Baby and Me Tobacco Free: Evaluation of Colorado Programs, 2012-2015

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Community Epidemiology & Program Evaluation Group  
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Key Findings

Between October 2012 and May 2015 the Baby and Me Tobacco Free (BMTF) program provided pre- and postnatal smoking cessation to 1,292 low-income women in Colorado. Upon enrollment, BMTF participants had smoked for an average of 8 years and attempted to quit 5 times previously. Over half the women had an exhaled carbon monoxide test consistent with current smoking (>6 parts per million (ppm)) at their prenatal enrollment visit. The majority had significant challenges to their quit attempt including a significant other who smoked, living in a household where smoking was allowed indoors and driving in a vehicle where smoking was allowed. Despite these challenges, over half (53%) remained abstinent from smoking during their pregnancy and 78% were smoke-free at their last prenatal visit before delivery. Each additional week of enrollment in the BMTF program increased the likelihood that a woman would remain abstinent from smoking during her pregnancy.

A large proportion of participants were lost to follow-up by the BMTF program after the birth of their baby (45%). Among women who returned to the program after delivery, 75% remained smoke-free for at least 3 months postpartum and quit rates at 3, 6 and 12 months postpartum were 92.5%, 72.5% and 53.5%, respectively. Based on a conservative “intention-to-treat” analysis that assumed all women who were lost to follow-up relapsed to smoking, the median duration of smoking abstinence from the time of program enrollment was 5.2 months. The “intention-to-treat” quit rates at 3, 6 and 12 months postpartum were 43.0%, 35.4% and 25.3%, respectively. The mean birth weight of babies whose mothers returned to the BMTF program after delivery was 7.0 pounds and one relapse during the prenatal period was not associated with lower birth weight, suggesting relapse recovery was vitally important for infant outcomes. Maintained smoking abstinence in the BMTF program was also associated with longer breastfeeding duration.

Characteristics associated with failed smoking abstinence during pregnancy included exposure to secondhand smoke in the homes and car, time from waking before first cigarette (before their quit attempt), having a significant other who smokes, and lower income level. Participant satisfaction was high with specific components of the BMTF program including trust and confidence in the counselors and the diaper vouches after delivery. The counselling and materials provided during pregnancy were rated higher than the counselling and materials provided after their baby was born. Support from family members and strategies to engage mothers in the program after the birth of their baby may improve pre- and postnatal quit rates.

Several specific recommendations are made for program improvement. First, it is recommended that strategies be developed to improve program retention after the birth of the baby including: ensuring that visits are family friendly; implementing systematic procedures for follow-up after the baby is born; addressing barriers to transportation; and developing specific counselling strategies and materials to support postpartum relapse recovery. Second, it is recommended that approaches be implemented to ensure access of the BMTF program to subpopulations disproportionately impacted by prenatal smoking in CO, such as African American women. Approaches could include partnering with health departments that serve a larger proportion of African American women such as Denver and El Paso county; development of specially tailored, culturally sensitive print or counselling materials; and engagement with community partners such as church-based cessation programs to recruit women. Finally, it is recommended that systematic data collection and evaluation continue through the next funding cycle to more accurately estimate quit rates at the later postnatal time points (6 and 12 months postpartum); and better understand barriers to quitting smoking during pregnancy and remaining abstinent after the baby is born.
Background

**Prevalence of Smoking during Pregnancy in Colorado**

Data collected by the Pregnancy Risk Assessment Monitoring System (PRAMS) between 2010 and 2012 estimates that 21.0% of women in Colorado (CO) smoked in the three months before getting pregnant and 8.3% smoked in the last trimester of pregnancy (1). Moderate but significant reductions in the prevalence of prenatal smoking were seen at the national level (from 13.3% to 12.3%) from 2000 to 2010 with even larger reductions occurring in CO (from 10.2% to 7.8%) (2). However, disparities in prenatal smoking remain stark across racial/ethnic subpopulations and among low-income women. Between 2010 and 2012 in Colorado, 5.5% of Hispanic women, 9.4% of non-Hispanic white women and 13.2% of Black women reported smoking in the last trimester of their pregnancy. During this same period in CO, 13.6% of women who were classified as low-income (based on a total household income ≤ 185% of the federal poverty level (FPL)) smoked during the last trimester of their pregnancy compared to 3.2% of women with incomes >185% of the FPL. Among women who smoking during the last trimester of their pregnancy in CO, 14.2% delivered a low birth weight infant. These data suggest a significant need for public health interventions to reduce prenatal smoking during pregnancy, especially for low-income women and among disproportionately impacted race/ethnic subpopulations.

**Consequences of Prenatal Smoking**

Prenatal smoking remains one of the most common preventable causes of infant mortality and morbidity. Maternal cigarette smoking during pregnancy increases the risk for pregnancy complications (e.g. placenta previa, placental abruption, and premature rupture of the membrane), birth defects (e.g. cleft lip and palate) and poor infant outcomes (e.g. preterm delivery, restricted fetal growth, sudden infant death syndrome [SIDS], and preterm-related death) (3). The link between prenatal smoking and poor birth outcomes has been extensively studied and the causal relationship is explicit (4). Meta-analysis of research conducted over three decades concludes that newborns prenatally exposed to smoking weigh an average of 150-200 grams less than those born to nonsmokers (5). Smoking during pregnancy is estimated to account for 5% to 7% in the variance in birth weight at the population-level in the United States, accounting for other important birth weight-related variables (6). The decrease in birth size is understood to be a result of reduced fat free mass including abdominal organ size, bone mineral content or density, birth length, or arm and head circumferences (8-12). The impact of prenatal smoking on gestational age at birth is not as strong as the effect on birth weight (7-10), suggesting that the impact on birth weight is primarily a result of reduced fetal growth rather than abbreviated gestation. Importantly, even small decreases in birth weight can have large impacts on outcomes and costs. It is estimated that an increase in birth weight of 250 grams saves an average of $2,000 per infant in medical costs in the first year of life (11).

Exposure to prenatal smoking appears to be associated not only with immediate consequences, such as growth restriction, but also with long-term health issues. One in five children in the U.S. is classified as obese (12;13), and several epidemiologic studies have found that intrauterine tobacco exposure increases the risk for childhood overweight or obesity (14-16), as well as asthma (17). Furthermore, recent evidence has linked tobacco exposure in-utero with decreased age of menarche (18).
Postnatal exposure to maternal smoking is also a potential risk to a child’s health. It has been shown to be associated with a higher rate of infant respiratory infections (19) and is the strongest maternal predictor of early weaning across populations (20).

**Smoking Cessation during Pregnancy**
The sooner women stop smoking during pregnancy, the better the outcomes for the offspring. On average, neonates of women who stop smoking in the first trimester of pregnancy have birth weight and other anthropometric measures similar to those born to nonsmoking mothers (21). Pregnancy is a unique period when women may consider smoking cessation. Risk factors for continued smoking during pregnancy include smoking heavily before pregnancy, having multiple children, low income, or a partner who smokes (22). According to the 2010-2012 PRAMS, 60.5% of mothers who smoked before becoming pregnant, quit smoking during pregnancy, however quit rates varied by maternal income status (1). Among low income women, only 52% reported quitting smoking during their pregnancy compared to 72% of women with incomes above the poverty threshold (185% of the Federal Income Level). Efforts focused on smoking cessation in the postnatal period are needed as indicated by the estimated 60% to 80% of women who quit smoking during pregnancy but relapse in the first year postpartum (23;24). Based on data from CO PRAMS, the likelihood of postnatal relapse by 3 months after delivery was 14% higher for low income women compared to women with incomes above the poverty threshold.

**Baby and Me Tobacco Free Program**
The Baby and Me Tobacco Free (BMTF) smoking cessation program targets low-income women who smoke, with a primary objective of helping them quit smoking during pregnancy and maintain abstinence for one year postpartum. The program offers up to four prenatal and 12 monthly postpartum counseling sessions with carbon monoxide (CO) testing validation of abstinence at each visit. Diaper-vouchers are given to participants who remain smoke-free at each visit after their baby is born. Program rules state that a participant who tests positive for smoking in the prenatal portion of the program is permitted to return for additional visits. Women are not permitted to return for additional visits if their CO test results are consistent smoking (>6ppms) after their baby is born.

The BMTF program was administered by the Rocky Mountain Health Plans Foundation (RMHPF) from October 1, 2012 through May 2015. The program was implemented in 11 counties starting in 2012 with an additional 40 counties joining after December 31, 2013. The program received referrals from community providers, clinics, health departments, and women themselves. To enroll, pregnant women had to reside in a participating county and smoke currently or within three months of starting pregnancy. Women participating in the program who changed residence to another participating county were administratively transferred.
Evaluation Objectives and Methods

The Colorado Department of Public Health and Environment (CDPHE) asked the Community Epidemiology & Program Evaluation Group (CEPEG) at the University of Colorado Denver to evaluate BMTF program implementation and outcomes. The evaluation questions are:

- Who and how many participants were reached?
- How satisfied were participants with the program?
- What challenges did participants experience in quitting or in program participation?
- How many participants were successful in abstaining from tobacco during their pregnancy and after their children were born?
- Is a higher level of participation in the program during pregnancy is associated with a higher likelihood of abstinence from smoking?
- How long did participants remain abstinent after their children were born?
- Was a higher level of participation in the program associated with improved birth outcomes?

Each participating site systematically collected data on program participation and implementation using standardized data collection instruments administered to participants by program staff at each site. Each participating site entered data into a web-based HIPPA-compliant database (RedCap) housed at the Colorado School of Public Health (ColoradoSPH). Webinar trainings on data collection using the standardized instruments and data entry into the RedCap system were provided by the ColoradoSPH in October of 2012 and January of 2014. A recorded version of the training was provided for new program staff at each site over the course of the program. Technical assistance was provided to all sites throughout the implementation period by a program evaluator at CEPEG.

Monthly reports were generated by CEPEG for each site on program enrollment, demographic characteristics of the population enrolled, number of visits completed and number of diaper vouchers distributed. Monthly data quality reports identified records with missing data on key variables, participants registered in the program who had no follow-up visits and participants with missing data entry forms. The reports were utilized during monthly calls with each site to improve data quality and reporting.

A structured exit interview was administered to each participant upon completion of the program. The exit interview was also administered to all participants who were lost to follow-up or who left the program due to a failed CO test within 2 months of program exit. The interview was administered over the phone by trained interviewers in the Survey Research Unit of CEPEG. The interview collected information on program satisfaction, perceived usefulness, most useful aspects of the program and barriers/challenges to cessation.

Participants

Demographic characteristics and smoking history were collected in a baseline survey administered to participants at enrollment or the first prenatal visit. Participant characteristics are reported with means and interquartile ranges (IQR) for continuous measures and counts and percentages for categorical data.

Quit Rates and Statistical Analyses

At each of the four prenatal and each monthly postnatal counselling session, participant smoking status was tested using exhaled carbon monoxide (CO) testing. Test results were classified as: ≤ 6 ppm consistent with nonsmoking and > 6 consistent with smoking. The hypothesis that increased participation in the program during pregnancy is associated with a higher likelihood of abstinence was
tested in a linear mixed effects model using a Wald Test and Kenward-Rogers degrees of freedom (25). An unstructured covariance matrix was used to model the correlation (dependence) between repeated measures on the same individual. Parameter estimates and 95% confidence intervals from the model are reported as the percent change in likelihood of smoking abstinence during pregnancy for each additional week of participation in the program.

Prenatal quit rates were calculated as the percent of participants who were abstinent from smoking at the last prenatal session they attended using an “intention-to-treat” assumption that those who were lost to follow-up returned to smoking after their last visit. In addition, the overall percent of participants that were abstinent from smoking at every prenatal visit they attended (up to 4) is reported.

Postnatal quit rates calculated for women who were eligible for a 3, 6 or 12 month postpartum visit based on the age of their baby. The rates are based on the percent of participants with a CO test result consistent with non-smoking (≤ 6 ppm) at 3, 6 and 12 months postpartum using an “intention-to-treat” assumption. A large proportion of women were not yet eligible for a 3, 6 or 12 month postpartum (36%, 53% and 86%, respectively). In addition, a high proportion of women delivered, but did not return to the program after their baby was born (45%). Thus postpartum quit rates are also reported for a subset of women who returned to the BMTF program after the birth of their baby for at least one postpartum visit (n=464).

Duration of abstinence (time to first failed CO test) was assessed using a Kaplan-Meier (KM) function and was defined as the time between the earliest CO test result consistent with not smoking (CO ≤ 6 ppm) and (a) the last visit if test results stayed ≤6 ppm, or (b) the first visit with a test result indicating smoking. Because some women had a relapse to smoking during the prenatal period, but then resumed their quit attempt and remained abstinent after their baby was born, a second survival analysis was conducted on a subset of women that attended at least one postnatal visit regardless of CO test results in the prenatal period (n=464). Women who dropped out of the program or who were lost to follow-up were analyzed under an assumption that they relapsed to smoking after their last (smoke-free) visit (“intention to treat” analysis).

Birth Outcomes and Postnatal Behaviors in the BMTF Program
To investigate the relationship between prenatal smoking abstinence and infant health outcomes (birth weight and breastfeeding duration), comparisons were made between participants who had a prenatal CO test result consistent with smoking and those who remained abstinent from smoking during pregnancy using an independent Student’s T-test.

Drop-outs and overall program satisfaction
Comparisons of demographic characteristics for those who dropped from the program before their baby’s first birthday and those who completed the program were made using a Chi-squared test for categorical variables or an independent Student’s T-test for continuous variables.
Findings

Program Participant Characteristics

A total of 1,381 pregnant women enrolled in the BMTF program. The analytic cohort for this analysis was limited to the 1,292 women completed at least 1 prenatal visit between October 1, 2012 and May 15, 2015 (Table 1). The mean maternal age at enrollment was 25.5 years (IQR, 21.0 – 29.5). Two-thirds of participants were Hispanic (66.3%), 18.7% were non-Hispanic white and less than 1% were non-Hispanic Black. The majority of participants had a total household income less than $25,000 (71.3%) and had completed a high school degree (76.5%). Medicaid was the primary source of insurance for most participants (88.0%).

<table>
<thead>
<tr>
<th>Table 1. Participant demographic characteristics in the BMTF program (N = 1,292)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maternal age at enrollment, mean (IQR)</td>
</tr>
<tr>
<td>Household income, n (%):</td>
</tr>
<tr>
<td>&lt; $25,000</td>
</tr>
<tr>
<td>≥ $25,000</td>
</tr>
<tr>
<td>Unknown</td>
</tr>
<tr>
<td>Race and ethnicity, n (%):</td>
</tr>
<tr>
<td>Non-Hispanic white</td>
</tr>
<tr>
<td>Non-Hispanic black</td>
</tr>
<tr>
<td>Hispanic</td>
</tr>
<tr>
<td>Other</td>
</tr>
<tr>
<td>Unknown</td>
</tr>
<tr>
<td>Education, n (%):</td>
</tr>
<tr>
<td>Less than high school</td>
</tr>
<tr>
<td>High school graduate (diploma or GED)</td>
</tr>
<tr>
<td>At least some college</td>
</tr>
<tr>
<td>Unknown</td>
</tr>
<tr>
<td>Health insurance, n (%):</td>
</tr>
<tr>
<td>Employer insurance</td>
</tr>
<tr>
<td>Private insurance</td>
</tr>
<tr>
<td>Medicaid</td>
</tr>
<tr>
<td>TRICARE</td>
</tr>
<tr>
<td>Child Health Plan Plus</td>
</tr>
<tr>
<td>Other</td>
</tr>
<tr>
<td>None</td>
</tr>
<tr>
<td>Unknown</td>
</tr>
</tbody>
</table>

Smoking history

Table 2 shows the smoking history for participants in the BMTF program. The average duration of smoking was 8 years (IQR, 4.0 – 11.0) and the average number of quit attempts prior to enrollment was 5.4 (IQR=2 – 5). On the day of enrollment, 53% of women reported that they currently smoked less than 1 cigarette per day. This was reflected in the CO test results at the baseline visit which were consistent with not smoking (≤6 ppm) for 56.2% of women, between 7-20 ppm for 32.0% of women and > 20ppms for 7.7% of women. In the 3 months prior to pregnancy, 54.2% of women reported being a light smoker (<10 cigarettes per day CPD), 29.6% were moderate smokers and 13.2% were heavy smokers. Over half (57%) of BMTF participants reported having a significant other who smoked. Most women (76%)
reported that smoking was not allowed inside their home, and 45.9% reported that smoking was not allowed in their car.

Table 2. Smoking characteristics and history of participants in the BMTF program (N = 1,292)

<table>
<thead>
<tr>
<th>Measure</th>
<th>Mean (IQR) or N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Years of tobacco use, mean (IQR)</td>
<td>8.4 (4.0 – 11.0)</td>
</tr>
<tr>
<td>Previous quit attempts, mean (IQR)</td>
<td>5.4 (2 – 5)</td>
</tr>
<tr>
<td>Number of QuitLine calls during or after pregnancy</td>
<td>2.6 (1-4)</td>
</tr>
<tr>
<td>Cigarettes smoked per day at enrollment, n (%):</td>
<td></td>
</tr>
<tr>
<td>&lt; 1</td>
<td>682 (52.8)</td>
</tr>
<tr>
<td>1 – 5</td>
<td>330 (25.5)</td>
</tr>
<tr>
<td>6 – 10</td>
<td>159 (12.3)</td>
</tr>
<tr>
<td>11 – 20</td>
<td>72 (5.6)</td>
</tr>
<tr>
<td>20+</td>
<td>8 (0.6)</td>
</tr>
<tr>
<td>Unknown</td>
<td>41 (3.7)</td>
</tr>
<tr>
<td>Carbon monoxide test level at enrollment, n (%):</td>
<td></td>
</tr>
<tr>
<td>0 – 6</td>
<td>726 (56.2)</td>
</tr>
<tr>
<td>7 – 10</td>
<td>200 (15.5)</td>
</tr>
<tr>
<td>11 – 20</td>
<td>213 (16.5)</td>
</tr>
<tr>
<td>20+</td>
<td>100 (7.7)</td>
</tr>
<tr>
<td>Unknown</td>
<td>53 (4.1)</td>
</tr>
<tr>
<td>Cigarettes smoked per day 3 months prior to pregnancy, n (%):</td>
<td></td>
</tr>
<tr>
<td>&lt; 1</td>
<td>30 (2.3)</td>
</tr>
<tr>
<td>1 – 5</td>
<td>296 (22.9)</td>
</tr>
<tr>
<td>6 – 10</td>
<td>375 (29.0)</td>
</tr>
<tr>
<td>11 – 20</td>
<td>383 (29.6)</td>
</tr>
<tr>
<td>20+</td>
<td>171 (13.2)</td>
</tr>
<tr>
<td>Unknown</td>
<td>37 (3.0)</td>
</tr>
<tr>
<td>Significant other who smokes, n (%):</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>739 (57.2)</td>
</tr>
<tr>
<td>No</td>
<td>510 (39.5)</td>
</tr>
<tr>
<td>Unknown</td>
<td>43 (3.3)</td>
</tr>
<tr>
<td>Smoking allowed in the house, n (%):</td>
<td></td>
</tr>
<tr>
<td>No one is allowed to smoke</td>
<td>982 (76.0)</td>
</tr>
<tr>
<td>Smoking is permitted in the house</td>
<td>280 (21.7)</td>
</tr>
<tr>
<td>Unknown</td>
<td>30 (2.3)</td>
</tr>
<tr>
<td>Smoking allowed in vehicle, n (%):</td>
<td></td>
</tr>
<tr>
<td>No one is allowed to smoke in the car</td>
<td>593 (45.9)</td>
</tr>
<tr>
<td>Smoking is permitted in the car</td>
<td>521 (40.3)</td>
</tr>
<tr>
<td>Unknown</td>
<td>178 (13.8)</td>
</tr>
</tbody>
</table>
**Figure 1** shows the total number of BMTF visits conducted during the prenatal and postnatal period. At each counselling session, participants were directed to the CO QuitLine and CO Quit Mobile.org for additional cessation support. At each BMTF visit, participants were asked if they had completed a QuitLine counselling call or received any messages from CO Quit Mobile.org since their last visit. Utilization of these services was higher at early prenatal visits but dropped after delivery.

**Prenatal Measures of Smoking Cessation in BMTF Program**

Over half (53.2%) of women in BMTF program who attended at least one prenatal visit remained smoke-free over the entire prenatal period and 74.8% were smoke-free at their last prenatal visit. **Figure 2** displays the proportion of failed CO tests during pregnancy by gestational age. On average, there was a 0.7% ± 0.09 increased likelihood of abstinence from smoking for each additional week of program enrollment during pregnancy, adjusted for different gestational ages at enrollment (p < 0.0001). The proportion of failed CO tests decreased with gestational age of pregnancy, suggesting that women were more likely to remain abstinent from smoking in the later stages of pregnancy. A slight increase in failed CO tests is evident in the first trimester; however variability is high, likely due to low numbers of participants who enrolled before 13 weeks gestation.

**Figure 2. Percent of participants in the BMTF program who returned to smoking during pregnancy, by time (gestational age)**
Out of the 1,292 women who attended BMTF counselling sessions during their pregnancy, 464 women returned for at least 1 postnatal visit after the birth of their baby. Of the remaining 828 women with no postnatal visits, 18.1% (n=234) had not yet delivered their baby, 11 had missing values on estimated delivery date (0.8%) and 45.1% (n=583) were lost to follow-up (did not return to the BMTF program after delivery). Table 3 shows the postnatal quit rates at 3, 6, and 12 months postpartum calculated by two methods: 1) for women who returned to the BMTF program after delivery, and 2) for all participants using an “intention-to-treat” analysis that assumes women who did not return to the program relapsed to smoking. Inclusion in the denominator was based on postnatal age of the child. For women who attended at least 1 postnatal BMTF visit, postnatal age was based on self-reported actual delivery date. For women who did not return to the BMTF program after the birth of their baby, the estimated date of delivery reported at the enrollment visit was used to determine eligibly. The quit rates for women who returned to BMTF after delivery were 92.5% at 3 months, 72.5% at 6 months and 53.5% at 12 months postpartum. Using the intention-to-treat analysis, the quit rates were 43.0% at 3 months, 35.5% at 6 months and 25.3% at 12 months postpartum.

| Table 3. Postnatal quit rates |
|-----------------------------|---------------------|-------------------|-----------------|-------------------|
|                            | Number of women who returned to BMTF for at least 1 postpartum visit (total N=464) | Number of women who were lost to follow-up after the birth of their baby (total N=828) | Number of women with CO test ≤ 6ppm | Quit Rates based on women who returned to BMTF after delivery |
|                            | 3 months postpartum | 6 months postpartum | 12 months postpartum |
|                            | 388                 | 446                | 298              | 312               | 86                | 96                | 46                |
|                            |                     | 359                | 216              | 46                | 92.5%             | 72.5%             | 53.5%             | 43.0%             | 35.4%             | 25.3%             |

Figure 3 displays the duration of smoking abstinence after delivery (Kaplan-Meier survival curve) with 95% confidence intervals (CI) for women who had delivered their baby and returned to the BMTF program for at least 1 postnatal visit (n=464). At the time of the analysis, greater than 50% of these women had not yet experienced a failed CO breath (remained abstinent). Seventy-five percent of mothers remained abstinent (had not failed) at 3.6 months (95% CI: 2.8, 4.9) after delivery.
Figure 3. Time to first failed CO breath test for women in the BMTF program who delivered their baby and returned for at least one postnatal visit

Figure 4 displays the duration of smoking abstinence (Kaplan-Meier survival curve) with 95% confidence intervals (CI) by months of enrollment in the BMTF program (from the first prenatal visit to 12 months postpartum). The model accounts for different gestational ages at the first prenatal visit. Women who did not return to the BMTF program after delivery were assumed to have returned to smoking (“intention to treat” analysis). The median time smoking abstinence was 5.2 months after the first prenatal visit (95% CI: 4.2, 6.4). Because 46.8% of women had at least 1 failed CO test during their pregnancy, the 75th percentile was 0 months and the 25th percentile was not reached.

Figure 4. Time to first failed CO breath test for women in the BMTF program who delivered their baby: “intention to treat” analysis
Characteristics associated with dropping out of the BMTF program after delivery

As an exploratory analysis, Gehan’s Generalized Wilcoxon test was used to detect differences in program retention after delivery by demographic and smoking history variables including: total household income, race/ethnicity, type of insurance, level of education, time after waking until first cigarette (before they quit), smoking allowed in the vehicle, smoking allowed in the home and significant other who smokes (Table 4). Characteristics associated with dropping out of the BMTF program after the baby was born included: smoking allowed in the vehicle (p<0.0001), smoking allowed in the home (p<0.0001), and shorter time from waking to first cigarette (before the quit attempt) (p=0.01). Borderline statistically significant factors include having a significant other who smokes (p=0.06) and having an income level less than $25,000 per year (0.06). Only 35% of low income women returned to the program after the birth of their baby compared to 42% of women with a total household income above $25,000 per year. The race/ethnicity of the client, type of insurance and level of education were not associated with the probability of dropping out of the program.

Table 4. Demographic and smoking history characteristics associated with increased probability of return to smoking

<table>
<thead>
<tr>
<th>Variable</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smoking allowed in vehicle (yes vs. no)</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Smoking allowed in the home (yes vs. no)</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Significant other who smokes (yes vs. no)</td>
<td>0.0576</td>
</tr>
<tr>
<td>Race/ethnicity (all other compared to non-Hispanic white)</td>
<td>0.8148</td>
</tr>
<tr>
<td>Income level (&lt; 25k/year vs. ≥ 25k/year)</td>
<td>0.0643</td>
</tr>
<tr>
<td>Type of Insurance (Medicaid vs. private)</td>
<td>0.2900</td>
</tr>
<tr>
<td>Education level (&lt; high school vs. ≥ high school)</td>
<td>0.1796</td>
</tr>
<tr>
<td>Minutes after waking to first cigarette (from baseline questionnaire)</td>
<td>0.0011</td>
</tr>
</tbody>
</table>

Birth Outcomes and Postnatal Behaviors in the BMTF Program

Self-reported birth weight was available from women who returned to the BMTF program after the birth of their child. The birth weight of infants born to mothers with a failed CO test during pregnancy was on average 7.0 pounds, and was not statistically different from the birth weight of babies born to women who did not fail any CO tests during their pregnancy (p = 0.93).

The BMTF exit interview included assessment of postnatal feeding behaviors, including duration of breastfeeding. The majority of women in the BMTF program who completed an exit interview (66%) reported that they had breastfed their infant at least once. However, participants who failed at least one CO test while they were pregnant reported a significantly lower total breastfeeding duration (mean = 2.0 months) compared to those who did not fail any prenatal CO tests while they were pregnant (mean = 4.1 months, p < 0.01). These results suggest a potentially important point for further intervention among women who struggle with smoking during pregnancy, given the established benefits of breastfeeding.

Qualitative Assessment of Participant Challenges and Program Satisfaction

A qualitative analysis was applied to open-ended questions asked of each mother at the monthly postnatal visits and at the final exit interview. Specific constructs included in this analysis included participant progress in the program (e.g. reasons for missed visits), challenges with staying smoke-free (e.g. stressful life events), and participant satisfaction with the program’s training, resources, and staff. Boolean operators were employed to search for key words representing three categories of responses including: participant progress in the program, challenges with staying smoke free, and participant
satisfaction with the BMTF program. A list of keywords associated with each of these categories is presented in Table 5.

<table>
<thead>
<tr>
<th>Major Theme</th>
<th>Key Words</th>
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<tr>
<td>Reasons for missed visits</td>
<td>work [worked, working]; child care [daycare, babysit]; time; sick [sickness, ill]</td>
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<tr>
<td>Challenges to staying smoke free</td>
<td>tempted [tempt, tempting, temptation]; stress [stressful, stressed]; partner [boyfriend, husband, girlfriend, wife]; craving [crave, craved]</td>
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<tr>
<td>Reasons for dropping from BMTF program</td>
<td>moved [moving]; miscarriage; smoking [smoked, failed, quit];</td>
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Words in brackets were also considered key words and included in the search.

Reports surrounding the challenges that participants faced in remaining abstinent from tobacco were reported in at the monthly postpartum visits (n=464). The most widely cited challenges were stress and cravings. Participants cited “thinking about a cigarette when stressed” and being presented with “some situations that cause [her] to crave a cigarette”. Trouble with interpersonal relationships (family members, spouse, boyfriend, or ex-boyfriend) was also discussed: “lots of stress, Dad moving in with her--he just got out of prison” and “[she] had resorted to a couple of cigarettes and expressed difficult stress in home life”. Other participants reported being tempted to smoke when around other smokers “it was hard when her husband’s father was here because he smokes her brand of cigarettes” and “if she goes out with the girls and has a drink, she is tempted”. Despite the challenges faced by participants, most reported being able to “work through” the cravings and found outlets for their stress such as exercise, “No cravings, run a lot and work out.” and alternatives to cigarettes, “[she] avoids smoking with sunflower seeds”.

Reasons for missed visits included conflicts with work, lack of childcare, and family responsibilities, “[she] has a hard time getting up here with balancing work, her son, and living [in the mountains]” and “working two jobs and missed a few appointments because [she] was working”. Unfortunately, and by design, missing visits was the predominant reason that women were discontinued from the BMTF program, especially after the birth of their baby. However, some women decided that the program was not appropriate for them at the time that they were enrolled or were unable to commit to quitting smoking, “could not quit smoking and decided [she] did not want to quit” and “could not quit smoking before baby was born”.

A total of 136 women completed the BMTF program exit interview. Table 6 presents mean levels of participant satisfaction related to specific aspects of the program based on a Likert scale of 1-7 where 1=“strongly disagree” and 7=“strongly agree”. The mean level of trust reported for the BMTF counselor(s) was 6.2 and the mean level of confidence in their counselor(s)’ ability to help them was 6.1. The mean value of perceived helpfulness of both counselling and materials received from the program while they were pregnant were higher than the counselling and materials received after delivery. The mean importance of diaper vouchers for keeping respondents involved in the program after they were no longer pregnant was high at 5.5. Participants were asked how many calls coaching calls they completed with the QuitLine during or after their pregnancy. The average number of calls was 2.6 with an IQR of 1-4. The mean importance of the QuitLine coaching in their quit attempt was rated at 2.9.
Table 6. Participant responses to BMTF program satisfaction questionnaire (N = 136)

<table>
<thead>
<tr>
<th>Response</th>
<th>Mean (standard deviation)</th>
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<tbody>
<tr>
<td>I trusted my counselor</td>
<td>6.2 (1.7)</td>
</tr>
<tr>
<td>I was confident in my counselor(s)’ ability to help me</td>
<td>6.1 (1.8)</td>
</tr>
<tr>
<td>The counseling I received was helpful in staying quit while I was pregnant</td>
<td>5.4 (2.0)</td>
</tr>
<tr>
<td>The materials I received were helpful with quitting smoking or staying quit while I was pregnant</td>
<td>5.4 (2.0)</td>
</tr>
<tr>
<td>The counseling I received was helpful in staying quit after I was no longer pregnant</td>
<td>4.6 (2.5)</td>
</tr>
<tr>
<td>The materials I received were helpful in staying quit after I was no longer pregnant</td>
<td>4.6 (2.5)</td>
</tr>
<tr>
<td>The diaper vouchers were important for keeping me involved in the program</td>
<td>5.5 (2.3)</td>
</tr>
<tr>
<td>The QuitLine coaching was important for my quit attempt during and after pregnancy</td>
<td>2.9 (2.5)</td>
</tr>
</tbody>
</table>

Limitations
The current findings are based on a program that started implementation at the majority of sites (40 counties) on December 31, 2014, therefore implementation was still in progress when this report was written and 19% of women enrolled in the program had not yet delivered their baby (n=245). Among those who delivered their baby, 64%, 47% and 14% were eligible for a 3, 6, or 12 month postpartum visit, respectively. The small number of individuals who reached the later postnatal time points may bias quit rates and added large amounts of censoring to the survival analysis. Importantly, for the 828 women who did not return to the BMTF program after the birth of their child, it is impossible to know if and when they relapsed to smoking. For this reason, postpartum quit rates and the survival analysis were derived by two methods 1) on a subset of women who returned to the program after the birth of their infant and 2) using an “intention-to-treat” method that assumed the worst case for anyone who did not return to the program (they relapsed to smoking without recovering abstinence). The “intention-to-treat” analysis is extremely conservative and dramatically underestimates program benefits, especially at later postnatal time points. The quit rate at 12 months postpartum based on the “intention-to-treat” analysis was only 25.3%, similar to estimates of cessation maintenance in the general population (23;24). However, this rate is based on 14% of women in the BMTF program who were eligible for a 12 month postpartum visit. Recommendations for the future include a longer study period to allow sufficient enrollment and follow-up after birth.

The BMTF program enrolled a majority of Hispanic women, perhaps due to the demographics of the populations being served by participating health departments which derive many of their participants from WIC offices. However, Hispanic women in CO have the lowest smoking prevalence at 5.5%, followed by non-Hispanic white women at 9.4% and Black women at 13.2% (1). Less than 1% of enrolled participants were Black therefore, a recommendation for the future is to target this disproportionately impacted population.
Program retention after birth was poor and may be due to several factors including limited transportation among participants, difficulty in bringing the new baby to visits and exclusion from program in the postnatal period after a failed CO test. Recommendations for future include strategies to bring women back to the program after the birth of their child. This could include targeting of barriers to participation after delivery including providing transportation vouchers, scheduling visits outside of working hours, making visits family friendly, and allowing women who relapse in the pre- or postpartum period to continue in the program.

Conclusions
The BMTF program had high levels of program participation during pregnancy, with high prenatal quit rates and excellent infant outcomes. Increased time in the program was associated with higher likelihood of smoking abstinence during pregnancy. Smoking relapse during pregnancy followed by a resumed quit attempt was not associated with lower infant birth weight. After delivery many women did not return for postpartum cessation counselling, however among those who did, quit rates were high. This program has a significant public health impact, including reduction in low birth weight, longer duration of breastfeeding. Interpretation of postnatal quit rates should be tempered by a lack of information on the women who had not yet completed the postnatal portion of the program.

Recommendations
Recommendation 1: Retention of participants after delivery
The BMTF program should develop and evaluate strategies to improve program retention after the birth of the baby. These could include:

- Ensure BMTF visits are family-friendly (allow the mother to bring the new baby and other children to the visit).
- Offer BMTF visits outside of typical work hours to accommodate working mothers.
- Develop materials to support women in reducing their exposure to secondhand smoke, both during their pregnancy and after their baby is born.
- Develop a systematic procedure for postnatal follow-up at 1 month after the estimated delivery date reported at the baseline enrollment visit (i.e., phone calls, congratulations postcards, or reminder letters).
- Provide transportation vouchers or offer occasional offsite clinics, especially in rural communities.
- Develop specific counselling strategies and materials to support postpartum relapse recovery.

Recommendation 2: Target subpopulations disproportionately impacted by prenatal smoking
Given that non-Hispanic Black women in CO have the highest prevalence of prenatal smoking but only represented 1% of the population enrolled in the BMTF program, strategies should be implemented to ensure the program access to African American women in CO. Several strategies have been previously evaluated and found to be effective in supporting African Americans to quit smoking in non-pregnant populations (26-27). This could include:

- Partner with health departments that serve a larger proportion of non-Hispanic Black women in CO such as Denver and El Paso County.
- Develop specially-tailored, culturally-appropriate print and self-help materials for African American women.
• Partner with church-based cessation programs in the African American community to recruit women.

**Recommendation 3: Additional data collection and evaluation of postpartum quit rates.**
It is important to continue systematic data collection and analysis to determine quit rates at the later postnatal time points (6 and 12 months postpartum). Limited program resources may not allow for continued administration of exit interviews to women who complete the program or drop-out. These interviews provide invaluable data on barriers to quitting smoking, usefulness of specific program tools and reasons for drop out. Additional funding should be sought to continue this data collection.
References

Appendix A: Program Success Stories

Programs were asked to share their greatest successes in response to the question “Describe your greatest successes so far in implementing the Baby & Me – Tobacco Free program. What is working well for you?”. Examples of responses are quoted below:

“Our greatest successes so far in implementing the Baby & Me -Tobacco Free program are being able to use education and tools to build self-efficacy, provide peer support and the fact that the girls feel accountable for their actions. What is working well for us is that we are establishing a good rapport with the young mothers throughout their routine OB appointments. We are then in a better position to encourage them in their quest to become tobacco free. Most of the time the young moms return to our clinic after delivery and they are usually quit motivated to receive their monthly diaper vouchers at their postpartum visits. In addition, we address the effect of tobacco/marijuana use in our monthly classes, as well as in their routine OB appointments when we discuss topics like SIDS and Shaken Baby Syndrome.”

“I feel like our biggest success since I started in late October has been our work with a pregnant mother who has a toddler and a complicated medical history. Her success has been outstanding and as her medical history is complex, the program has allowed us to better support her smoking cessation.”

“We are able to screen and enroll the women in BMTF program right after their WIC appointments. I’m able to schedule their sessions with their WIC appointments. It is easy for the women because they only have to make one trip and they get seen right away.”

“One of the cases that I presently have, her significant other has been a smoker since his teen years. He reports that he has tried to stop smoking in the past but has been unsuccessful. He did not come in with his girlfriend for the sessions as requested. I stressed to his girlfriend to have him read the materials I presented to her and encourage him to at least cut back on his smoking. After she delivered her baby, she did report that he is starting to cut back on his smoking. YEAH!!!!!”

“We have graduated 9 Moms from the Baby & Me program since we started. Another big success for us has been to involve the live-in partners. Some have even quit along with the client. Internal referrals from our department are working very well. Most clients like the diaper vouchers and see it as a big incentive and say the education they have received from the program has been very helpful in quitting.”

“It has been working very well to pair the BMTF program with other programs already established in Jefferson County Public Health. The program fits well with WIC and the WIC Compass system. In addition, it has been a huge success to be able to offer our WIC participants who smoke to join the BMTF program during their already scheduled WIC appointments. Prior to this WIC was only able to refer participants to smoking cessation programs, but now we can support them in quitting and offer incentives for them to quit, which is a benefit to all parties involved.”

“The fact that our Agency sees almost every child in the entire county, either for vaccinations, WIC, Support Services PreNatal, Nurse Family Partnership etc., gives us great accessibility on a regular basis to make their visit a one stop shopping type of experience- that truly helps alleviate a lot of barriers for our clients if they don't have to keep coming back for appointments.”

“One of our greatest successes so far in implementing the BMTF program is seeing women stay smoke free after giving birth. Another great success is seeing how family members and/or significant others join in during the sessions. Seeing other family members quit smoking because of the program is astonishing. The informational handouts are very helpful. It's amazing to see the "light bulb" go off in their heads as we read along to the handouts.”
“We seem to have the most success with WIC clients. This may be related to our Educator already having a rapport with the women. Word of mouth still seems to provide the best referral potential in this frontier county. We have very small numbers of participants but we also have a very small population. Currently we have three moms receiving a voucher which is very exciting! And one of the moms is encouraging others to participate in the program.”

“The one on one interaction and follow up has worked the best, and the feedback the clients receive when the monitor substantiates their success in quitting.”

“The mothers are always willing to start the program and it is very helpful that the program can be administered during the client’s WIC visit.”

“The number of patients who are participating in the program is our greatest success. Even for the women who cannot complete the program significantly reduce their smoking and gain increased awareness of the dangers of second hand smoke. Other staff members and providers have been vital in identifying and directing patients to BMTF so that no one is missed.”

“The educational materials given during each session provide practical tips and advice for our patients. The incentives provided at sessions and the diaper vouchers provided postpartum are great motivators for our patients.”

“My greatest success is when a client finishes the program after her baby is one year old. My prenatal visits go very well as there is an urgency to complete all the visits before the baby is born. I'm proud to say that in this county, I've utilized home visits with each client rather than office visits. There is 15 miles between each town in our county, so it is a lot to ask for the client to drive 15 miles to come to the LPHA. We're bringing the program directly to the client.”

“Having Baby and Me Tobacco Free housed in the WIC office has been an effective use of time. It allows participants to complete 2 appointments at once. This also allows WIC staff to enroll pregnant women as soon as they are identified in the office as a daily smoker before becoming pregnant.”

“The greatest success has been the networking. We have half our referred women come in this way. We receive these referrals by fax or by a flag in the computer. We also make sure to follow up with women who no show or cancel appointments. We always do reminder calls for upcoming appointments and for the convenience of these women we try to coordinate BMTF appointments with other appointments they may have in the clinic such as WIC or prenatal.”

“The program has been very successfully promoted through our WIC Office, which is housed in the public health office. Eligible women are identified by the WIC Educator, and often the BMTF coordinator is available to discuss the program, enroll, and schedule a BMTF appt, with the potential client at that WIC visit. It is a very stream-lined process.”