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Title

Disparities in Smoking Cessation Outcomes among Multi-ethnic Pregnant Smokers in San Bernardino County, CA: Findings from the Loma Linda University Health Comprehensive Tobacco Treatment Program

Authors

Anne Berit Petersen, PhD, MPH, RN[1]

Temidayo Ogunrinu, MPH[2]

Shane Wallace, BS[2]

Jane Yun, MD[3]

Juan Carlos Belliard, PhD, MPH[4]

Pramil N. Singh, DrPH[2,5]

Affiliations

[1] Loma Linda University School of Nursing, 11262 Campus Street, Loma Linda, CA 92350, USA
[2] Center for Health Research, Loma Linda University School of Public Health, 11234 Anderson St, Loma Linda, CA 92354, USA
[3] Loma Linda University Health SACHS Clinic, 250 S G St, San Bernardino, CA 92410, USA
[4] Institute for Community Partnerships, Loma Linda University, 11234 Anderson St, Loma Linda, CA 92354, USA
[5] Transdisciplinary Tobacco Research Program, Loma Linda University Cancer Center, 11234 Anderson St, Loma Linda, CA 92354 USA

Corresponding author: psingh@llu.edu

Key words

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Abstract

Smoking during pregnancy remains one of the most significant risk factors for poor birth outcomes. The Loma Linda University Health Comprehensive Tobacco Treatment Program (CTTP) is the largest maternal tobacco cessation program in San Bernardino County – the largest county in the contiguous US. CTTP is an eight week, incentivized, behavioral intervention for tobacco cessation for pregnant smokers. As part of program evaluation, we used a retrospective cohort design to assess smoking abstinence and to identify predictors of relapse/smoking after enrollment. Among CTTP cohort enrollees (n=233) from 2012-2013 we found: 1) a 28.4% 8 week point prevalence abstinence (PPA), and at a median of 9 months of follow-up after the PPA, 81.6% continued to indicate tobacco cessation, and 2) a high rate of relapse or loss to follow-up (56%). Our modeling of the odds of relapse/smoking after enrollment indicated that this was higher in young mothers, non-Hispanic mothers (White, Black), first/third trimester mothers, and rural mothers. The evaluation identified efficacy of the behavioral intervention model at 8 weeks, but that relapse/smoking was occurring in disparity populations. Formative research is needed to expand the programmatic outreach and enrollment of mothers wanting to quit smoking.

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Background

Maternal smoking remains one of the most important modifiable causes of poor pregnancy outcomes in the US and globally[1 2]. In addition to the risk for adverse health effects for the mother, tobacco use during the prenatal period is associated with poor fetal outcomes such as tobacco-induced abortions, and stillbirths, and numerous risks to the infant postpartum, including low birth weight (LBW), sudden infant death syndrome (SIDS), preterm birth (PTB), neurological and cognitive delays, birth defects, colic, asthma and atopic[1 2]. However, despite general awareness of these well-established risks associated with prenatal smoking, a significant number of women continue to smoke during pregnancy[3].

Overall, the current rate of cigarette smoking among non-pregnant and pregnant U.S. women of reproductive age (15-44 years) is declining but remains relatively high (20.8% during 2007-2016)[3]. Of great concern is a disparity whereby smoking is higher in rural women of reproductive age (Non-Pregnant (Rural, 24% vs. Urban, 17%), Pregnant (Rural, 20% vs. Urban, 9%))[3]. Some of this effect has been further attributed to a socioeconomic disparity with a higher prevalence of low income women in rural, sparsely populated regions[4]. Nighbhor et al have further noted lower access to health care and public health infrastructure in rural, sparsely populated areas[3].

Research has demonstrated that smoking cessation during pregnancy can reduce the risk of adverse health outcomes for infants, including decreasing the proportion of infants born with LBW [5] and prematurity [6 7]. While a high proportion of women who smoke spontaneously quit before or in the early stages of pregnancy (up to 40%) [8 9], the risk of relapse remains high[10]. Predictors of quitting during pregnancy and maintaining abstinence include partner's smoking status, education level, age, and

 doi:10.20944/preprints202001.0150.v1

parity[11 12]. Behavioral factors include the level of nicotine dependence, while cognitive factors include self-efficacy to quit as well as the willingness to quit [13]. Those who continue to smoke during pregnancy are more likely to belong to a disparity population by rurality, low income, or ethnicity that are causal in multiple stressors and/or higher levels of nicotine dependence [11 12].

The U.S. Preventive Services Task Force (USPSTF) 2015 clinical guidelines for counseling and interventions to prevent tobacco use and tobacco-related diseases among adults, recommends that “clinicians ask all pregnant women about tobacco use, advise them to stop using tobacco, and provide behavioral interventions for cessation”; the recommendation cites inconclusive evidence for using pharmacotherapy or electronic nicotine delivery devices as cessation aids[14]. The most common behavioral or psychosocial interventions include counseling, seeking feedback, implementing health education, providing incentives, and peer or social support [14]. A recent systematic review found counseling, feedback, and incentives to be most effective, while the evidence for health education and social support is less clear [5].

Despite these recommendations, there continues to be a lack of provision and access to evidenced-based smoking cessation interventions during pregnancy. A systematic review conducted in 2019 by Gould et al.[15] evaluated the pooled prevalence of health providers provision of the recommended 5As components of smoking cessation care during pregnancy and found high levels (>79%) of performance of ‘Ask,’ ‘Advise’ and ‘Assess’; however, significantly lower rates of ‘Assist’ (59.2%) and ‘Arrange’ (33.3%). Further research is needed on the effectiveness of interventions to enhance the provision of smoking cessation [16]. Furthermore, the data suggest that

 doi:10.20944/preprints202001.0150.v1

pregnant women underutilize existing smoking cessation services covered by Medicaid [17]. There continues to be a wide call for enhanced theory based tailored smoking cessation programs for pregnant women, designed to effectively target identified barriers and facilitators of quitting and staying quit among this vulnerable population [12 16 18].

Our program evaluation focuses on San Bernardino County, CA—the largest county in the contiguous US—in which nearly 12% of pregnant women reported having smoked during the three months prior to their pregnancy (vs 10.8% statewide)[19-21]. The county maternal smoking rates show clear disparity trends by rurality (22.7% in rural vs 10.2% in urban regions), access to health insurance (15.5% among Medi-Cal recipients vs 6% among those insured privately), education (20.8% among those with <High School), and ethnicity (23.8% among Whites, 18% among Blacks vs 7.4% among Hispanics) [22].

In San Bernardino County, Loma Linda University Health developed through state funding (First 5 CA.gov) the Comprehensive Tobacco Treatment Program (CTTP) – the largest maternal tobacco cessation and relapse prevention program in the County. The CTTP is an eight week, incentivized program that utilizes trained health educators who provide individualized smoking cessation education and support for pregnant smokers during weekly individual or group sessions. Virtually all enrollees were from disparity population by rurality, low income, or ethnicity. Thus, the overall aim of this program evaluation was to evaluate the effectiveness of the CTTP behavioral smoking cessation method in helping pregnant smokers from disparity populations achieve tobacco abstinence. The specific aims of this study were to 1) Identify demographic,

 doi:10.20944/preprints202001.0150.v1

behavioral, and gestational variables associated with successful completion of the CTTP, and 2) Assess the impact of program enrollment on point-prevalence smoking abstinence during treatment and at three or more months of follow-up.

Methods

Program Description

Coverage and Outreach. The Comprehensive Tobacco Treatment Program model consists of an 8-week program, with weekly in person meetings and telephone follow-up intervals at 3, 6, and 9-months, delivered by trained perinatal health educators (BS or MPH prepared). Participants are referred to the program during prenatal visits by collaborating primary care providers at selected sites within San Bernardino County. The referral sites include outpatient clinics, hospitals, and rehabilitation homes. The four main localized regional referral sites include 1) Desert region sites within Barstow, Apple Valley, Joshua Tree, Yucca Valley, and Del Pueblo, 2) Loma Linda, 3) South San Bernardino City, and 4) Fontana & Rialto. Patients are screened for tobacco use at each of the collaborating sites using standardized prenatal protocols, and when indicated, referred to the CTTP for smoking cessation support (most often via fax). In addition, program announcements in the form of printed flyers are posted at WIC Offices, and distributed at community outreach events and health fairs. The flyers included eligibility criteria, contact information, and requested interested participants to call to self-enroll.

Intervention. The main goal of the CTTP is to support smoking cessation among pregnant women that are currently smoking or have smoked at any time during their pregnancy before the referral and point of enrollment. Upon receipt of the referral, perinatal health educators contact participants to schedule a face-to-face individual

 doi:10.20944/preprints202001.0150.v1

informal meeting at a mutually agreed upon meeting location or invite them to a small group session conducted at the premises of one of the referral sites. Most common meeting locations include public spaces near the participant's home, obstetric clinics, community partner agencies, hospitals, and outpatient rehabilitation centers. During the initial face-to-face visit, the perinatal health educators assess participants' smoking status, the risk for maternal depression and substance abuse (alcohol and other drugs), and when appropriate, referrals are made based on the CTTP protocol.

The CTTP utilizes evidence-based materials developed by the American College of Obstetricians and Gynecologists which recommended 5 A's program [23], and motivational interviewing techniques.[5] The health educator provides tobacco cessation-related education that highlights the risks associated with smoking during pregnancy and the benefits of cessation, and works with the participant to develop an individualized quit plan. The purpose of the quit plan is to provide individualized support participants in setting a quit date, and outlining personalized goals and strategies for quitting and staying quit. At the weekly sessions, health educators review the individualized quit plan , support cessation efforts, and provide supplemental material based on the individual's needs. Weekly biomarker feedback, using urinary cotinine, is used to confirm abstinence. Incentives, in the form of infant diapers and xylitol gum to assist with cravings, are provided for each week that a participant tests negative for cotinine. A participant is considered to have completed the program when she has achieved eight consecutive weeks of testing negative for cotinine. It is important to note that a participant can be enrolled within the program for longer than 8-weeks, as they may not test negative for cotinine in the initial weeks of participation. After successful

 doi:10.20944/preprints202001.0150.v1

completion of eight (or more) weeks in the program, participants are followed up via telephone at 3, 6, and 9-month intervals. During these follow-up telephone calls, participants are asked about the well-being of the baby, their smoking status, and if they have relapsed, how much they are currently smoking (number of cigarettes/day), and when (date) they relapsed. If relapse has occurred, they are referred to the 1-800-NOBUTTS California Smoker's Helpline.

Evaluation Methods

We used a retrospective cohort design to assess the efficacy of the CTTP in promoting smoking cessation among pregnant women, and identify predictors of program completion and non-completion. Human subjects' approval for the program evaluaton was obtained from the Loma Linda University Institutional Review Board (IRB # 5190418).

Cohort. The current analysis is based on a cohort of 233 pregnant women from San Bernardino County who were enrolled in the CTTP program during one year between July 2012 and July 2013.

Program completion (Outcome variable). Participants were determined to have completed the program if they stayed quit for eight consecutive weeks, as evidenced by negative urinary cotinine measured weekly. In addition, regardless of their completion status, participants' smoking status (yes/no) was re-assessed at 3, 6, and 9 months intervals via telephone follow-up.

Covariates. Gestational age was categorized into trimesters; women with gestational age <13 weeks were classified as first trimester; those between 13 and 28 weeks as second trimester and those greater than 28 weeks as third trimester. Smoking status at

 doi:10.20944/preprints202001.0150.v1

enrollment indicates whether the participant was still smoking or not on the day of program enrollment as validated by biochemical feedback (urinary cotinine). The ethnicity/race variable had the following four levels: Asians, Blacks, Hispanics, and Whites. Age in years was obtained as a continuous variable.

Statistical analysis. We used logistic regression to assess the effect of individual socio-demographic variables on program completion. We conducted two multiple logistic regression analyses. The first assessed the effect of smoking status at enrollment, age, and race on program completion [24 25]. The second analysis looked at the adjusted effects of gestational age, race, and age on program completion (defined as 8-week point-prevalence abstinence). Non-completion was defined as relapse within any of the eight weeks of program enrollment. All the analyses were conducted using SAS 9.3 [26].

Results

Participant Characteristics

In 2012-2013, the CTTP enrolled 233 participants (Table 1). At the time of enrollment, the majority of participants were under 25 years of age (59%, n = 137) with 12 years of education or less (71%, n = 125), in the second or third trimester of their pregnancy (86%, n = 196), a single parent (62.9%, n = 110), and had a partner who currently smoked (54.3%, n = 119) (See Table 1). Approximately 46% (n = 107) of the participants were Hispanic, while 31% were non-Hispanic White (n = 72) and 16.4% were non-Hispanic Black.

8 week point prevalence abstinence (PPA), relapse, and loss to follow-up

Figure 1 depicts the program's participant rates of 8 week PPA, relapse, and loss to follow-up. We found that the immediate results of an 8 week intervention (post quit

 doi:10.20944/preprints202001.0150.v1

date) indicated a 28.4% 8 week PPA verified by weekly urinary cotinine tests. After a median of 9.04 months of follow-up after the 8 week intervention, 81.6% reported no tobacco use (85% postnatal reports). Among the 71.6% of subjects who relapsed during the 8 weeks post quit date, we found that 28.5% reported no tobacco use (66% postnatal reports) after a median of 3.35 months after the 8 week intervention. There was an overall 44% loss to follow-up among all subjects who enrolled in the 8 week intervention.

Variables associated with Relapse/Smoking during and after the intervention

In tables 2-4 we conducted a logistic regression analysis to identify variables associated with relapse/smoking during and after the intervention. In univariable models depicted in table 2 we found that younger mothers (ages 21-25) were three times more likely than mothers 31 and older to relapse/smoke. Those mothers who had not adhered to quit date at the start of the 8 week program (i.e. were current smokers) were 3 times more likely to relapse/smoke (OR= 3.17 95% CI [1.44, 6.95]), and this effect was even more pronounced for the heaviest smokers (OR for > 5 cigarettes per day = 4.68 [1.36, 16.18]). Black (OR=2.84 95% CI [1.07, 7.52]) and White (OR=3.93 95% CI [1.75, 8.85]) mothers were more likely than Hispanic/Latino mothers to relapse/smoke. The highest rates of relapse/smoking were also found at the first and third trimester. These univariable findings persisted in multivariable models (tables 3-4).

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Discussion

Our program evaluation of CTTP identified notable efficacy of the 8 week incentivized health educator-delivered model. Specifically, we found a 28.4% 8 week PPA rate after the intervention and that during a median of 9 months of follow-up after the intervention 81.6% self reported currently using no tobacco. The limitation of our approach was the overall high rate of relapse or loss to follow-up (56%). Our modeling of relapse/smoking in enrollees indicated that this was significantly higher in young mothers, non-Hispanic mothers (White, Black), those mothers who did not adhere to a quit date at enrollment, and first/third trimester mothers. Also noteworthy was a 64% higher rate of relapse/smoking in the rural "High Desert" region.

Cessation rates and outreach

The major cessation outcome findings in this study suggest that the CTTP model was successful in supporting the cessation efforts in a sample of multi-ethnic women, but evidence for statewide disparity trends remained. A recent systematic review, which included 102 randomized control trials, evaluated the effectiveness of various psychological (vs. pharmacological) interventions to support pregnant women to stop smoking and found moderate- to high quality evidence that these types of interventions increase the proportion of women who stop smoking in late pregnancy (by 35%) [5]. In this review differences in the main intervention strategies across studies prohibited pooling effects; however, a meta-analysis of U.S. effectiveness trials of tobacco treatment methods tailored for pregnant women reported quit rates ranging between 6.2% to 32%, with quit rates in the experimental group averaging 7% higher than the control groups [27]. Based on these reports, outcomes of the CTTP appear to be

comparable to those found in evidenced-based interventions provided to multi-ethnic populations of pregnant women who smoke. For example, when administered to a representative Medicaid-supported prenatal care population, the evidence-based Smoking Cessation and Reduction in Pregnancy Treatment (SCRIPTS) program which includes standardized educational materials and counseling, reported a 12% cessation rate, and an 18.2% significant reduction rate among the experimental group at three months or less postpartum [28]. In contrast, the BABY & ME-Tobacco Free® program which utilizes counseling, and biomarker feedback with monthly incentives in the form of diaper voucher reported an intention to treat quit rate of 60% during pregnancy and sustained results during postpartum (64% at 6 months) in a model that utilized itinerant smoking cessation specialists [29].

While the cessation rates observed in this sample of the CTTP are encouraging, of considerable concern is the observation that approximately 44% of the total number of participants enrolled in the CTTP were loss to follow-up, which is substantially higher than the loss to follow-up rates observed in other intervention studies [5 28 30]. In studies conducted among pregnant women, loss to follow-up has been associated with differences in smoking/quitting beliefs, including intention to quit, self-efficacy, and interest in receiving risk information [13]. Additionally, subgroups of pregnant women who have consistently had low retention rates include women who are single, less educated, alcohol and drug users, non-working, and not enrolled in WIC programs [30]. However, a large community-based study conducted by El-Khorazaty et al. (2007) among minority pregnant women was able to achieve markedly enhanced recruitment and retention rates compared to similar reports among ethnic minorities in clinical research. These

 doi:10.20944/preprints202001.0150.v1

results were attributed to the implementation of a range of health systems processes and culturally-sensitive retention strategies, including the collection of multiple telephone numbers, regular updates of contact information using a computerized data management system that was available to all project staff, integration of cultural competence training and consideration with all study procedures [30]. This same study also found differences between those that are lost-to-follow-up and those that drop out—thereby suggesting the need for different strategies for engaging both groups [30].

In this sample of CTTP participants, both smoking and the number of cigarettes smoked (smoking intensity) at the time of enrollment (i.e. not adhering to a quit date) were predictive of relapse/smoking. According to the literature, smoking at low intensity before pregnancy has continued to be strongly predictive of quitting during pregnancy, while addiction or of level of nicotine dependence is predictive of continuing to smoke during pregnancy, maintaining abstinence postpartum and program dropout rates [13 29 31]. In addition to higher levels of nicotine dependence, pregnant women who continue to smoke when compared to those who quit during pregnancy have also been found to have significant differences in smoking-related symptomology, including cravings and physical withdrawal symptoms [31 32]. Therefore, the differences in completion rates observed in this CTTP sample may partially be explained by varied levels of smoking intensity and nicotine dependence. Understanding the effectiveness of the CTTP program for pregnant women with different smoking behaviors may be enhanced by including assessment of additional behavioral and physiological factors that have been associated with quitting and sustained abstinence among this population, including

 doi:10.20944/preprints202001.0150.v1

abstinence motivations, self-efficacy, nicotine dependence, and smoking-related symptomatology [32 33].

Health Disparities

Rurality. In this sample, one of the predictors of relapse/smoking was the program referral site. Participants who were referred from sites in the High Desert region had a 64% increase in odds towards relapse/smoking during or after the intervention. The Desert Region (including the High and Eastern desert regions) of the county comprises 93% of the county's 20,000 square mile land area and is far more sparsely populated than the Mountain or Valley Regions [34]. As has been noted, women living in rural communities within San Bernardino County have significantly higher rates of smoking before and during pregnancy [22]. Many Desert Region cities received failing tobacco control grades in the American Lung Association State of Tobacco Control 2019 Report in all categories, including in smoke-free housing and reducing sales of tobacco products [35]. Additionally, in this region, the overall increased rates of tobacco use are compounded by a higher prevalence of substance use. Over the past five years, San Bernardino County has experienced a +102% increase in hospital admissions related to opiates, and the High Desert region has been most severely impacted.[34] During the study period, the CTTP program had only two referral sites within the High Desert Region. Travel distances and lack of public transportation have been described as the most significant barriers limiting access to health and community services in this region and are likely to be factors impacting completion and retention rates of the CTTP as well [34]. These contextual factors along with the findings from this study warrant a comprehensive needs assessment to evaluate the most effective

 doi:10.20944/preprints202001.0150.v1

strategies for expanding reach and engagement of program participants from the High and Eastern Desert regions of the county.

Ethnicity. Whites and Blacks had significantly higher odds of program non-completion in this study, while those who identified as Hispanic had the highest rates of program completion. These findings are consistent with national cessation rates during pregnancy, which is highest among non-Hispanic Asians and Hispanics [21]. National, state, and county level reports consistently report a higher prevalence of maternal smoking among those who identify as White and Black vs. Hispanics, and the highest prevalence among those who identify as non-Hispanic American Indian or Alaska Native women (up to 18% nationally) [19 21 34]. Furthermore, in a recent report on smoking intensity during pregnancy, the highest prevalence of high intensity smoking (≥10 cigs/day) before and during pregnancy was among Non-Hispanic White women, followed by Black women [36]. These disparities underscore the limitations of the CTTP's outreach, and speak to the need for further formative research to understand how the program can increase its effectiveness in supporting smoking cessation among pregnant women in these subgroups.

Over 45% of the CTTP participants in this sample were of Hispanic decent, which reflects the race/ethnic group proportions in San Bernardino County, with Latino residents comprising approximately 54% (2018) of the population [34]. Racial differences in smoking behavior have been attributed partially to sociocultural influences and differences in the acceptability to tobacco use [37 38]. These contextual factors along the higher rates of program completion among this group appear to be consistent with what has been called the "Hispanic Paradox" or Latino Epidemiologic Paradox [39 40]. The

 doi:10.20944/preprints202001.0150.v1

Hispanic/Latino Paradox here refers to the suggestive a priori research that concludes that there may be maternal and infant health advantages among Hispanics women with quitting smoking during pregnancy [39]. These advantages are thought to stem from shared culture, social networks, and higher levels of social capital. This phenomenon has since been observed at the national level in the US and the implications warrant further exploration at the state and county levels. For example, within San Bernardino County, many regions have Hispanic ethnic densities that are representative of larger than 50% of the total population residing there [41]. Studies have also shown that the maternal and infant-related health benefits attributed to smoking cessation, in some circumstances, may also extend to other ethnicities, such as non-Hispanic Whites and non-Hispanic Blacks [40]. One analysis found an approximate 80% reduction in the odds of smoking, with an approximate 33% reduction in infant mortality, as well as moderate reductions in preterm delivery risk, for white and black mothers that may live in regions where the Hispanic ethnic densities are greater than 50% [40]. However, it has also been shown that these benefits may balance between ethnicities when taking into consideration the mother's level of acculturation. As a result of acculturation, mothers may have adapted to new sociocultural norms, and the literature suggests a negative influence of acculturation on tobacco use among Hispanic immigrants [42].

Studies have also found variation in smoking intensity and nicotine metabolism by demographic subgroups [43]. A recent study conducted by Kondracki (2019), utilizing nationally representative birth certificate data, found that among Hispanic women, the odds of high intensity smoking in early pregnancy were 88% lower when compared to non-Hispanic women [36]. The author of this study underscores that while high intensity

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smoking before and during pregnancy remains an urgent concern in the US, there is also a need for interventions that focus on the proportion of “low intensity quitters and reducers” who are ready to stop smoking [36]. Therefore, while the discussions concerning the Hispanic Paradox continue to caution against presumptions of cultural homogeneity among immigrant women [37], when considering community level assets (adopting a strengths perspective), the higher Hispanic ethnic densities observed across San Bernardino may present an opportunity to capitalize on the positive impact of the associated cultural and social networks within these communities.

Program modifications

In the literature, individual-level (vs. population-level) smoking cessation interventions for pregnant women have tended to differ substantially relevant to main intervention strategies, intensity, duration, and in the people involved in their implementation [5]. In the aforementioned systematic review on smoking cessations for pregnant women, quality of evidence was graded higher for more intense counseling, incentives that provided feedback, and interventions based on financial incentives vs. alternative non-contingent incentive interventions [5]. The current format of the CTTP incorporates some of these strategies; however, based on the literature, the intensity of support women receive in successful smoking cessation programs has increased over time [5]. In utilizing trained perinatal health educators, incentive and biomarker feedback, the CTTP model far exceeded the Clinical Practice Guideline recommendations to offer self-help materials and 10 min face-to-face psychosocial intervention [14]. However, the program has since been discontinued from state funding, and the cost-effectiveness of

 doi:10.20944/preprints202001.0150.v1

the health educator model has been determined to be unsustainable. Therefore, these study findings present an opportunity to explore other models

There is mounting evidence that the timing of smoking cessation interventions may be especially critical in preventing poor birth outcomes, as the period late in the first and early in the second trimester is a potential biologically vulnerable window for risk of PTB, and this may be most pronounced late in the first trimester [44]. These findings speak to the importance of identifying and extending smoking cessation support to women as early as possible in their pregnancy. In addition to the importance of including smoking cessation interventions in routine preconception care [45], there is a need to refine referral processes to ensure more effective contact procedures. The evidence also suggests that the use of routine CO monitoring and “Opt-Out” referral programs during antenatal visits with culturally appropriate support have the potential to increase rates of quitting [16 45-47].

The observed patterns among Hispanic populations both nationally and in this sample may assist in determining priorities and inform programmatic modifications of the CTTP. For example, the effectiveness of engaging lay health advisors, *promotores* or community health workers (CHW) to provide culturally tailored evidence-based smoking cessation interventions for pregnant women has been cited as holding promise, particularly for underserved minority and rural communities [37 48 49]. The use of CHWs is based on Rogers’ innovation diffusion theory where diffusion of innovation or behavior change is communicated through another member of the community [50]. CHWs have been shown to be effective in promoting many types of health behavior changes in diverse settings, and with regard to smoking cessation, especially when trained in

 doi:10.20944/preprints202001.0150.v1

specific interventions such as motivational interviewing, when compared to professional counselors, studies have shown that the effectiveness is not diminished in a CHW model [51].

A recent systematic review of the literature identified features that enable positive CHW program outcomes, such as community embeddedness, and supportive supervision, continuous education, and adequate logistical support and supplies [52]. The effectiveness of CHWs among Hispanic women has been well established and increasing evidence of their effectiveness among other ethnicities [49]. In a large study conducted recently in the Appalachian region of Ohio among a predominantly white female sample, Wewers et al. (2017) evaluated two evidence-based CHW models of tobacco dependence treatment, including a face-to-face condition and a referral to a state-sponsored quit line condition, and found that both approaches offer promise to low-resource settings and underserved regions [48].

The LLUH health system has utilized CHWs in the community setting for some time, and has led the region in training and integrating clinic-based CHW in healthcare settings ranging from primary to tertiary clinical settings. The LLUH training program has graduated over 150 CHWs between 2016-2019 and works with the region's largest health plan to reach the most complex patients in our community. One of the largest cohorts to be trained was the Victoville CHW cohort, which would provide a pool of CHWs from one of the regions that suffer from maternal tobacco and substance use the most. Currently LLUH employs CHWs in the NICU, diabetes treatment center, and the Emergency Department. While the current scope of the clinic-based CHW role has yet to include tobacco use treatment, there has been a growing interest in using CHWs to

 doi:10.20944/preprints202001.0150.v1

support perinatal efforts. Formative mix-methods studies have been conducted within the same health system to explore patient and CHW's perceptions related to clinical integration of CHWs into a primary care setting, as well as organizational readiness for CHW training and implementation of clinic-based CHWs [53-55]. This work could be highly useful in providing the context-specific elements and considerations that experts advocate are necessary in order to maximize the full potential of this role [52].

Finally, there is also growing evidence that mobile phone text messaging and app-based interventions result in greater quit rates when compared with minimal smoking cessation support [56]. In a 2019 systematic review, only one of the 26 studies included specifically targeted pregnant women and mothers [56]. While further research is indicated, these types of platforms may offer a mechanism for enhancing the reach and engagement with CTTP participants between face-to-face sessions, or as an integrated strategy in the development of revised multi-component model.

Limitations

This retrospective study utilized a quasi-experimental one-group design that presents a threat to internal validity. Additionally, the high LOSS TO FOLLOW-UP rates may have introduced attrition bias or systematic differences between participants who continued in the program vs. those who dropped out. Future recommendations include testing the effectiveness of the CTTP utilizing a randomized control trial design and incorporating additional measures to prevent loss of data from attrition. The study was strengthened by the use of biochemical validation of smoking abstinence during program enrollment; however, alcohol and drug use and follow-up assessments were assessed via self-report and are therefore susceptible to underreporting due to social desirability bias.

 doi:10.20944/preprints202001.0150.v1

In regards to the sample size, the data resulted in only 60 events, allowing for only six terms to be in each model. This prevented us from testing statistical power as well as confounders and effect modifiers, and may also have prevented us from seeing other variables that could have attributed to program non-completion. Furthermore, inconsistencies in the data collection and data entry procedures increased the amount of missing data, which in turn contributed to the smaller sample size.

Future evaluations may benefit from the re-evaluation of outcome measures and data collection points, as the binary (completion/non-completion) primary program outcome variable did not allow for the characterization of participants' struggles with relapse while enrolled in the program. Additionally, we did not have access to referral site data concerning the number of women who were initially eligible for the program vs. number referred to the program, which would have provided useful information about the acceptability, and degree of selection bias in the study population [57].

Conclusions

Our findings identify that incentivized maternal smoking cessation delivered by a health care organization was effective for program participants. However, there is a critical need to enhance participation and engagement among disparity populations (by rurality and non-Hispanic ethnicity). Formative research is needed to increase understanding of contextual factors affecting outreach and enhance cost effectiveness in order to expand the programmatic support being extended to mothers in San Bernardino County who want to quit smoking and stay quit.

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Table 1: Demographic, behavioral, and gestational variables among enrollees in the Comprehensive Tobacco Treatment Program (San Bernardino County, California) during 2012-2013 (*N* = 233) [1]

Variable	N (%)
Age category	
20 or younger	**41** (17.67)
21-25	**96** (41.38)
26-30	**50** (21.55)
31 or older	**45** (19.4)
Total	**232**
Gestational age at enrollment	
First trimester	**32** (14.04)
Second trimester	**89** (39.04)
Third trimester	**107** (46.93)
Total	**228**
Race/Ethnicity	
Asian/Other	**15 (**6.47)
Hispanic	**107**(46.12)
NH Black	**38**(16.38)
NH White	**72** (31.03)
Total	**232**
Education	
9th Grade or less	**61** (34.66)
High school graduate	**64** (36.36)
College education or more	**51** (28.98)
Total	**176**
Income	
Less than $10,000	**69** (51.49)
$10,000-$25,000	**40** (29.85)
More than $25,000	**25** (18.66)
Total	**134**
Single parent	
No	65 (37.14)
Yes	110 (62.86)
Total	**175**
Partner smokes	
No	100 (45.66)
Yes	119 (54.34)

Variable	N (%)
Total	**219**
Number of cigarettes/day at enrollment	
Quit	159 (68.83)
≥ 1 Cigarette/day	72 (31.17)
Total	**231**
Drug use	
No	140 (76.5)
Yes	43 (23.5)
Total	**183**
Alcohol use	
No	96 (52.46)
Yes	87 (47.54)
Total	**183**
Smoking status at enrollment	
No (Quit)	153 (67.7)
Yes (Current smoking)	73 (32.3)
Total	**226**
Number of pregnancies	
1 or none	63 (27.75)
2	48 (21.15)
3	40 (17.62)
4	35 (15.42)
5 or more	41 (18.06)
Total	**227**
Number of children	
None	80 (35.09)
1	60 (26.32)
2	39 (17.11)
3 or more	49 (21.49)
Total	**228**
Program location by region within SB County	
Linda Linda	78 (33.62)
High Desert	76 (32.76)
San Bernardino City	54 (23.28)
Fontana/Rialto	24 (10.34)

[1] Demographic data missing for 1 participant

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Figure 1. Rates of biospecimen verified (urinary cotinine) 8 week point prevalence abstinence (PPA), relapse, and loss to follow-up among the 233 enrollees in the 2012-2013 cohort of the Comprehensive Tobacco Treatment Program (San Bernardino County, California).

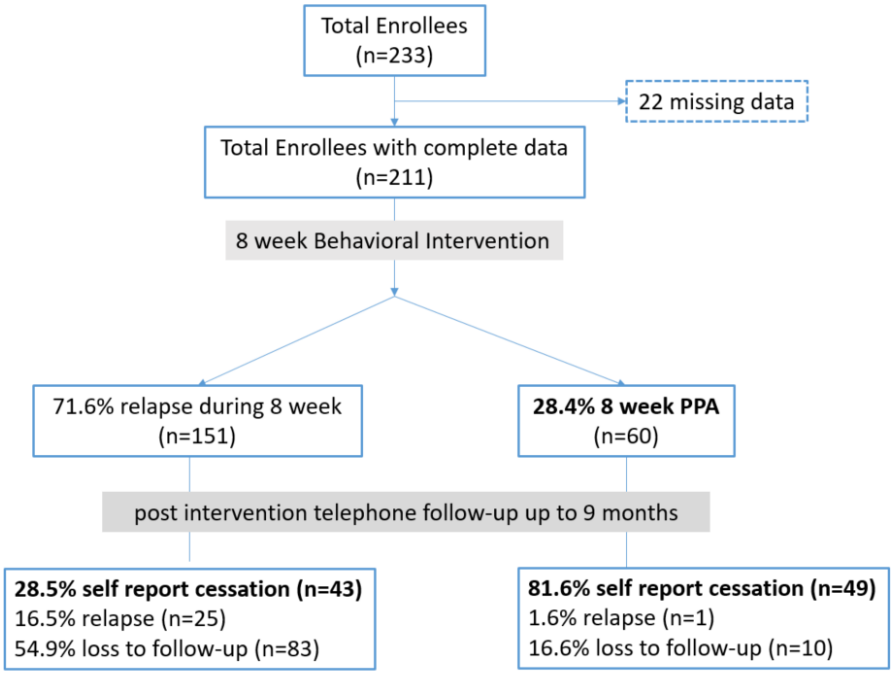

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Table 2: Univariable odds ratios relating selected variables to program non-completion among participants enrolled in the Comprehensive Tobacco Treatment Program (San Bernardino County, California) from 2012-2013 (*N* = 233).

Covariates	OR	95% Confidence Interval	
Age			
20 or younger vs. 21-25	0.63	0.26	1.51
26-30 vs. 21-25	0.59	0.26	1.33
31 or older vs. 21-25	**0.33**	**0.15**	**0.75**
Race			
Asian/Other vs. Hispanic	1.31	0.42	4.12
NH Black vs. Hispanic	**2.84**	**1.07**	**7.52**
NH White vs. Hispanic	**3.93**	**1.75**	**8.85**
Education			
9th Grade or less vs. College education or more	1.64	0.72	3.70
High school graduate vs. College education or more	1.45	0.66	3.16
Income			
$10,000-$25,000 vs. More than $25,000	1.05	0.37	2.98
Less than $10,000 vs. More than $25,000	1.77	0.67	4.67
Single parent			
Yes vs. No	1.49	0.76	2.92
Partner smokes			
Yes vs. No	1.59	0.86	2.94
Program location			
Fontana/Rialto vs. Loma Linda	0.76	0.28	2.04
High Desert vs. Loma Linda	1.64	0.73	3.68
San Bernardino City vs. Loma Linda	0.57	0.26	1.22
Smoking status at time of enrollment (Current smoking vs. Quit)			
Yes vs. No	**3.17**	**1.44**	**6.95**
Cigarettes			
5 or less/day vs. Non smoker	2.17	0.84	5.62
More than 5/day vs. Non smoker	**4.68**	**1.36**	**16.18**
Alcohol use			
Yes vs. No	0.99	0.52	1.89
Drug use			
Yes vs. No	1.65	0.72	3.78
Gestational age at enrolment			
First trimester vs. Second trimester	**4.04**	**1.28**	**12.72**
Third trimester vs. Second trimester	**2.36**	**1.23**	**4.50**
Parity			
2 vs. 1	0.74	0.31	1.76

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3 vs. 1	0.96	0.38	2.46
4 vs. 1	0.91	0.35	2.41
5 or more vs. 1	0.74	0.30	1.84
Number of Children			
1 vs. None	0.91	0.42	1.99
2 vs. None	1.04	0.43	2.53
3 or more vs. None	0.82	0.36	1.87

Table 3. Multivariable model relating gestational age, age, and ethnicity variables to program non-completion among participants enrolled in the Comprehensive Tobacco Treatment Program (San Bernardino County, California) from 2012-2013 (*N* = 233).

Covariates	OR	95% Confidence Interval	
1st Trimester vs. 2nd Trimester	**3.87**	**1.15**	**13.04**
3rd Trimester vs. 2nd Trimester	**2.87**	**1.43**	**5.77**
Age	**0.93**	**0.87**	**0.99**
Asian/Other vs. Hispanic	0.86	0.25	2.98
NH Black vs. Hispanic	**3.13**	**1.13**	**8.69**
NH White vs. Hispanic	**4.38**	**1.87**	**10.25**

Table 4. Multivariable model relating smoking status at enrollment, ethnicity, and age to program non-completion among participants enrolled in the Comprehensive Tobacco Treatment Program (San Bernardino County, California) from 2012-2013 (*N* = 233).

Covariates	OR	95% Confidence Interval	
Smoking vs. Quit	**2.440**	**1.030**	**5.776**
Age	**0.923**	**0.868**	**0.982**
Asian/Other vs. Hispanic	1.225	0.377	3.981
NH Black vs. Hispanic	**3.019**	**1.101**	**8.274**
NH White vs. Hispanic	**2.949**	**1.236**	**7.036**

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Author Contributions

The following statements should be used

Conceptualization, P.S. and T.O.; Methodology, P.S.; Software, T.O. and S.W.; Validation, S.W.; Formal Analysis, X.X.; Writing – Original Draft Preparation,T.O.; Writing – Review & Editing, A.B.P, J.Y. and J.C.B.; Supervision, P.S.; Project Administration, P.S.; Funding Acquisition, P.S.

Conflict of Interest

The authors declare no conflict of interest.

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