF, Baby and Me Tobacco Free; NICU, neonatal intensive care unit; PRAMS, Pregnancy Risk Assessment Monitoring System.

<sup>a</sup>Medicaid reimbursement for each outcome = Average Medicaid reimbursement (in dollars) for a delivery complicated with each outcome minus the average Medicaid reimbursement for an uncomplicated delivery.

<sup>b</sup>Total per person cost savings of the BMTF program = the Medicaid cost reimbursement for each outcome \* the observed risk difference between the BMTF intervention group and referent groups.

<sup>c</sup>Total cost savings in the BMTF program (annual) = (the total per person cost savings associated with prevention of adverse maternal delivery and neonatal complications in the BMTF intervention \* the total number of BMTF intervention participants over the 39 month study period)/years in study period.

<sup>d</sup>Total cost savings for the state of Colorado (annual) = The per person cost savings of BMTF, extrapolated to all susceptible women in the state of Colorado.

<sup>e</sup>Return on Investment = Total Per Person Cost Savings /Per Person Cost of BMTF