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Evaluation of a federally-funded mass media campaign and smoking cessation in pregnant women: a population-based study in three states

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Abstract

Objectives

In 2012, the Centers for Disease Control and Prevention initiated a national anti-smoking campaign, *Tips from Former Smokers* (*Tips*). As a result of the campaign, quit attempts among smokers increased in the general population by 3.7 percentage points. In the current study, we assessed the effects of *Tips* on smoking cessation in pregnant women.

Methods

We used 2009-2013 certificates of live births in three U.S. states: Indiana, Kentucky, and Ohio. Smoking cessation by the third trimester of pregnancy was examined among women who smoked in the three months pre-pregnancy. Campaign exposure was defined as overlap between the airing of *Tips* 2012 (March 19-June 10) and the pre-pregnancy and pregnancy periods. Women who delivered before *Tips* 2012 were not exposed. Adjusted logistic regression was used to determine whether exposure to *Tips* was independently associated with smoking cessation.

Results

Cessation rates were stable during 2009-2011, but increased at the time *Tips* 2012 aired, and remained elevated. Overall, 32.9% of unexposed and 34.7% of exposed smokers quit by the third trimester ($p<0.001$). Exposure to *Tips* 2012 was associated with increased cessation (adjusted odds ratio: 1.07, 95% Confidence Interval: 1.05-1.10).

Conclusions

Exposure to a national anti-smoking campaign for a general audience was associated with smoking cessation in pregnant women.

Words: 206

Strengths and limitations of this study

- This is the first study to examine the association between a general mass media anti-tobacco campaign (*Tips* from Former Smokers) and smoking cessation in pregnant women.
- Women with live births in 3 states were examined; trimester-specific smoking status and temporal relationship to airing of the *Tips* campaign.

- Analysis was an ecological time-series; we did not have information on exposure to the *Tips* campaign at the individual level.
- Smoking status was based on self-report contained in the birth certificate.

Introduction

Tobacco use is a leading cause of preventable disease and death in the United States[1] and worldwide.[2] In 2012, the U.S. Centers for Disease Control and Prevention delivered a national anti-smoking campaign called *Tips from Former Smokers* (*Tips* 2012). The campaign included graphic images of the health consequences of smoking, and reached an estimated 80% of U.S. cigarette smokers.[3] An evaluation of *Tips* 2012 found that quit attempts among smokers increased in the general population, from 31.1% to 34.8% as a result of the campaign.[2] Of those who made a quit attempt, 13.4% were abstinent at follow up immediately after the campaign ended. Based on relapse survival-curve analysis, it is estimated that approximately half of those with short-term abstinence achieved long-term abstinence.[3] In the second *Tips* campaign, which aired in 2013, the effect of media dose on quit attempt rates was evaluated. Sixty-seven of 190 media markets were randomly selected to receive a higher dose media buy (3 times the media buy of the standard dose). [4] An evaluation of *Tips* 2013 found the relative quit attempt rate was significantly higher in higher-dose markets (38.8%) than in standard-dose markets (34.9%).[5]

Smoking is a leading cause of infant disease and death in the U.S. An estimated 5.3%–7.7% of preterm deliveries, 13.1%–19.0% of term low birth weight deliveries, and 23.2%–33.6% of Sudden Infant Death Syndrome (SIDS) cases are attributable to prenatal smoking.[6] Despite the known adverse effects, prenatal smoking prevalence remains unacceptably high. In a population-based analysis in the U.S. from 2009-2011, nearly one-quarter (24%) of women with a recent live birth smoked in the three months before pregnancy, and 11% smoked during the last 3 months of pregnancy.[7] Furthermore, U.S. prenatal smoking prevalence and cessation rates have not improved appreciably over time.[7, 8] Currently available clinical cessation interventions for pregnant women are only modestly effective (with pooled relative risks for cessation less than 1.5), [9,10] and by themselves are unlikely to result in large changes in prenatal smoking at the population level.[11]

To our knowledge, no studies have assessed the impact of a general anti-smoking campaign on smoking cessation in pregnant women. To address this gap, we used U.S. birth certificate data from three contiguous states to evaluate cessation rates in pregnant women before (2009-2011) and during the *Tips* 2012 campaign. We also assessed whether exposure to the *Tips* 2012 campaign was independently associated with cessation after adjusting for potential confounders.

Methods

Study design and setting

We performed an observational study of patterns of smoking cessation in pregnant women. Because the current analysis necessitated state-level data-sharing and therefore could not be readily completed using national data, we used birth certificates files for resident live births from three states: Indiana, Kentucky, and Ohio, from 2009-2013. These states were selected based on the overall annual number of births, the relatively high prevalence of cigarette smoking during pregnancy[12,13] and their geographical proximity (the three states are geographically contiguous with overlapping *Tips* media markets). In addition, none had introduced new state-level tobacco control programs at the time of the airing of *Tips* 2012.

Tips Media Campaign

Tips 2012 aired for 12 weeks, from March 19 through June 10, 2012, with sufficient media placement to reach three-quarters of US adults on multiple occasions.[3] Advertisements appeared on television in all U.S. media markets through a national buy of commercial advertising time on cable television networks. *Tips* 2012 had a ubiquitous national buy and a local "buy up" strategy in which the campaign was broadcast through smaller local television channels in media markets with high cigarette smoking prevalence. All three states included in our analysis had multiple markets that received the additional local television ad buys. The total campaign dose was approximately 70% higher than the national

average dose in Ohio and Kentucky, and approximately 25% higher in Indiana. It is estimated that 80% of U.S. cigarette smokers saw at least one *Tips* 2012 message, and that those who saw any advertisement averaged 23 views over the 12-week period.[3]

Campaign exposure

Exposure to the *Tips* campaign was defined as temporal overlap between each woman's pregnancy and the preceding three months (pre-pregnancy), and airing of *Tips* 2012. A woman's date of conception and the beginning dates for each trimester were calculated from the obstetric estimate of the gestational age at delivery in completed weeks and from the infant's date of birth, which was ascertained directly from the birth certificate. The 3-month period preceding her date of conception was then calculated. The date 3 months before conception and the date of delivery were compared with the dates of the *Tips* campaign to determine temporal overlap. Women were categorized as "not exposed" to the campaign if they delivered before the first day of the *Tips* 2012 campaign, and women were categorized as "exposed" to the campaign if any day from the first date of the 3 months before conception through the end of the second trimester overlapped with the airing of the *Tips* 2012 campaign. We included the 3 months before conception in our exposure window because it aligned with the period of baseline smoking status included in the birth certificate and because we felt it was reasonable to assume that women who viewed the campaign in that time period would still remember the material after becoming pregnant.

Intensity of exposure to the *Tips* campaign was assessed using weekly media market-level *Tips* gross rating points (GRPs) for national and local television advertising as a continuous variable. GRPs are a standard measure of advertising "dose" delivered to a given audience in a given media market and time period, and are defined as the product of the percentage of the audience that is exposed (i.e., audience reach) and the frequency with which that exposure occurs (i.e., the number of times ads are aired). GRPs are calculated at the market level by Nielson Media Research based on TV viewership estimates. We used women's cumulative *Tips* television GRPs in each designated market area (DMA).[14] Cumulative

GRPs were computed by summing the weekly GRPs in each DMA based on maternal county of residence at the time of delivery for the weeks during which the woman was exposed to the *Tips* campaign.

Smoking Cessation

The main outcome was smoking cessation by the third trimester of pregnancy among women who smoked in the three months before pregnancy, as recorded on the 2003 revision of the U.S. standard certificate of live birth.[15] On the birth certificate, cigarette smoking status is determined from four questions about the average number of cigarettes smoked per day in the three months before pregnancy and during each trimester of pregnancy. Our study population of pre-pregnancy smokers were women who reported smoking > 0 cigarettes per day in the three months before pregnancy. Cessation was defined as occurring in pre-pregnancy smokers who reported smoking 0 cigarettes per day in the third trimester.

Covariates

Co-variates were ascertained from the birth certificate and included following continuous and categorical variables: maternal age; race/ethnicity (non-Hispanic white, non-Hispanic African American, Hispanic, or other); education (less than high school, GED or high school diploma, some college or college graduate); marital status (married, unmarried); parity, Special Supplemental Nutrition Program for Woman, Infants and Children (WIC) enrollment (yes/no); pre-pregnancy body mass index (BMI); health insurance status (Medicaid, private insurance, self-pay/uninsured, or other [Indian Health Service, CHAMPUS/TRICARE, etc.]); state of maternal residence; and number of cigarettes smoked per day in the three months before pregnancy.

Analysis

Trends in Cessation with Respect to Airing of the *Tips* Campaign

All women who delivered in the study period and who smoked in the three months before pregnancy were included in the trend analysis. Crude and standardized cessation rates were calculated and plotted by delivery date in 3 month intervals for 2009 through 2013. Data were examined for the 3 states individually and combined. We used jointpoint regression to identify the line segments with the best fit across the study period for the combined data.[16] Cessation rates were standardized for four variables that are established in the literature as being associated with cessation (some categories were collapsed to assure adequate sample size in each stratum): maternal age (< 18, 18-34, and ≥ 35 years of age), race/ethnicity (non-Hispanic white and other), education (< high school, high school, > high school), and parity (first or higher order birth).[8, 17-19] Direct methods were used and were based on the 2009 first quarter population for each state for state-specific analyses, and for the combined 2009 first quarter population for the combined analysis. Generalized linear models were used to generate a linear baseline trend for the pre-campaign period (from January 1, 2009 through March 18, 2012). Because only 9 months separated the airing of the *Tips* 2012 and 2013 campaigns, the exposure period for most women who delivered after March 18, 2012 (the first day of the *Tips* 2012 campaign) overlapped with *Tips* 2012 or *Tips* 2012 and 2013. Thus, few women who delivered after March 18, 2012 were unexposed to the *Tips* campaign.

Association between *Tips* Campaign Exposure and Smoking Cessation

Smoking cessation in women categorized as exposed or not exposed to the *Tips* 2012 campaign were examined using standardized rates and regression analysis in a subgroup of the study population from the trend analysis. The study population was restricted for this analysis in the following ways: women who were only exposed to *Tips* 2012 during the third trimester of pregnancy were excluded because of the proximity of exposure to delivery, and women who became pregnant more than 3-months after *Tips* 2012 aired (post-campaign) were excluded because they were considered *not* exposed to *Tips* 2012.

During our analysis, we noted that some women in our study who were exposed to *Tips* 2012 were also exposed to *Tips* 2013, which aired from March 4 through June 21, 2013, and featured content similar to *Tips* 2012 (neither campaign targeted pregnant women nor featured pregnancy-related health outcomes).[3, 5] To address this, we created a separate set of mutually exclusive exposure variables for a secondary analysis—not exposed to *Tips,* exposed to *Tips* 2012 only, and exposed to *Tips* 2012 and *Tips* 2013. We did not conduct an analysis of women who were only exposed to *Tips* 2013 (women who were previously excluded because they became pregnant more than 3 months after *Tips* 2012 aired), because we did not have data for the full cohort of women, many of whom delivered in 2014.

We compared demographic characteristics and cessation rates in unexposed and exposed women using descriptive statistics. Standardized cessation rates were calculated using the methods previously described to standardize for maternal age, race/ethnicity, education, and parity.

Logistic regression was used to generate crude and adjusted odds ratios (ORs) and 95% confidence intervals (CIs) for cessation in women exposed to the *Tips* campaign. In the unadjusted analysis, the results were stratified by maternal demographic characteristics. In multivariate regression models, results were adjusted for maternal age (continuous), race/ethnicity (non-Hispanic white, non-Hispanic African American, Hispanic, or other), education (less than high school, GED or high school diploma, some college or college graduate), marital status, parity (first or higher order birth), WIC enrollment, pre-pregnancy BMI (underweight or <18.5 kg/m^2, normal weight or 18.5-24.9 kg/m^2, overweight or 25-29.9 kg/m^2, and obese or > 30 kg/m^2);[20] insurance status (Medicaid, private insurance, self-pay/uninsured, or other), state of residence, and the number of cigarettes smoked per day in the 3 months before pregnancy (1-10, 11-20, <20). Observations with missing co-variate values were excluded from logistic regression, but represented less than 5% of the total. Separate models were constructed with exposure as a dichotomous variable (unexposed and exposed to *Tips* 2012), a 3-level variable (unexposed, exposed only to *Tips* 2012, and exposed to *Tips* 2012 and 2013), and as a continuous

variable based on cumulative GRPs for *Tips* 2012 and 2013 combined. We calculated ORs and 95% CIs for every 600 GRP increase, or approximately 6 weeks of exposure at the national level (the average cumulative exposure for the three-state area was 1857 GRPs).

Potential Changes in Misclassification of Smoking Status

Pregnant women who smoke have high rates of nondisclosure.[21,22] Because we were concerned that the airing of the *Tips* campaign could have increased nondisclosure among smokers (if smokers felt more stigmatized after the campaign began airing), we sought to determine whether an increase in the misclassification of continuing smokers as self-reported quitters could have occurred. Infant birth weight is highly sensitive to tobacco smoke exposure,[23] and we assumed that an increase in misclassification of active smokers as quitters would result in a lower mean birth weight among quitters in the *Tips* exposed vs. the unexposed group. To assess this possibility, we compared mean birth weight among quitters (obtained from birth certificates) with singleton deliveries using analysis of covariance. Mean birth weight was adjusted for maternal age, race, education, marital status, parity, WIC enrollment, pre-pregnancy BMI, insurance status, state of residence, and gestational age at delivery.

In all analyses, tests were two-sided, and α-values of 0.05 were considered statistically significant. Statistical analyses were performed using SAS software, version 9.3 (SAS Institute Inc., Cary, NC, USA) for Windows. This study was reviewed and approved as research by the Institutional Review Boards of each state. This study was determined to be exempt from review as research without human subjects by the Institutional Review Board at the Centers for Disease Control and Prevention.

Results

Sample Characteristics

During the study period, there were 1,401,561 live births, of which 10,213 (0.7%) were excluded because the 2003 revised birth certificate was not used or because smoking status or gestational age was

missing (Figure 1). Of the 1,391,343 remaining, there were 894,258 births to women who were unexposed because they delivered before the *Tips* 2012 campaign; 209,053 births (23.4%) in this group were to women who smoked in the three months before pregnancy. There were 329,706 births to women whose pregnancies overlapped with the *Tips* 2012 (exposed); 73,582 (22.3%) of these smoked in the three months before pregnancy. Of these, 12,835 (17.4%) were exposed to *Tips* 2012 in the third trimester only, and so were excluded from further analysis. Thus, there were 60,747 births for inclusion in the analysis of the association between *Tips* campaign exposure and smoking cessation. Of these, 13,610 (22.4%) were also exposed to *Tips* 2013.

Trends in Cessation with Respect to Airing of the *Tips* Campaign

During the pre-campaign period (from January 2009 through March 18, 2012) cessation rates among smokers who delivered before *Tips* 2012 aired remained flat. (Figure 2). Cessation rates then increased between the 12th and the 15th quarter, coinciding with the airing of *Tips* 2012 and reached a plateau by the end of *Tips* 2012. The plateau was sustained through the end of 2013. Analysis using joinpoint regression verified the number of significant jointpoints at the $p = 0.05$ level.

When states were examined individually, trends in Ohio and Indiana resembled those using the aggregated data, but an increase in cessation that began approximately 1 quarter before *Tips* 2012 was observed in Kentucky (data not shown).

Association between *Tips* Campaign Exposure and Smoking Cessation

Demographic characteristics of women exposed and unexposed to the *Tips* campaign differed slightly but significantly for all variables examined (Table 1). Overall, 33.0% of unexposed smokers quit by the third trimester. In contrast, 34.8% of exposed smokers quit by the third trimester, an absolute increase of 1.8 percentage points ($p < 0.001$) (Table 2). Standardized cessation rates were 32.8% in unexposed women and 34.3% in exposed women, an absolute increase of 1.5 percentage points ($p < 0.001$). For

individual states, there was a 0.9 percentage point increase in exposed vs. unexposed women for Indiana, a 1.0 percentage point increase for Ohio, and a 3.4 percentage point increase for Kentucky. Cessation rates were significantly higher in exposed vs. unexposed women for nearly all subpopulations examined. Significant increases in cessation rates were observed in all age groups, in all race/ethnicity groups except Hispanic women, in all education categories, in married and unmarried women, in first and higher order parity groups, in all BMI groups, in those enrolled in WIC and not enrolled, and in all insurance categories except self-pay. Significant increases were also seen in women smoking 1-10 cigarettes/day before pregnancy and in those smoking ≥ 21cigarettes/day, but not in those smoking 11-20 cigarettes/day (data not shown).

In unadjusted regression models, cessation in smokers was significantly associated with *Tips* 2012 campaign exposure (OR 1.08, 95% CI 1.06-1.10) (Table 3). After adjustment for potential confounders, results remained significant (AOR 1.07, 95% CI 1.05-1.10). Because the increase in cessation was substantially higher in Kentucky than the other two states, the analysis was repeated after excluding Kentucky. Results were attenuated, but remained significant (AOR 1.03, 95% CI 1.01-1.06). Including exposure to *Tips* 2013 in the model did not increase the odds of quitting (*Tips* 2012 only: AOR 1.07 (95% CI 1.04-1.09); *Tips* 2012 and 2013, AOR =1.06, 95% CI 1.01-1.10).

On average, exposed women in our analysis were exposed to 176.6 GRPs per week. When *Tips* 2012 and 2013 exposure dose was examined as a continuous variable, the adjusted odds of quitting rose significantly for each increase of 600 GRPs (AOR= 1.07, 95% CI 1.03-1.11).

Potential Changes in Misclassification of Smoking Status

The mean crude and adjusted birthweights of infants born to women who quit smoking and were not exposed to the campaign were not significantly different from those of infants born to women who quit smoking and were exposed to the campaign (crude mean birthweight difference -5.2 g, 95% CI -14.1,

3.8; adjusted mean birthweight difference -2.0 g, 95% CI -9.0, 5.0) (Table 4). These findings did not change when we restricted our analysis to term births (data not shown). Thus, we found no evidence of a substantial change in the proportion of smokers misclassified as quitters after the *Tips* campaigns aired.

Discussion

The *Tips* 2012 campaign was the first federally-funded mass-media anti-smoking campaign to air in the U.S. It reached the majority of U.S. cigarette smokers and resulted in a 3.7 percentage point absolute increase in quit attempts in a general population of smokers.[3] Although the campaign did not include pregnancy-specific messages, we found that *Tips* 2012 was associated with increased cessation in pregnant women. Furthermore, we observed cessation benefits across most subgroups, including adolescents under 18 years of age, Medicaid-insured women, and women with less than a high school education, and that media buy dose was positively associated with cessation rates. National ad campaigns have the potential to improve public health not because they have large effects on quit rates, but because they reach so many smokers. The Tips 2014 campaign increased the percentage of smokers who quit by a modest 0.25 percentage points overall, but resulted in 104,000 additional quitters nationally.[24] In our analysis, the percentage of smokers who had quit by the third trimester increased by 1.8 percentage points, which compares favorably to national estimates for Tips and has the potential to substantially reduce adverse tobacco-related pregnancy outcomes.

There are few studies in the U.S. or elsewhere which have formally evaluated the effects of anti-tobacco campaigns in pregnant women. In 2001, the America Legacy Foundation launched a national campaign targeting pregnant women called “Great Start,” which included television, radio, print, and website components and established a quitline for pregnant women.[25] The campaign reached 26 million television viewers and generated over 11,000 calls to the quit line.[25] However, the number of women who quit smoking as a result of the campaign was not reported. A smaller social marketing campaign

targeting African American women called "One Tiny Reason to Quit," promoted the use of quitlines to pregnant women in Richmond, Virginia.[26] Post-campaign quitline calls from pregnant women increased significantly compared with pre-campaign calls, but again, effects on cessation rates were not assessed.[26] A mass media campaign conducted in 1994 throughout England targeting pregnant women resulted in a 14% increase in calls to quitlines from pregnant women, but no significant changes in prenatal smoking prevalence were documented.[27] Findings from the current study indicate that a graphic anti-smoking campaigns developed for a general audience could also increase cessation rates among pregnant women.

Our study has several strengths, including its novel topic and its large, population-based sample. Our study also has some limitations. First, our analysis was an ecological time series; we do not have data on exposure to the campaign at the individual level. However, previous studies have estimated that *Tips* reached about 80% of cigarette smokers [3] and it is likely that our population of pregnant women had high exposure levels as well. Inferences about potential causal effects of the campaign assume no other tobacco control efforts were implemented at or near the time the *Tips* 2012 campaign aired, and the possibility exists that an unrecognized factor might have affected cessation rates. The increase in cessation in Kentucky that slightly preceded the airing of *Tips* 2012 could have been the result of such an unrecognized factor. However, our research revealed no evidence of other large-scale media campaigns, interventions, or policy changes leading up to or during the *Tips* campaign in these three states.[3] The magnitude of the change in cessation rates, which took place following a period during which quarterly cessation rates had been flat for at least 3 years, provides additional support for a potential causal relationship. The increase in cessation rates was sustained through the end of 2013. Because *Tips* campaigns have aired each year since 2012, we currently do not have a post-campaign, unexposed population in which to determine whether cessation rates would return to pre-campaign levels. Other limitations include that quit status was not biochemically validated, which would be

problematic if non-disclosure increased after the introduction of the *Tips* campaign. However, we examined mean birth weight among infants of quitters by *Tips* exposure status and did not find evidence of increased misclassification. Our results apply to pregnancies ending in a live birth in three states and can't be generalized to the U.S. population or to pregnancies ending in miscarriage or stillbirth. The fact that cessation rates in Kentucky increased disproportionately after *Tips* 2012 was aired compared with Ohio and Indiana supports that effects of the campaign may vary by state. Kentucky had the highest smoking prevalence and the lowest quit rate during the baseline period, which could have contributed to its dramatic improvement in quit rates. Additional research is needed to address the effects of the *Tips* campaign on smoking cessation in pregnant women in other states and regions of the U.S. Finally, unlike the *Tips* 2013 campaign in which media markets were randomized to receive a higher or lower media buy, the national media buy for *Tips* 2012 was supplemented with broadcasts in smaller local television channels in media markets with high smoking prevalence.[3] Thus, our finding that cessation was positively associated with media buy dose could be the result of confounding.

It is unknown whether the 2012 *Tips* campaign was as effective among pregnant smokers as a campaign specifically targeting pregnant women would have been. Some qualitative studies,[25, 28] but not all,[29] have found that pregnant women prefer positive and empowering smoking cessation ads. However, it has not been established which types of ads actually increase cessation behavior and how they compare with one another. It is inefficient to mount a mass media campaign focused solely on pregnant women since pregnancy is temporary and incidence is spread out across the entire population of women of child-bearing age at a low frequency. Therefore, a general campaign that affects cessation rates in both general and pregnant populations could be more cost effective than a campaign only targeting pregnant women. More research is warranted to determine the optimal frequency and duration of a general campaign, as well as the demographic and geographic subpopulations of pregnant women

who are most likely to benefit. Similar campaigns in other countries might also benefit pregnant women, and inclusion of pregnant women in future evaluations of such programs should be considered.

In conclusion, a general, national anti-smoking media campaign was associated with increased smoking cessation in a pregnant population. Future research comparing effectiveness of campaigns designed to target pregnant women with those targeting the general population could help inform the future development, implementation, and sustainment of anti-smoking campaigns to benefit pregnant women.

Contributors: All authors fulfill the authorship criteria recommended by the ICMJE. LJE conceived of the study, contributed to the analysis and interpretation of data, and drafted the paper. VTT co-designed the methods, and contributed to the analysis and interpretation of data. KR co-designed the methods, and conducted the analysis and contributed to the analysis and interpretation of data. JS co-designed the methods, provided statistical oversight, and contributed to the interpretation of data. TM contributed to the analysis and interpretation of data. DP contributed to the analysis and interpretation of data. KR contributed to the acquisition of data, analysis and interpretation of data. EJC contributed to the acquisition of data, analysis and interpretation of data. CV contributed to the acquisition of data, analysis and interpretation of data. KD contributed to the acquisition of data, analysis and interpretation of data, and provided statistical oversight. Each author contributed to drafting the manuscript or to critical revisions for intellectual content; and each approved the final version for publication. Each author takes final responsibility for the paper.

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Competing interests: None declared.

Data sharing statement:

Data described as "not shown" is available from the author upon request. Please Contact Lucinda England, Centers for Disease Control and Prevention, lbe9@cdc.gov

GRP data are available upon request through the Centers for Disease Control and Prevention. Please contact Rebecca Murphy, Centers for Disease Control and Prevention Rebecca.Murphy@cdc.hhs.gov

State-level birth certificate data are available to researchers whose research proposals meet criteria set by each of the individual states**.** Please contact the Indiana State Department of Health (KaRupp@isdh.in.gov) to request the release of Indiana birth certificate data. Please access the website: http://chfs.ky.gov/os/omb/irb/ for information on how to request Kentucky birth certificate data. Please access the website: http://www.odh.ohio.gov/en/healthstats/irb/irb.aspx for information on how to request Ohio birth certificate data.

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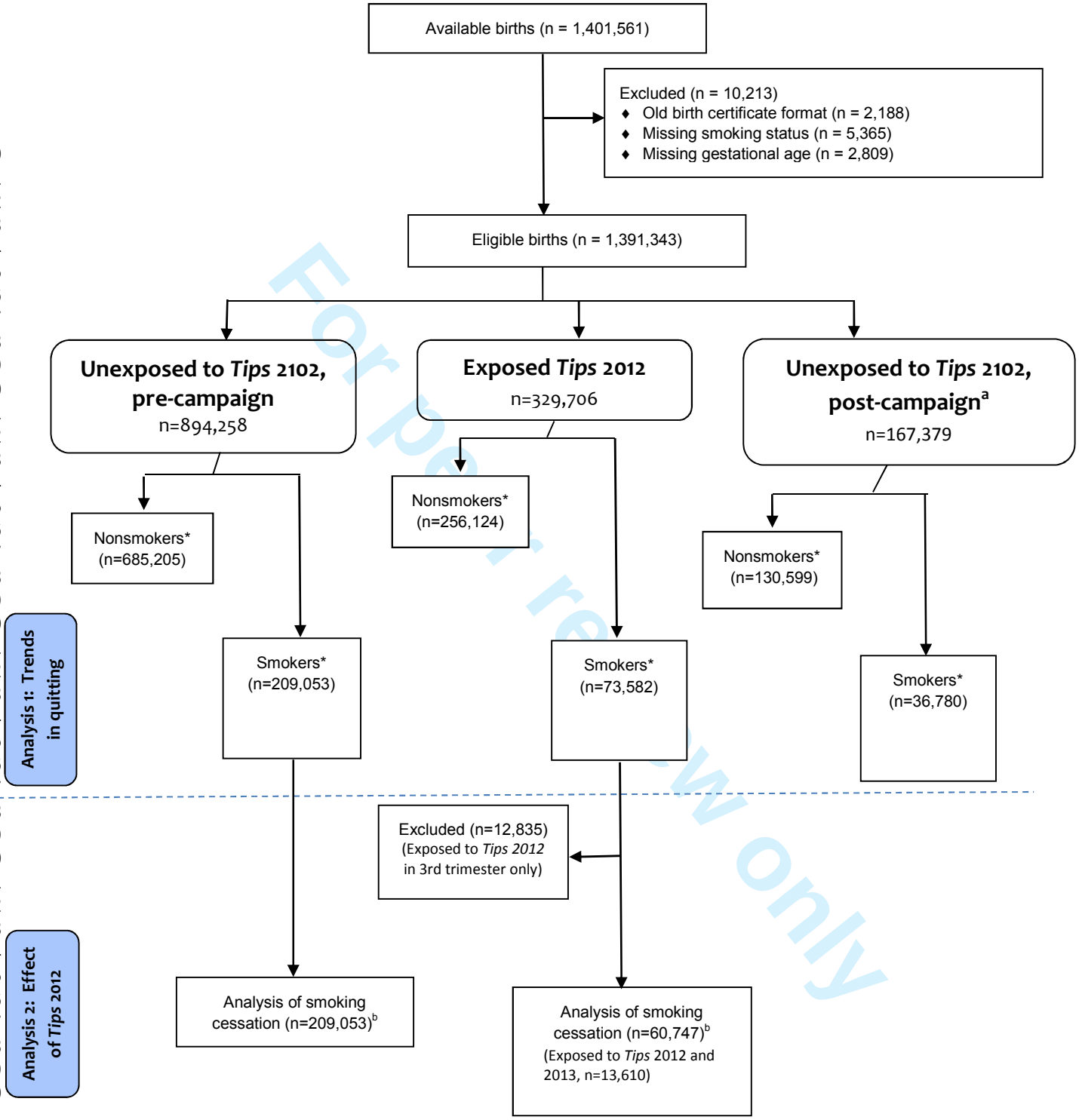
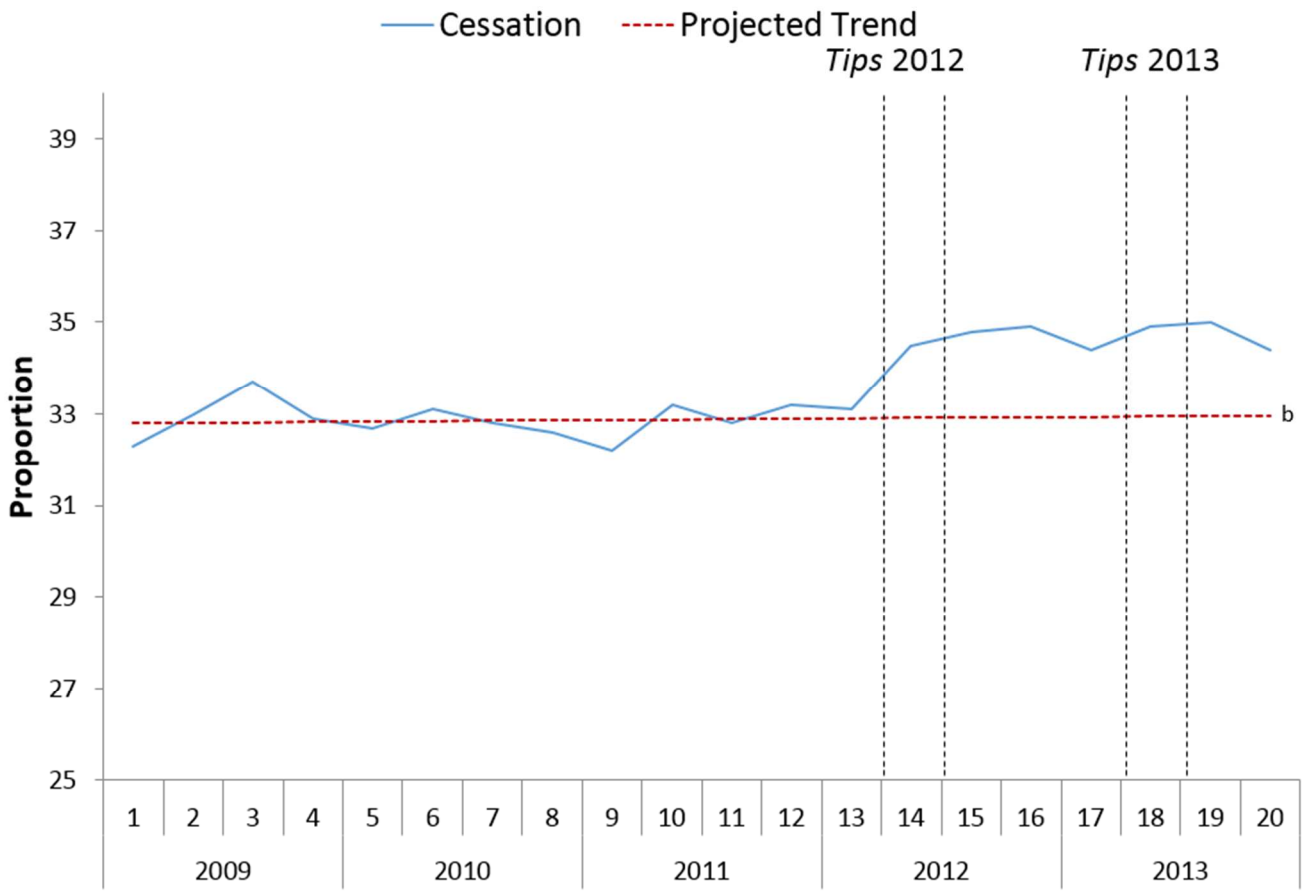
Figure 1. Flow chart for study inclusion, Indiana, Kentucky, Ohio, 2009-2013



[a] Became pregnant more than 3 months after *Tips* 2012, exposed to *Tips* 2013 only.
[b]Non-smokers were those who reported no smoking during the 3 months before pregnancy; smokers were those who reported any smoking in the 3 months before pregnancy (sou[c]Of n=60,747, 13,610 women (22.4%) were exposed to *Tips* 2012 and *Tips* 2013. When examining birthweight, only singleton births with no birth defects were analyzed (pre-campaign, n=201,030; during campaign, n=58,231).

Figure 2. Trends in smoking cessation rates [a] among women who smoked in the 3 months before pregnancy (crude) Indiana, Kentucky, Ohio, 2009-2013.



[a] The percentage of women who reported smoking >0 cigarettes per day for the three months before pregnancy and then reported smoking 0 cigarettes per day during the third trimester of pregnancy.

[b] Projected cessation trend using PROC GLM and pre-campaign data from January 1, 2009 through March 18, 2012, and extrapolated for 2012-2013 (intercept= 32.8; slope = 0.009). The *Tips* 2012 campaign ran from March 19-June 10, 2012, and *Tips* 2013 ran from March 4-June 24,2013.

Table 1. Characteristics of women who smoked in the 3 months before pregnancy, by exposure to *Tips* 2012. Indiana, Kentucky, Ohio, 2009-2013.

Maternal characteristics[a]	Unexposed[b] (n= 209,053)	Exposed[c] (n= 60,747)	P-value[d]
Mean maternal age (yrs)	25.2 (±5.3)	25.6 (±5.3)	<.0001
Maternal race/ethnicity			
White, non-Hispanic	86.5	86.1	<.0001
Black, non-Hispanic	10.3	10.3	
Hispanic	2.3	2.4	
Other	0.9	1.2	
Maternal education			
< High school	27.0	24.3	<.0001
High school or GED	38.0	37.9	
College of graduate	35.0	37.8	
Marital status			
Married	33.1	31.7	<.0001
Unmarried	66.9	68.3	
Parity			
First birth	38.5	37.2	<.0001
Second or later birth	61.5	62.8	
Missing[d]			
WIC enrollment			
No	32.7	33.6	<.0001
Yes	67.3	66.4	
Pre-pregnancy BMI			
Underweight (<18.5)	6.9	6.6	<.0001
Normal Weight (18.5-24.9)	44.6	43.6	
Overweight (25-29.9)	23.1	23.4	

Insurance status[j]			
Medicaid	67.4	67.3	0.0261
Private insurance	23.7	24.1	
Self-pay	2.2	2.3	
Other	6.7	6.4	
State			
Indiana	27.5	26.9	<.0001
Kentucky	21.7	23.3	
Ohio	50.7	49.8	
Cigarette smoked per day before pregnancy			
1-10	21.0	22.6	<.0001
11-20	30.7	31.8	
≥21	48.3	45.5	

[a] Missing values not included in column totals: maternal age 0.1%, race/ethnicity 0%, education 0.7%, marital status 0.3%, parity 0%, WIC enrollment 0.6%, BMI 2.2%, insurance 1.3%, state 0%, cigarettes/day 0%.
[b]Women who delivered prior to the *Tips* 2012 campaign (January 1, 2009 to March 18, 2012).
[c] Women for whom there was temporal overlap between the *Tips* 2012 campaign and the period including her pregnancy and the preceding three months. Women only exposed during the third trimester were excluded.
[c]Proc regress used for continuous variable (age); and chi-square test used for categorical variables.

Table 2. Cessation rates[a] in women who smoked in the 3 months before pregnancy by exposure status to the *Tips* 2012 campaign, crude and standardized. Indiana, Kentucky, Ohio, 2009-2013.

	Crude				Standardized[b]			
	Unexposed	Exposed	Absolute %	Relative %	Unexposed	Exposed	Absolute %	Relative %
IN	32.2	33.5	1.3	3.9	32.1	33.0	0.9	2.7
KY	21.9	26.3	4.4	20.3	21.7	25.1	3.4	15.6
OH	38.2	39.4	1.3	3.4	37.8	38.8	1.0	2.6
Overall	33.0	34.8	1.8	5.4	32.8	34.3	1.5	4.4
IN + OH	36.1	37.4	1.3	3.6	35.8	36.8	0.9	2.6

[a]The percentage of women who reported smoking > 0 cigarettes per day for the three months before pregnancy and then reported smoking 0 cigarettes per day during the third trimester of pregnancy.

[b]Standardized for maternal age, race/ethncity, education, and parity using direct methods based on the 2009 first quarter population for each state for state-specific analyses, and for the combined 2009 first quarter population for the combined analysis.

Table 3. Proportion and odds ratio of smoking cessation by last trimester among women who were smoking in 3 months before pregnancy and pregnant before or during a national media campaign. Indiana, Kentucky, Ohio, 2009-2013.

	Pre-campaign[a] (n= 209,053)	During campaign[b] (n= 60,747)	P-value	Crude OR (95% CI)	Adjusted OR (95% CI)[c]
Smoking cessation by last trimester	32.9%	34.7%	<.0001	1.08 (1.06-1.10)	1.07 (1.05-1.10)

[a] Women who smoked in the 3 months before pregnancy and delivered prior to the *Tips* 2012 campaign (January 1, 2009 to March 18, 2012).
[b]Women who smoked in the 3 months before pregnancy and for whom there was temporal overlap between the *Tips* 2012 campaign and the period including her pregnancy (1st and 2nd trimesters) and the preceding three months.
[c]Adjusted for maternal age, race, education, marital status, parity, WIC enrollment, pre-pregnancy BMI, insurance status, state, and cigarettes smoked before pregnancy (n=256,886).

Table 4. Unadjusted and adjusted mean birth weight (grams) among quitters, before and during the *Tips* campaign. Indiana, Kentucky, Ohio, 2009-2013.

	Women who quit smoking by the third trimester			
	Unadjusted		Adjusted [a]	
Exposure	**Mean birth weight**	**Mean difference**	**Mean birth weight**	**Mean difference**
Unexposed (pre-campaign) (n= 65,658)[b]	3309	-5.2 95% CI -14.1, 3.8	3228	-2.0 95% CI -9.0, 5.0
Exposed (during campaign) (n=20,092)[c]	3314		3230	

[a] Adjusted for maternal age, race, education, marital status, parity, WIC enrollment, pre-pregnancy BMI, insurance status, state, and gestational age.
[b] Births to women who smoked in the 3 months before pregnancy and delivered prior to the *Tips* 2012 campaign (January 1, 2009 to March 18, 2012).
[c] Births to women who smoked in the 3 months before pregnancy and for whom there was temporal overlap between the *Tips* 2012 campaign and the period including her pregnancy (1st and 2nd trimesters) and the preceding three months.

STROBE Checklist

Evaluation of a federally-funded mass media campaign and smoking cessation in pregnant women: a population-based study in three states

Title and abstract	**Page** 1	✓ Indicate the study's design with commonly used terms in the title or abstract
	2	✓ Provide in the abstract an informative and balanced summary of what was done and what was found
Introduction		
Background/rationale	4-5	✓ Explain he scientific background and rationale for the investigation being reported
Methods		
Study design	5-8	✓ Present key elements early in the paper
Setting	(a) 5 (b) 5 (c) 5,8 (d) n/a (e) 6,7 (f) 5 (g) 5-7	✓ Describe (a) settings, (b) locations, (c) relevant dates, (d) periods of recruitment, (e) exposure, (f) follow up, and (g) data collection
Participants	(a)5-8, 19 (b) 5-8, 19 (c) n/a	✓ *Cohort study*—Give the (a) eligibility criteria, and (b) the sources and methods of selection of participants. (c) Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants
	n/a	(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case
Variables	(a)5-7 (b)n/a	✓ (a) Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. (b) Give diagnostic criteria, if applicable
Data sources/ measurement	(a)5-7 (b)n/a	✓ (a) For each variable of interest, give sources of data and details of methods of assessment (measurement). (b) Describe comparability of assessment methods if there is more than one group
Bias	9-10	✓ Describe any efforts to address potential sources of bias
Study size	5	✓ Explain how the study size was arrived at
Quantitative variables	7-10	✓ Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why
	7-10	✓ Describe all statistical methods, including those used to control for confounding
	10	✓ Describe any methods used to examine subgroups and interactions
	9	✓ Explain how missing data were addressed

	n/a	*Cohort study*—If applicable, explain how loss to follow-up was addressed
	n/a	*Case-control study*—If applicable, explain how matching of cases and controls was addressed
	n/a	*Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy
	n/a	Describe any sensitivity analyses
Results		
Participants	10-11, 19	✓ Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed
	10-11, 19	✓ Give reasons for non-participation at each stage
	19	✓ Consider use of a flow diagram
Descriptive data	19, 21-22	✓ Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders
	9, 23	✓ Indicate number of participants with missing data for each variable of interest
	n/a	*Cohort study*—Summarise follow-up time (eg, average and total amount)
Outcome data	11, 21, 23	✓ *Cohort study*—Report numbers of outcome events or summary measures over time
	21-22	*Case-control study*—Report numbers in each exposure category, or summary measures of exposure
	n/a	*Cross-sectional study*—Report numbers of outcome events or summary measures
Main results	23, 24	✓ Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included
	21, 22	✓ Report category boundaries when continuous variables were categorized
	23	✓ If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period
Other analyses	12, 24	✓ Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses
Discussion		
Key results	13	✓ Summarise key results with reference to study objectives
Limitations	14,15	✓ Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of

		any potential bias
Interpretation	15,16	✓ Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence
Generalizability	14,15	✓ Discuss the generalisability (external validity) of the study results
Other information		
Funding	17	✓ Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based

BMJ Open

Evaluation of a federally-funded mass media campaign and smoking cessation in pregnant women: a population-based study in three states

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Evaluation of a federally-funded mass media campaign and smoking cessation in pregnant women: a population-based study in three states

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The findings and conclusions of this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention. This study includes data by the Ohio Department of Health which should not be considered as an endorsement of this study or its conclusions.

Word count: 4263

Key words: pregnancy, smoking cessation, mass media campaign

Abstract

Objectives

In 2012, the Centers for Disease Control and Prevention initiated a national anti-smoking campaign, *Tips from Former Smokers* (*Tips*). As a result of the campaign, quit attempts among smokers increased in the general population by 3.7 percentage points. In the current study, we assessed the effects of *Tips* on smoking cessation in pregnant women.

Methods

We used 2009-2013 certificates of live births in three U.S. states: Indiana, Kentucky, and Ohio. Smoking cessation by the third trimester of pregnancy was examined among women who smoked in the three months pre-pregnancy. Campaign exposure was defined as overlap between the airing of *Tips* 2012 (March 19-June 10) and the pre-pregnancy and pregnancy periods. Women who delivered before *Tips* 2012 were not exposed. Adjusted logistic regression was used to determine whether exposure to *Tips* was independently associated with smoking cessation.

Results

Cessation rates were stable during 2009-2011, but increased at the time *Tips* 2012 aired, and remained elevated. Overall, 32.9% of unexposed and 34.7% of exposed smokers quit by the third trimester ($p<0.001$). Exposure to *Tips* 2012 was associated with increased cessation (adjusted odds ratio: 1.07, 95% Confidence Interval: 1.05-1.10).

Conclusions

Exposure to a national anti-smoking campaign for a general audience was associated with smoking cessation in pregnant women.

Words: 206

Strengths and limitations of this study

- This is the first study to examine the association between a general mass media anti-tobacco campaign (*Tips* from Former Smokers) and smoking cessation in pregnant women.
- Women with live births in 3 states were examined; trimester-specific smoking status and temporal relationship to airing of the *Tips* campaign.

- Analysis was an ecological time-series; we did not have information on exposure to the *Tips* campaign at the individual level.
- Smoking status was based on self-report contained in the birth certificate.

Introduction

Tobacco use is a leading cause of preventable disease and death in the United States[1] and worldwide.[2] In 2012, the U.S. Centers for Disease Control and Prevention delivered a national anti-smoking campaign called *Tips from Former Smokers* (*Tips* 2012). The campaign included graphic images of the health consequences of smoking, and reached an estimated 80% of U.S. cigarette smokers.[3] An evaluation of *Tips* 2012 found that quit attempts among smokers increased in the general population, from 31.1% to 34.8% as a result of the campaign.[3] Of those who made a quit attempt, 13.4% were abstinent at follow up immediately after the campaign ended. Based on relapse survival-curve analysis, it is estimated that approximately half of those with short-term abstinence achieved long-term abstinence.[3] In the second *Tips* campaign, which aired in 2013[4], the effect of media dose on quit attempt rates was evaluated. Sixty-seven of 190 media markets were randomly selected to receive a higher dose media buy (3 times the media buy of the standard dose). [5] An evaluation of *Tips* 2013 found the relative quit attempt rate was significantly higher in higher-dose markets (38.8%) than in standard-dose markets (34.9%).[5]

Smoking is a leading cause of infant disease and death in the U.S. An estimated 5.3%–7.7% of preterm deliveries, 13.1%–19.0% of term low birth weight deliveries, and 23.2%–33.6% of Sudden Infant Death Syndrome (SIDS) cases are attributable to prenatal smoking.[6] Despite the known adverse effects, prenatal smoking prevalence remains unacceptably high. In a population-based analysis in the U.S. from 2009-2011, nearly one-quarter (24%) of women with a recent live birth smoked in the three months before pregnancy, and 11% smoked during the last 3 months of pregnancy.[7] Furthermore, U.S. prenatal smoking prevalence and cessation rates have not improved appreciably over time.[7, 8] Currently available clinical cessation interventions for pregnant women are only modestly effective (with pooled relative risks for cessation less than 1.5), [9,10] and by themselves are unlikely to result in large changes in prenatal smoking at the population level.[11]

To our knowledge, no studies have assessed the impact of a general anti-smoking campaign on smoking cessation in pregnant women. To address this gap, we used U.S. birth certificate data from three contiguous states to evaluate cessation rates in pregnant women before (2009-2011) and during the *Tips* 2012 campaign. We also assessed whether exposure to the *Tips* 2012 campaign was independently associated with cessation after adjusting for potential confounders.

Methods

Study design and setting

We performed an observational study of patterns of smoking cessation in pregnant women. Because the current analysis necessitated state-level data-sharing and therefore could not be readily completed using national data, we used birth certificates files for resident live births from three states: Indiana, Kentucky, and Ohio, from 2009-2013. These states were selected based on the overall annual number of births, the relatively high prevalence of cigarette smoking during pregnancy [12,13] and their geographical proximity (the three states are geographically contiguous with overlapping *Tips* media markets). In addition, none had introduced new state-level tobacco control programs at the time of the airing of *Tips* 2012.

Tips Media Campaign

Tips 2012 aired for 12 weeks, from March 19 through June 10, 2012, with sufficient media placement to reach three-quarters of US adults on multiple occasions.[3] Advertisements appeared on television in all U.S. media markets through a national buy of commercial advertising time on cable television networks. *Tips* 2012 had a ubiquitous national buy and a local "buy up" strategy in which the campaign was broadcast through smaller local television channels in media markets with high cigarette smoking prevalence. All three states included in our analysis had multiple markets that received the additional local television ad buys. The total campaign dose was approximately 70% higher than the national

average dose in Ohio and Kentucky, and approximately 25% higher in Indiana. It is estimated that 80% of U.S. cigarette smokers saw at least one *Tips* 2012 message, and that those who saw any advertisement averaged 23 views over the 12-week period.[3]

Campaign exposure

Exposure to the *Tips* campaign was defined as temporal overlap between each woman's pregnancy and the preceding three months (pre-pregnancy), and airing of *Tips* 2012. A woman's date of conception and the beginning dates for each trimester were calculated from the obstetric estimate of the gestational age at delivery in completed weeks and from the infant's date of birth, which was ascertained directly from the birth certificate. The 3-month period preceding her date of conception was then calculated. The date 3 months before conception and the date of delivery were compared with the dates of the *Tips* campaign to determine temporal overlap. Women were categorized as "not exposed" to the campaign if they delivered before the first day of the *Tips* 2012 campaign, and women were categorized as "exposed" to the campaign if any day from the first date of the 3 months before conception through the end of the second trimester overlapped with the airing of the *Tips* 2012 campaign. We included the 3 months before conception in our exposure window because it aligned with the period of baseline smoking status included in the birth certificate and because we felt it was reasonable to assume that women who viewed the campaign in that time period would still remember the material after becoming pregnant. We did not examine exposure that occurred only in the third trimester because the cessation status of women who quit in response to seeing the campaign very late in pregnancy might not have been captured in the birth certificate, which only notes whether a woman smoked in the third trimester or not.

Intensity of exposure to the *Tips* campaign was assessed using weekly media market-level *Tips* gross rating points (GRPs) for national and local television advertising as a continuous variable. GRPs are a standard measure of advertising "dose" delivered to a given audience in a given media market and time period, and are defined as the product of the percentage of the audience that is exposed (i.e., audience

reach) and the frequency with which that exposure occurs (i.e., the number of times ads are aired). GRPs are calculated at the market level by Nielson Media Research based on TV ratings for shows on which *Tips* ads aired. For example, if an ad was viewed by 20% of the TV viewing audience across all shows that aired the ads during a given week, and if the ad was aired 5 times during that week, this would yield a GRP of 100 (20 x 5) for that week. We used women's cumulative *Tips* television GRPs in each designated market area (DMA).[14] Cumulative GRPs were computed by summing the weekly GRPs in each DMA based on maternal county of residence at the time of delivery for the weeks during which the woman was exposed to the *Tips* campaign.

Smoking Cessation

The main outcome was smoking cessation by the third trimester of pregnancy among women who smoked in the three months before pregnancy, as recorded on the 2003 revision of the U.S. standard certificate of live birth.[15] On the birth certificate, cigarette smoking status is determined from four questions about the average number of cigarettes smoked per day in the three months before pregnancy and during each trimester of pregnancy. Our study population of pre-pregnancy smokers were women who reported smoking > 0 cigarettes per day in the three months before pregnancy. Cessation was defined as occurring in pre-pregnancy smokers who reported smoking 0 cigarettes per day in the third trimester.

Covariates

Co-variates were ascertained from the birth certificate and included following continuous and categorical variables: maternal age; race/ethnicity (non-Hispanic white, non-Hispanic African American, Hispanic, or other); education (less than high school, GED or high school diploma, some college or college graduate); marital status (married, unmarried); parity, Special Supplemental Nutrition Program for Woman, Infants and Children (WIC) enrollment (yes/no); pre-pregnancy body mass index (BMI); health insurance status (Medicaid, private insurance, self-pay/uninsured, or other [Indian Health Service,

CHAMPUS/TRICARE, etc.]); state of maternal residence; and number of cigarettes smoked per day in the three months before pregnancy.

Analysis

Trends in Cessation with Respect to Airing of the *Tips* Campaign

All women who delivered in the study period and who smoked in the three months before pregnancy were included in the trend analysis. Crude and standardized cessation rates were calculated and plotted by delivery date in 3 month intervals for 2009 through 2013. Data were examined for the 3 states individually and combined. We used joinpoint regression to identify the line segments with the best fit across the study period for the combined data.[16] Cessation rates were standardized for four variables that are established in the literature as being associated with cessation (some categories were collapsed to assure adequate sample size in each stratum): maternal age (< 18, 18-34, and ≥ 35 years of age), race/ethnicity (non-Hispanic white and other), education (< high school, high school, > high school), and parity (first or higher order birth).[8, 17-19] Standardization was repeated using the number of cigarettes smoked per day before pregnancy (< 10 and ≥10) in place of race/ethnicity. Standardization was limited to four variables because of sample size constraints. Direct methods were used and were based on the 2009 first quarter population for each state for state-specific analyses, and for the combined 2009 first quarter population for the combined analysis. Generalized linear models were used to generate a linear baseline trend for the pre-campaign period (from January 1, 2009 through March 18, 2012). Because only 9 months separated the airing of the *Tips* 2012 and 2013 campaigns, the exposure period for most women who delivered after March 18, 2012 (the first day of the *Tips* 2012 campaign) overlapped with *Tips* 2012 or *Tips* 2012 and 2013. Thus, few women who delivered after March 18, 2012 were unexposed to the *Tips* campaign.

Association between *Tips* Campaign Exposure and Smoking Cessation

Smoking cessation in women categorized as exposed or not exposed to the *Tips* 2012 campaign were examined using standardized rates and regression analysis in a subgroup of the study population from the trend analysis. The study population was restricted for this analysis in the following ways: women who were only exposed to *Tips* 2012 during the third trimester of pregnancy were excluded because of the proximity of exposure to delivery, and women who became pregnant more than 3-months after *Tips* 2012 aired (post-campaign) were excluded because they were considered *not* exposed to *Tips* 2012.

During our analysis, we noted that some women in our study who were exposed to *Tips* 2012 were also exposed to *Tips* 2013, which aired from March 4 through June 21, 2013, and featured content similar to *Tips* 2012 (neither campaign targeted pregnant women nor featured pregnancy-related health outcomes).[3, 5] To address this, we created a separate set of mutually exclusive exposure variables for a secondary analysis—not exposed to *Tips,* exposed to *Tips* 2012 only, and exposed to *Tips* 2012 and *Tips* 2013. We did not conduct an analysis of women who were only exposed to *Tips* 2013 (women who were previously excluded because they became pregnant more than 3 months after *Tips* 2012 aired), because we did not have data for the full cohort of women, many of whom delivered in 2014.

We compared demographic characteristics and cessation rates in unexposed and exposed women using descriptive statistics. Cessation rates in exposed and unexposed women were compared using chi-square tests. Standardized cessation rates were calculated using the methods previously described to standardize for maternal age, race/ethnicity, education, parity, and cigarettes/day.

Logistic regression was used to generate crude and adjusted odds ratios (ORs) and 95% confidence intervals (CIs) for cessation in women exposed to the *Tips* campaign. In the unadjusted analysis, the results were stratified by maternal demographic characteristics. In multivariate regression models, results were adjusted for maternal age (continuous), race/ethnicity (non-Hispanic white, non-Hispanic African American, Hispanic, or other), education (less than high school, GED or high school diploma,

some college or college graduate), marital status, parity (first or higher order birth), WIC enrollment, pre-pregnancy BMI (underweight or <18.5 kg/m^2, normal weight or 18.5-24.9 kg/m^2, overweight or 25-29.9 kg/m^2, and obese or > 30 kg/m^2);[20] insurance status (Medicaid, private insurance, self-pay/uninsured, or other), state of residence, and the number of cigarettes smoked per day in the 3 months before pregnancy (1-10, 11-20, <20). Observations with missing co-variate values were excluded from logistic regression, but represented less than 5% of the total. Separate models were constructed with exposure as a dichotomous variable (unexposed and exposed to *Tips* 2012), a 3-level variable (unexposed, exposed only to *Tips* 2012, and exposed to *Tips* 2012 and 2013), and as a continuous variable based on cumulative GRPs for *Tips* 2012 and 2013 combined. We then calculated ORs and 95% CIs for every 600 GRP increase, which corresponds to approximately 6 weeks of exposure at the national level (the average cumulative exposure for the three-state area was 1857 GRPs).

Potential Changes in Misclassification of Smoking Status

Pregnant women who smoke have high rates of nondisclosure.[21,22] Because we were concerned that the airing of the *Tips* campaign could have increased nondisclosure among smokers (if smokers felt more stigmatized after the campaign began airing), we sought to determine whether an increase in the misclassification of continuing smokers as self-reported quitters could have occurred. Infant birth weight is highly sensitive to tobacco smoke exposure,[23] and we assumed that an increase in misclassification of active smokers as quitters would result in a lower mean birth weight among quitters in the *Tips* exposed vs. the unexposed group. To assess this possibility, we compared mean birth weight among quitters (obtained from birth certificates) with singleton deliveries using analysis of covariance. Mean birth weight was adjusted for maternal age, race, education, marital status, parity, WIC enrollment, pre-pregnancy BMI, insurance status, state of residence, and gestational age at delivery.

In all analyses, tests were two-sided, and α-values of 0.05 were considered statistically significant. Statistical analyses were performed using SAS software, version 9.3 (SAS Institute Inc., Cary, NC,

USA) for Windows. This study was reviewed and approved as research by the Institutional Review Boards of each state. This study was determined to be exempt from review as research without human subjects by the Institutional Review Board at the Centers for Disease Control and Prevention.

Results

Sample Characteristics

During the study period, there were 1,401,561 live births, of which 10,218 (0.7%) were excluded because the 2003 revised birth certificate was not used or because smoking status or gestational age was missing (Figure 1). Of the 1,391,343 remaining, there were 894,258 births to women who were unexposed because they delivered before the *Tips* 2012 campaign; 209,053 births (23.4%) in this group were to women who smoked in the three months before pregnancy. There were 329,706 births to women whose pregnancies overlapped with the *Tips* 2012 (exposed); 73,582 (22.3%) of these smoked in the three months before pregnancy. Of these, 12,835 (17.4%) were exposed to *Tips* 2012 in the third trimester only, and so were excluded from further analysis. Thus, there were 60,747 births for inclusion in the analysis of the association between *Tips* campaign exposure and smoking cessation. Of these, 13,610 (22.4%) were also exposed to *Tips* 2013.

Trends in Cessation with Respect to Airing of the *Tips* Campaign

During the pre-campaign period (from January 2009 through March 18, 2012) cessation rates among smokers who delivered before *Tips* 2012 aired remained flat. (Figure 2). Cessation rates then increased between the 12th and the 15th quarter, coinciding with the airing of *Tips* 2012 and reached a plateau by the end of *Tips* 2012. The plateau was sustained through the end of 2013. Analysis using joinpoint regression verified the number of statistically significant joinpoints at the p = 0.05 level.

When states were examined individually, trends in Ohio and Indiana resembled those using the aggregated data, but an increase in cessation that began approximately 1 quarter before *Tips* 2012 was observed in Kentucky (data not shown).

Association between *Tips* Campaign Exposure and Smoking Cessation

Demographic characteristics of women exposed and unexposed to the *Tips* campaign differed slightly for all variables examined; these differences were statistically significant (Table 1). Overall, 33.0% of unexposed smokers quit by the third trimester. In contrast, 34.8% of exposed smokers quit by the third trimester, an absolute increase of 1.8 percentage points ($p < 0.001$) (Table 2). Standardized cessation rates were 32.8% in unexposed women and 34.3% in exposed women, an absolute increase of 1.5 percentage points ($p < 0.001$). Including cigarettes/day in standardization calculations did not change these findings (data not shown). For individual states, there was a 0.9 percentage point increase in exposed vs. unexposed women for Indiana, a 1.0 percentage point increase for Ohio, and a 3.4 percentage point increase for Kentucky. Cessation rates were statistically significantly higher in exposed vs. unexposed women for nearly all subpopulations examined. Statistically significant increases in cessation rates were observed in all age groups, in all race/ethnicity groups except Hispanic women, in all education categories, in married and unmarried women, in first and higher order parity groups, in all BMI groups, in those enrolled in WIC and not enrolled, and in all insurance categories except self-pay. Statistically significant increases were also seen in women smoking 1-10 cigarettes/day before pregnancy and in those smoking ≥ 21cigarettes/day, but not in those smoking 11-20 cigarettes/day (data not shown).

In unadjusted regression models, cessation in smokers was statistically significantly associated with *Tips* 2012 campaign exposure (OR 1.08, 95% CI 1.06-1.10) (Table 3). After adjustment for potential confounders, results remained statistically significant (AOR 1.07, 95% CI 1.05-1.10). Because the increase in cessation was substantially higher in Kentucky than the other two states, the analysis was

repeated after excluding Kentucky. Results were attenuated, but remained statistically significant (AOR 1.03, 95% CI 1.01-1.06). Including exposure to *Tips* 2013 in the model did not increase the odds of quitting (*Tips* 2012 only: AOR 1.07 (95% CI 1.04-1.09); *Tips* 2012 and 2013, AOR =1.06, 95% CI 1.01-1.10).

On average, exposed women in our analysis were exposed to 176.6 GRPs per week. When *Tips* 2012 and 2013 exposure dose was examined as a continuous variable, the adjusted odds of quitting rose for each increase of 600 GRPs and this finding was statistically significant (AOR= 1.07, 95% CI 1.03-1.11).

Potential Changes in Misclassification of Smoking Status

The mean crude and adjusted birthweights of infants born to women who quit smoking and were not exposed to the campaign were not statistically significantly different from those of infants born to women who quit smoking and were exposed to the campaign (crude mean birthweight difference -5.2 g, 95% CI -14.1, 3.8; adjusted mean birthweight difference -2.0 g, 95% CI -9.0, 5.0) (Table 4). These findings did not change when we restricted our analysis to term births (data not shown). Thus, we found no evidence of a substantial change in the proportion of smokers misclassified as quitters after the *Tips* campaigns aired.

Discussion

The *Tips* 2012 campaign was the first federally-funded mass-media anti-smoking campaign to air in the U.S. It reached the majority of U.S. cigarette smokers and resulted in a 3.7 percentage point absolute increase in quit attempts in a general population of smokers.[3] The campaign was also highly cost-effective, spending approximately $480 per quitter and $393 per life year saved.[24] Although the campaign did not include pregnancy-specific messages, we found that *Tips* 2012 was associated with increased cessation in pregnant women. Furthermore, we observed cessation benefits across most subgroups, including adolescents under 18 years of age, Medicaid-insured women, and women with less

than a high school education, and that media buy dose was positively associated with cessation rates. National ad campaigns have the potential to improve public health not because they have large effects on quit rates, but because they reach so many smokers. The Tips 2014 campaign increased the percentage of smokers who quit by a modest 0.25 percentage points overall, but resulted in 104,000 additional quitters nationally.[25] In our analysis, the percentage of smokers who had quit by the third trimester increased by 1.8 percentage points, which compares favorably to national estimates for Tips and has the potential to substantially reduce adverse tobacco-related pregnancy outcomes.

There are few studies in the U.S. or elsewhere which have formally evaluated the effects of anti-tobacco campaigns in pregnant women. In 2001, the America Legacy Foundation launched a national campaign targeting pregnant women called "Great Start," which included television, radio, print, and website components and established a quitline for pregnant women.[26] The campaign reached 26 million television viewers and generated over 11,000 calls to the quit line.[26] However, the number of women who quit smoking as a result of the campaign was not reported. A smaller social marketing campaign targeting African American women called "One Tiny Reason to Quit," promoted the use of quitlines to pregnant women in Richmond, Virginia.[27] Post-campaign quitline calls from pregnant women increased significantly compared with pre-campaign calls, but again, effects on cessation rates were not assessed.[27] A mass media campaign conducted in 1994 throughout England targeting pregnant women resulted in a 14% increase in calls to quitlines from pregnant women, but no significant changes in prenatal smoking prevalence were documented.[28] Findings from the current study indicate that a graphic anti-smoking campaigns developed for a general audience could also increase cessation rates among pregnant women.

Our study has several strengths, including its novel topic and its large, population-based sample. Our study also has some limitations. First, our analysis was an ecological time series; we do not have data on exposure to the campaign at the individual level. However, previous studies have estimated that *Tips*

reached about 80% of cigarette smokers [3] and it is likely that our population of pregnant women had high exposure levels as well. Inferences about potential causal effects of the campaign assume no other tobacco control efforts were implemented at or near the time the *Tips* 2012 campaign aired, and the possibility exists that an unrecognized factor might have affected cessation rates. The increase in cessation in Kentucky that slightly preceded the airing of *Tips* 2012 could have been the result of such an unrecognized factor. However, our research revealed no evidence of other large-scale media campaigns, interventions, or policy changes leading up to or during the *Tips* campaign in these three states.[3] The magnitude of the change in cessation rates, which took place following a period during which quarterly cessation rates had been flat for at least 3 years, provides additional support for a potential causal relationship. The increase in cessation rates was sustained through the end of 2013. Because *Tips* campaigns have aired each year since 2012, we currently do not have a post-campaign, unexposed population in which to determine whether cessation rates would return to pre-campaign levels. Other limitations include that quit status was not biochemically validated, which would be problematic if non-disclosure increased after the introduction of the *Tips* campaign. However, we examined mean birth weight among infants of quitters by *Tips* exposure status and did not find evidence of increased misclassification. Our results apply to pregnancies ending in a live birth in three states and can't be generalized to the U.S. population or to pregnancies ending in miscarriage or stillbirth. The fact that cessation rates in Kentucky increased disproportionately after *Tips* 2012 was aired compared with Ohio and Indiana supports that effects of the campaign may vary by state. Kentucky had the highest smoking prevalence and the lowest quit rate during the baseline period, which could have contributed to its dramatic improvement in quit rates. Additional research is needed to address the effects of the *Tips* campaign on smoking cessation in pregnant women in other states and regions of the U.S; the effects of the Tips campaign could be more modest in states with lower smoking prevalence. Finally, unlike the *Tips* 2013 campaign in which media markets were randomized to receive a higher or lower media buy,

the national media buy for *Tips* 2012 was supplemented with broadcasts in smaller local television channels in media markets with high smoking prevalence.[3] Thus, our finding that cessation was positively associated with media buy dose could be the result of confounding.

It is unknown whether the 2012 *Tips* campaign was as effective among pregnant smokers as a campaign specifically targeting pregnant women would have been. Some qualitative studies,[26, 29] but not all,[30] have found that pregnant women prefer positive and empowering smoking cessation ads. However, it has not been established which types of ads actually increase cessation behavior and how they compare with one another. It is inefficient to mount a mass media campaign focused solely on pregnant women since pregnancy is temporary and incidence is spread out across the entire population of women of child-bearing age at a low frequency. A general campaign that affects cessation rates in both general and pregnant populations could be more cost effective than a campaign only targeting pregnant women, and additional research is needed to compare these two approaches. In addition, more research is warranted to determine the optimal frequency and duration of a general campaign, as well as the demographic and geographic subpopulations of pregnant women who are most likely to benefit. Similar campaigns in other countries might also benefit pregnant women, and inclusion of pregnant women in future evaluations of such programs should be considered.

In conclusion, a general, national anti-smoking media campaign was associated with increased smoking cessation in a pregnant population. Future research comparing effectiveness of campaigns designed to target pregnant women with those targeting the general population could help inform the future development, implementation, and sustainment of anti-smoking campaigns to benefit pregnant women.

Contributors: All authors fulfill the authorship criteria recommended by the ICMJE. LJE conceived of the study, contributed to the analysis and interpretation of data, and drafted the paper. VTT co-designed the methods, and contributed to the analysis and interpretation of data. KR co-designed the methods, and conducted the analysis and contributed to the analysis and interpretation of data. JS co-designed the methods, provided statistical oversight, and contributed to the interpretation of data. TM contributed to the analysis and interpretation of data. DP contributed to the analysis and interpretation of data. KR contributed to the acquisition of data, analysis and interpretation of data. EJC contributed to the acquisition of data, analysis and interpretation of data. CV contributed to the acquisition of data, analysis and interpretation of data. KD contributed to the acquisition of data, analysis and interpretation of data, and provided statistical oversight. Each author contributed to drafting the manuscript or to critical revisions for intellectual content; and each approved the final version for publication. Each author takes final responsibility for the paper.

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Competing interests: None declared.

Data sharing statement:

Data described as "not shown" is available from the author upon request. Please Contact Lucinda England, Centers for Disease Control and Prevention, lbe9@cdc.gov

GRP data are available upon request through the Centers for Disease Control and Prevention. Please contact Rebecca Murphy, Centers for Disease Control and Prevention Rebecca.Murphy@cdc.hhs.gov

State-level birth certificate data are available to researchers whose research proposals meet criteria set by each of the individual states**.** Please contact the Indiana State Department of Health (KaRupp@isdh.in.gov) to request the release of Indiana birth certificate data. Please access the website: http://chfs.ky.gov/os/omb/irb/ for information on how to request Kentucky birth certificate data. Please access the website: http://www.odh.ohio.gov/en/healthstats/irb/irb.aspx for information on how to request Ohio birth certificate data.

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Figure 1. Flow chart for study inclusion, Indiana, Kentucky, Ohio, 2009-2013

[Insert Figure 1]

Figure 2. Trends in smoking cessation[a] rates (observed and projected[b]) among women who smoked in the 3 months before pregnancy (crude) and airing of the Tips campaigns,[c] Indiana, Kentucky, Ohio, 2009-2013.

[Insert Figure 2]

Table 1. Characteristics of women who smoked in the 3 months before pregnancy, by exposure to *Tips* 2012. Indiana, Kentucky, Ohio, 2009-2013.

Maternal characteristics[a]	Unexposed[b] (n= 209,053)	Exposed[c] (n= 60,747)	P-value[d]
Mean maternal age (yrs)	25.2 (±5.3)	25.6 (±5.3)	<.0001
Maternal race/ethnicity			
White, non-Hispanic	86.5	86.1	<.0001
Black, non-Hispanic	10.3	10.3	
Hispanic	2.3	2.4	
Other	0.9	1.2	
Maternal education			
< High school	27.0	24.3	<.0001
High school or GED	38.0	37.9	
College of graduate	35.0	37.8	
Marital status			
Married	33.1	31.7	<.0001
Unmarried	66.9	68.3	
Parity			
First birth	38.5	37.2	<.0001
Second or later birth	61.5	62.8	
Missing[d]			
WIC enrollment			
No	32.7	33.6	<.0001
Yes	67.3	66.4	
Pre-pregnancy BMI			
Underweight (<18.5)	6.9	6.6	<.0001
Normal Weight (18.5-24.9)	44.6	43.6	
Overweight (25-29.9)	23.1	23.4	

Obese (≥30)	25.4	26.4	
Insurance status			
Medicaid	67.4	67.3	0.0261
Private insurance	23.7	24.1	
Self-pay	2.2	2.3	
Other	6.7	6.4	
State			
Indiana	27.5	26.9	<.0001
Kentucky	21.7	23.3	
Ohio	50.7	49.8	
Cigarette smoked per day before pregnancy			
1-10	21.0	22.6	<.0001
11-20	30.7	31.8	
≥21	48.3	45.5	

[a] Missing values not included in column totals: maternal age 0.1%, race/ethnicity 0%, education 0.7%, marital status 0.3%, parity 0%, WIC enrollment 0.6%, BMI 2.2%, insurance 1.3%, state 0%, cigarettes/day 0%.
[b] Women who delivered prior to the *Tips* 2012 campaign (January 1, 2009 to March 18, 2012).
[c] Women for whom there was temporal overlap between the *Tips* 2012 campaign and the period including her pregnancy and the preceding three months. Women only exposed during the third trimester were excluded.
[d] *t* tests used for continuous variable (age); and chi-square test used for categorical variables.

Table 2. Cessation rates[a] in women who smoked in the 3 months before pregnancy by exposure status to the *Tips* 2012 campaign, crude and standardized. Indiana, Kentucky, Ohio, 2009-2013.

	Crude				Standardized[b]			
	Unexposed	Exposed	Absolute %[c]	Relative %[c]	Unexposed	Exposed	Absolute %[c]	Relative %[c]
IN	32.2	33.5	1.3	3.9	32.1	33.0	0.9	2.7
KY	21.9	26.3	4.4	20.3	21.7	25.1	3.4	15.6
OH	38.2	39.4	1.3	3.4	37.8	38.8	1.0	2.6
Overall	33.0	34.8	1.8	5.4	32.8	34.3	1.5	4.4
IN+OH	36.1	37.4	1.3	3.6	35.8	36.8	0.9	2.6

[a]The percentage of women who reported smoking > 0 cigarettes per day for the three months before pregnancy and then reported smoking 0 cigarettes per day during the third trimester of pregnancy.

[b]Standardized for maternal age, race/ethnicity, education, and parity using direct methods based on the 2009 first quarter population for each state for state-specific analyses, and for the combined 2009 first quarter population for the combined analysis.

[c]All changes in cessation rates were significant at $p < 0.01$.

Table 3. Proportion and odds ratio of smoking cessation by last trimester among women who were smoking in 3 months before pregnancy and pregnant before or during a national media campaign. Indiana, Kentucky, Ohio, 2009-2013.

	Pre-campaign[a] (n= 209,053)	During campaign[b] (n= 60,747)	P-value	Crude OR (95% CI)	Adjusted OR (95% CI)[c]
Smoking cessation by last trimester	32.9%	34.7%	<.0001	1.08 (1.06-1.10)	1.07 (1.05-1.10)

[a] Women who smoked in the 3 months before pregnancy and delivered prior to the *Tips* 2012 campaign (January 1, 2009 to March 18, 2012).
[b]Women who smoked in the 3 months before pregnancy and for whom there was temporal overlap between the *Tips* 2012 campaign and the period including her pregnancy (1st and 2nd trimesters) and the preceding three months.
[c]Adjusted for maternal age, race, education, marital status, parity, WIC enrollment, pre-pregnancy BMI, insurance status, state, and cigarettes smoked before pregnancy (n=256,886).

Table 4. Unadjusted and adjusted mean birth weight (grams) among quitters, before and during the *Tips* campaign. Indiana, Kentucky, Ohio, 2009-2013.

	Women who quit smoking by the third trimester			
	Unadjusted		Adjusted [a]	
Exposure	**Mean birth weight**	**Mean difference**	**Mean birth weight**	**Mean difference**
Unexposed (pre-campaign) (n= 65,658)[b]	3309	-5.2 95% CI -14.1, 3.8	3228	-2.0 95% CI -9.0, 5.0
Exposed (during campaign) (n=20,092)[c]	3314		3230	

[a] Adjusted for maternal age, race, education, marital status, parity, WIC enrollment, pre-pregnancy BMI, insurance status, state, and gestational age.
[b] Births to women who smoked in the 3 months before pregnancy and delivered prior to the *Tips* 2012 campaign (January 1, 2009 to March 18, 2012).
[c] Births to women who smoked in the 3 months before pregnancy and for whom there was temporal overlap between the *Tips* 2012 campaign and the period including her pregnancy (1st and 2nd trimesters) and the preceding three months.

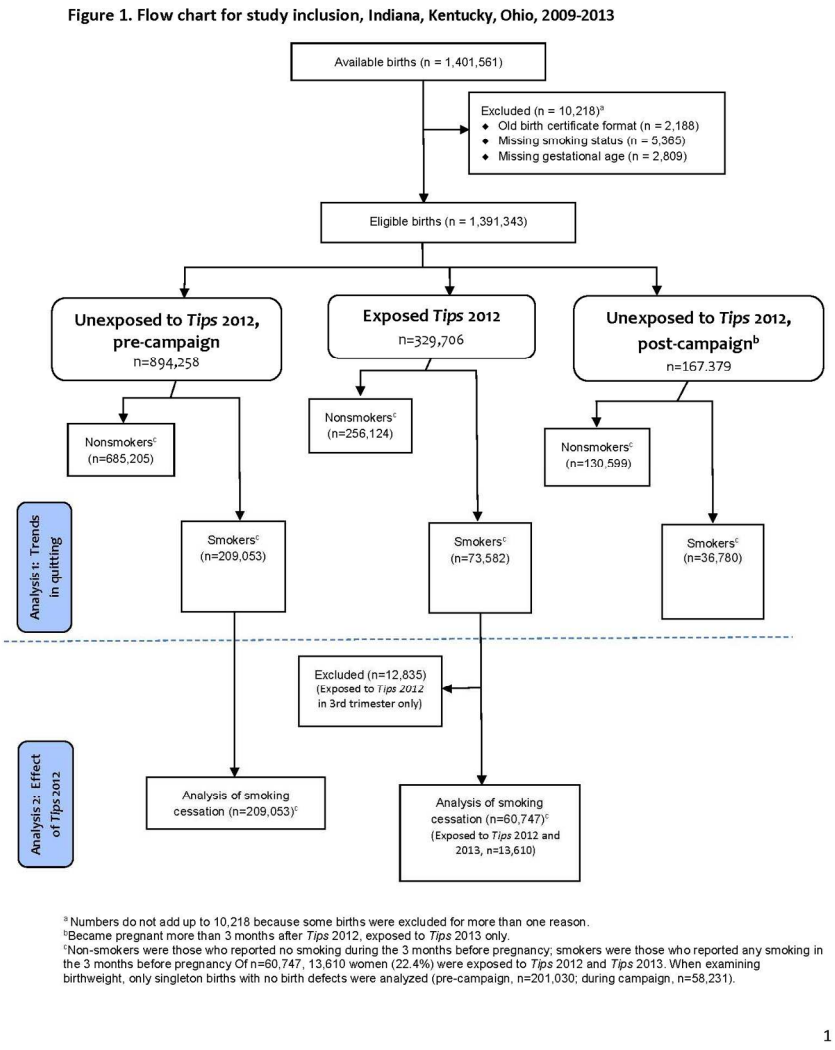

Figure 1. Flow chart for study inclusion, Indiana, Kentucky, Ohio, 2009-2013 (clean)

143x186mm (300 x 300 DPI)

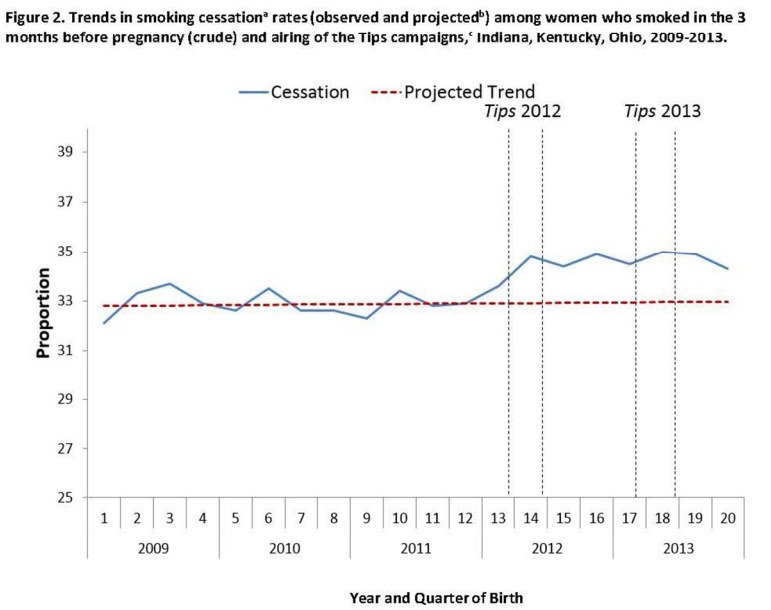

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Figure 2. Trends in smoking cessation rates (observed and projected) among women who smoked in the 3 months before pregnancy (crude) and airing of the Tips campaigns, Indiana, Kentucky, Ohio, 2009-2013.

100x129mm (300 x 300 DPI)

STROBE Checklist

Evaluation of a federally-funded mass media campaign and smoking cessation in pregnant women: a population-based study in three states

Title and abstract	**Page** 1	✓ Indicate the study's design with commonly used terms in the title or abstract
	2	✓ Provide in the abstract an informative and balanced summary of what was done and what was found
Introduction		
Background/rationale	4-5	✓ Explain he scientific background and rationale for the investigation being reported
Methods		
Study design	5-8	✓ Present key elements early in the paper
Setting	(a) 5 (b) 5 (c) 5,8 (d) n/a (e) 6,7 (f) 5 (g) 5-7	✓ Describe (a) settings, (b) locations, (c) relevant dates, (d) periods of recruitment, (e) exposure, (f) follow up, and (g) data collection
Participants	(a)5-8, 19 (b) 5-8, 19 (c) n/a	✓ *Cohort study*—Give the (a) eligibility criteria, and (b) the sources and methods of selection of participants. (c) Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants
	n/a	(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case
Variables	(a)5-7 (b)n/a	✓ (a) Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. (b) Give diagnostic criteria, if applicable
Data sources/ measurement	(a)5-7 (b)n/a	✓ (a) For each variable of interest, give sources of data and details of methods of assessment (measurement). (b) Describe comparability of assessment methods if there is more than one group
Bias	9-10	✓ Describe any efforts to address potential sources of bias
Study size	5	✓ Explain how the study size was arrived at
Quantitative variables	7-10	✓ Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why
	7-10	✓ Describe all statistical methods, including those used to control for confounding
	10	✓ Describe any methods used to examine subgroups and interactions
	9	✓ Explain how missing data were addressed

	n/a	*Cohort study*—If applicable, explain how loss to follow-up was addressed
	n/a	*Case-control study*—If applicable, explain how matching of cases and controls was addressed
	n/a	*Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy
	n/a	Describe any sensitivity analyses
Results		
Participants	10-11, 19	✓ Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed
	10-11, 19	✓ Give reasons for non-participation at each stage
	19	✓ Consider use of a flow diagram
Descriptive data	19, 21-22	✓ Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders
	9, 23	✓ Indicate number of participants with missing data for each variable of interest
	n/a	*Cohort study*—Summarise follow-up time (eg, average and total amount)
Outcome data	11, 21, 23	✓ *Cohort study*—Report numbers of outcome events or summary measures over time
	21-22	*Case-control study*—Report numbers in each exposure category, or summary measures of exposure
	n/a	*Cross-sectional study*—Report numbers of outcome events or summary measures
Main results	23, 24	✓ Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included
	21, 22	✓ Report category boundaries when continuous variables were categorized
	23	✓ If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period
Other analyses	12, 24	✓ Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses
Discussion		
Key results	13	✓ Summarise key results with reference to study objectives
Limitations	14,15	✓ Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of

		any potential bias
Interpretation	15,16	✓ Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence
Generalizability	14,15	✓ Discuss the generalisability (external validity) of the study results
Other information		
Funding	17	✓ Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based