

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Evaluation of a federally-funded mass media campaign and smoking cessation in pregnant women: a population-based study in three states
AUTHORS	England, Lucinda; Tong, Van; Rockhill, Kari; Hsia, Jason; McAfee, Tim; Patel, Deesha; Rupp, Katelin; Conrey, Elizabeth; Valdivieso, Claudia; Davis, Kevin

VERSION 1 - REVIEW

REVIEWER	Stephen T. Higgins, PhD Vermont Center on Behavior and Health University of Vermont United States
REVIEW RETURNED	07-Apr-2017

GENERAL COMMENTS	<p>This report describes results of an evaluation of whether a mass-media campaign directed at the general population of cigarette smokers increased cessation rates among pregnant smokers. The investigators examined smoking rates in three contiguous states with high smoking prevalence rates generally and during pregnancy that were exposed to the media campaign. They examined smoking rates prior to and during the campaign controlling for potential confounders. The results suggest a 1.8% increase in cessation rates. The study was well conceptualized and implemented. The report is very well written. The analyses outlined are detailed, thoughtful, and rigorous. The results are largely compelling and discussion and interpretation of them is measured and justified by the results. I see no substantive flaws and commend the authors on a creative and important study offering evidence in support of the Tips mass media campaign for reducing smoking in this highly vulnerable population. That is welcome news in an area of tobacco control where we need to do a great deal more to reduce smoking rates and associated serious adverse maternal and infant impacts. To make the headway that is needed on reducing smoking among vulnerable populations, we are going to need a multipronged approach involving creative, evidence-based tobacco control efforts at the population and individual levels as well as creative, evidence-based tobacco regulatory efforts.</p> <p>Below I offer four comments/questions for consideration by the investigators.</p> <p>1. I see pre-pregnancy smoking rates listed among the list of potential covariates, but not among the variables included in standardizing smoking-cessation rates. Pre-pregnancy smoking rate</p>
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	<p>is a robust predictor of cessation among pregnant women. Can you clarify?</p> <p>2. On a very minor note, looks like obesity was omitted as a category in the Table comparing participant characteristics.</p> <p>3. I commend the authors for parsing out the contributions of each of the three states to the overall effect reported on smoking-cessation rates, and demonstrating that the effect is significant when based on the results of Ohio and Indiana alone (Kentucky excluded). That information is reported in tables at this point. Might it be worthwhile to add a figure showing standardized graphs of trends over time for each of the individual states as you've done for them collapsed? Not necessary but might tell a more complete story.</p> <p>4. Considering the power in this study to discern quite small magnitude differences as shown in the comparisons on participant characteristics, did you analyze whether increases in mean birth weight are discernible comparing Tips exposed versus unexposed infants? That may be a pipe dream on my end, but I thought I'd raise the question.</p>
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REVIEWER	Assoc Prof Marita Lynagh University of Newcastle Australia
REVIEW RETURNED	24-Apr-2017

GENERAL COMMENTS	A well written manuscript reporting on an important area of public health research that is eminently publishable.
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REVIEWER	Mette Rasmussen Clinical Health Promotion Centre Bispebjerg and Frederiksberg Hospital Denmark
REVIEW RETURNED	18-May-2017

GENERAL COMMENTS	<p>1) This is an important research topic evaluating the effect of a mass media campaign (measured as smoking cessation among pregnant women) in Ohio, Indiana and Kentucky, using secondary data.</p> <p>2) In the introduction the sentence starting with "An evaluation of Tips 2012 found that quit attempts... " you use reference #2 (WHO global report), should it be replaced with #3 (Effect of the first federally funded US antismoking...)?</p> <p>3) Campaign exposure: I found myself having to reread the methods section to understand the "course of events", meaning who was included/excluded and who was exposed/unexposed. I appreciate it is complicated to explain the course of such events. I found the "not exposed" / "exposed" part (in Campaign exposure, page 6) quit clear. However, that left me with the question: "What happens if a pregnant woman is exposed to Tips in the 3. trimester?". This information is available on the bottom of page 8. To me it would be</p>
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very helpful if you compile all the information on inclusion/exclusion criteria as well as criteria for being considered not exposed/exposed in one section.

4) Be consistent with the use of joinpoint/jointpoint regression (to my knowledge it's joinpoint regression, but I might be wrong).

5) Please use "statistically significant" and not just "significant" when relevant.

6) I'm not familiar with GRP. On top of page 10 you write "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)". It is unclear to me if 600 GRP corresponds to app. 6 weeks of exposure or if you are calculating different ORs for the different measurements?. Please be more precise on this matter. If you don't mean that 600 GRPs correspond to 6 weeks of exposure, if possible, add a comment on how many GRPs corresponds to how many weeks of exposure.

7) Regarding the sample characteristics on page 10 the numbers in the first three lines does not add up. 1,401,561 live births; 10,213 births were excluded; 1,391,343 remaining. This should also be corrected in figure 1, see more below.

8) I can not find what test you used to compare the crude and standardized cessation rates (bottom of page 11)?

9) I miss a discussion on the magnitude of your results. It is true that the results of Tips 2012 are statistically significant, but please mention the relevans of the results. You are dealing with OR's (+/- 95% CI) down to 1.01. I would be relevant to now a little bit about the costs of a campaign like Tips. Is it cost-effective to have huge media campaigns resulting in an outcome of that size?

Most places you put a "size" on other results mentioned in this paper, but you do not evaluate the "size" of the main result.

Example:

In the last sentence on page 4, starting with "Currently available clinical cessation interventions for pregnant women..." you state that current interventions are only modestly effective (RR <1.5); however this seems to be a very good result compared to the effect of Tips 2012.

On page 11 "Association between Tips Campaign Exposure and Smoking Cessation" you write that "Demographic characteristics of women exposed and ... differ slightly but significantly...".

11) In terms of generalisability it is important to know what cessation programmes are already available to pregnant women in the three states. If there are no offers to pregnant smokers the effect of Tips 2012 may be overestimated if generalised to other states.

Figures and tables:

Figure 1) Available births, excluded births and eligible births do not add up. Furthermore, the reasons for exclusion do not add up to the total number of excluded births (excluded = 10,213; reasons for exclusion: 2,188 + 5,365 + 2,809 = 10,362). Footnote for b) in the first sentence "sou^c" is put en front of "Of n=60,747, ..." Please explain what that means.

Figure 2) This is a very nice and informative figure. If I understand the x-axis correct each number (1-20) represents a quarter. If that is correct, the intervals for Tips 2012 and Tips 2013 should be adjusted/moved to represent the correct intervals of the campaigns. Footnote b) Please state what statistical test you used, and not just the command used in SAS.

Table 1) Footnote c) Please state what statistical test you used, and not just the command used in SAS.

REVIEWER	Dr Johnson George Monash University Australia
REVIEW RETURNED	23-May-2017

GENERAL COMMENTS	<p>An interesting paper and the authors have to be appreciated for undertaking such a study; however, the findings have to be interpreted with extreme caution given the high stakes policy implications, not just locally, but internationally. I personally won't be surprised if the authors' statement about confounding in the limitations section is actually the case. The trend reported in Kentucky supports this possibility. Pregnant women who are still smoking in second trimester is a very challenging group and it often requires very complex interventions to achieve cessation. A mass media campaign, that too not targeting pregnant women, may not be that effective in the absence of other motivating factors. The statement in the second last paragraph about a general campaign being more cost effective than one targeting pregnant women is not evidence-based and has to be removed.</p> <p>I have a number of questions about the study design and potential bias, which are listed below:</p> <ol style="list-style-type: none"> 1. Have you measured exposure to smoking cessation treatments that are gaining popularity among smokers, including pregnant women, due to more safety data on nicotine replacement therapy? Can you adjust for this based on sales data? 2. Have you measured and adjusted for e-cigarette use in these states? 3. It is not clear why a random selection of states or combinations was not attempted. 4. Multiple testing and lack of objective measures of exposure and outcomes are major limitations. Can you perform at least some interviews on a random sample to confirm the exposure and outcomes? 5. The design of the study automatically excludes women who had a poor outcome potentially due to smoking (e.g. foetal death or miscarriage) 6. Why smoking status during 2nd trimester was not used as an outcome? Or a combined second-third trimester smoking status as the outcome? Many women give up smoking as they find out that they are pregnant. Also on page 8 it is stated that women who were only exposed to Tips 2012 during third trimester were excluded. Why can't the authors undertake a sensitivity analysis rather than
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	<p>excluding them completely from the analysis?</p> <p>7. Tobacco prices are always going up and it is one of the motivating factors to quit. Has this been accounted for?</p> <p>8. Smoking status of partner is another potential confounder that was not adjusted for.</p> <p>9. Changes in cigarette types available (e.g. menthol cigarettes) and restrictions on tobacco sales may have contributed to changes in smoking patterns (more light smokers). This may have contributed to the higher proportions smoking less than 21 cigarettes in the exposed group in Table 1. They may be more willing to quit.</p> <p>Minor comments</p> <p>It will be useful to know what times of the day/night these campaigns were used and what proportion of the pregnant women actually had exposure or not (e.g. due to work status). Why work status was not used as a covariate in the regression model?</p> <p>It is possible that there was an increase in self-reported abstinence rates by pregnant women (rather than actual abstinence) due to social desirability bias.</p> <p>Is the magnitude of change reported in the manuscript regarded as of public health significance in light of all the limitations and potential confounding?</p> <p>Figure 1 has multiple typographical errors (e.g. Tips 2102)</p>
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VERSION 1 – AUTHOR RESPONSE

Reviewer: 1

Reviewer Name: Stephen T. Higgins, PhD

This report describes results of an evaluation of whether a mass-media campaign directed at the general population of cigarette smokers increased cessation rates among pregnant smokers. The investigators examined smoking rates in three contiguous states with high smoking prevalence rates generally and during pregnancy that were exposed to the media campaign.

They examined smoking rates prior to and during the campaign controlling for potential confounders. The results suggest a 1.8% increase in cessation rates. The study was well conceptualized and implemented. The report is very well written. The analyses outlined are detailed, thoughtful, and rigorous. The results are largely compelling and discussion and interpretation of them is measured and justified by the results. I see no substantive flaws and commend the authors on a creative and important study offering evidence in support of the Tips mass media campaign for reducing smoking in this highly vulnerable population. That is welcome news in an area of tobacco control where we

need to do a great deal more to reduce smoking rates and associated serious adverse maternal and infant impacts. To make the headway that is needed on reducing smoking among vulnerable populations, we are going to need a multipronged approach involving creative, evidence-based tobacco control efforts at the population and individual levels as well as creative, evidence-based tobacco regulatory efforts.

Below I offer four comments/questions for consideration by the investigators.

1. I see pre-pregnancy smoking rates listed among the list of potential covariates, but not among the variables included in standardizing smoking-cessation rates. Pre-pregnancy smoking rate is a robust predictor of cessation among pregnant women. Can you clarify?

Response: The reviewer raises a good point. While we included pre-pregnancy smoking in our regression models, we did not include it in our standardized rates. We repeated the standardization analysis, replacing race with pre-pregnancy smoking. Our findings did not change; we added this information to the paper on pages 8 and 12.

2. On a very minor note, looks like obesity was omitted as a category in the Table comparing participant characteristics.

Response: The reviewer is correct; this line was inadvertently omitted but has been replaced in Table 1.

3. I commend the authors for parsing out the contributions of each of the three states to the overall effect reported on smoking-cessation rates, and demonstrating that the effect is significant when based on the results of Ohio and Indiana alone (Kentucky excluded). That information is reported in tables at this point. Might it be worthwhile to add a figure showing standardized graphs of trends over time for each of the individual states as you've done for them collapsed? Not necessary but might tell a more complete story.

Response: We opted not to show the individual trends because the journal restricts the number of tables and figures and because the combined data provide more stable point estimates and a smoother trend pattern.

However, we did want to be certain that readers were aware that the increase in percentage of quitters slightly preceded the Tips campaign in Kentucky, and this information is included in the manuscript (page 12).

4. Considering the power in this study to discern quite small magnitude differences as shown in the comparisons on participant characteristics, did you analyze whether increases in mean birth weight are discernible comparing Tips exposed versus unexposed infants? That may be a pipe dream on my end, but I thought I'd raise the question.

Response: We agree this would be interesting. We anticipated that we would be underpowered to detect a difference in birth weight between exposed and unexposed smokers, and so had not looked at this outcome. In response to the reviewer's request, we did estimate the mean birth weights, and, as expected, found a very small (1.5 grams) and insignificant increase in the exposed group compared with the unexposed group. We did not add this to the manuscript.

Reviewer: 2

Reviewer Name: Assoc Prof Marita Lynagh

A well written manuscript reporting on an important area of public health research that is eminently

publishable.

Response: Thank you. We see no specific changes requested by this reviewer.

Reviewer: 3

Reviewer Name: Mette Rasmussen

1) This is an important research topic evaluating the effect of a mass media campaign (measured as smoking cessation among pregnant women) in Ohio, Indiana and Kentucky, using secondary data.

2) In the introduction the sentence starting with "An evaluation of Tips 2012 found that quit attempts... you use reference #2 (WHO global report), should it be replaced with #3 (Effect of the first federally funded US antismoking...)?

Response: Thank you for pointing this out. This reference and one other have been corrected and remaining references checked.

3) Campaign exposure: I found myself having to reread the methods section to understand the "course of events", meaning who was included/excluded and who was exposed/unexposed. I appreciate it is complicated to explain the course of such events. I found the "not exposed" / "exposed" part (in Campaign exposure, page 6) quit clear. However, that left me with the question: "What happens if a pregnant woman is exposed to Tips in the 3. trimester?". This information is available on the bottom of page 8. To me it would be very helpful if you compile all the information on inclusion/exclusion criteria as well as criteria for being considered not exposed/exposed in one section.

Response: The reviewer's comments reflect the complexity of this section. It is difficult to compile all of the information in one section because there are two different analytical groups (one used in the trend analysis, and the second is used in the association analyses); this is why we opted to include Figure 1. We agree that the treatment of women with exposure only in the third trimester could be clearer and have modified the paragraph of page 6 accordingly.

4) Be consistent with the use of joinpoint/jointpoint regression (to my knowledge it's joinpoint regression, but I might be wrong).

Response: "Jointpoint" was a misspelling and it has been corrected. Thank you for calling it to our attention.

5) Please use "statistically significant" and not just "significant" when relevant.

Response: This change has been made.

6) I'm not familiar with GRP. On top of page 10 you write "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)". It is unclear to me if 600 GRP corresponds to app. 6 weeks of exposure or if you are calculating different ORs for the different measurements? Please be more precise on this matter. If you don't mean that 600 GRPs correspond to 6 weeks of exposure, if possible, add a comment on how many GPRs corresponds to how many weeks of exposure.

Response: Please see pages 6-7 for an expanded explanation of GRPs. Please see page 10 for

clarifying language.

7) Regarding the sample characteristics on page 10 the numbers in the first three lines does not add up. 1,401,561 live births; 10,213 births were excluded; 1,391,343 remaining. This should also be corrected in figure 1, see more below.

Response: This correction has been made. Thank you for calling it to our attention.

8) I cannot find what test you used to compare the crude and standardized cessation rates (bottom of page 11)?

Response: We used chi-square tests. This has been added to page 9.

9) I miss a discussion on the magnitude of your results. It is true that the results of Tips 2012 are statistically significant, but please mention the relevance of the results. You are dealing with OR's (+/- 95% CI) down to 1.01. I would be relevant to now a little bit about the costs of a campaign like Tips. Is it cost-effective to have huge media campaigns resulting in an outcome of that size?

Response: The reviewer raises a good point. It is important to note that the benefits of the campaign for pregnant smokers are in addition to the effects of cessation on the general population that have already been described in the literature. A general campaign may be preferable in some circumstances to a campaign targeting pregnant women. States and localities need to weigh a number of factors, including overall resources, effects sizes of the different interventions, and smoking prevalence in pregnant and non-pregnant populations, when deciding what types of campaign to develop and disseminate.

Regarding the cost of the campaign, Tips has been found to compare favorably with other public health interventions. The campaign cost approximately \$480 per quitter, \$2,819 per premature death averted, \$393 per life year saved, and \$268 per quality-adjusted life year gained. See Xu X et al., *Am J Prev Med*, 2015, doi 10.1016/j.amepre.2014.10.011 (this reference has been added to the manuscript). In comparison, a commonly used threshold in the U.S. for cost effectiveness from a societal perspective is \$50,000 per LY or QALY gained.

The magnitude of the effect of the campaign on pregnant smokers in the 3 states in our study (a 1.8 percentage point increase in the cessation rate) compares favorably to national estimates of the effect on non-pregnant smokers (a 0.25 percentage point increase in the cessation rate) (see page 13).

Most places you put a "size" on other results mentioned in this paper, but you do not evaluate the "size" of the main result.

Example:

In the last sentence on page 4, starting with "Currently available clinical cessation interventions for pregnant women..." you state that current interventions are only modestly effective (RR <1.5); however this seems to be a very good result compared to the effect of Tips 2012.

Response: Agreed. Please see previous response. In general, interventions at the national level like an ad campaign will have more modest effects of a lower magnitude, but reach a larger audience than clinical interventions. Combining interventions that are administered at multiple levels will likely have the greatest impact on cessation.

On page 11 "Association between Tips Campaign Exposure and Smoking Cessation" you write that

"Demographic characteristics of women exposed and ... differ slightly but significantly...".

Response: We are not clear if there is a change that needs to be addressed here.

11) In terms of generalisability it is important to know what cessation programmes are already available to pregnant women in the three states. If there are no offers to pregnant smokers the effect of Tips 2012 may be overestimated if generalised to other states.

Response: All states in the US have smoking cessation quitlines, and almost all states have cessation services tailored for pregnant women. In addition, several organizations including The American Congress of Obstetricians and Gynecologists and the US Preventive Services Task Force recommend screening and psychosocial interventions for tobacco use and cessation. Finally, for low income women, the Affordable Care Act (ACA) requires states to provide tobacco-cessation services without cost-sharing for pregnant women who are Medicaid-beneficiaries. The 3 states included in this analysis were selected because they had a large number of births and high smoking prevalence. Thus, we agree with the reviewer that our findings might not be generalizable to other states, particularly those with low smoking prevalence. This limitation is now more clearly stated on page 15. We did not add information about services available to pregnant smokers in the U.S. because of space constraints, but we would be happy to do so at the editor's request.

Figures and tables:

Figure 1) Available births, excluded births and eligible births do not add up. Furthermore, the reasons for exclusion do not add up to the total number of excluded births (excluded = 10,213; reasons for exclusion: 2,188 + 5,365 + 2,809 = 10,362). Footnote for b) in the first sentence "sou^c" is put en front of "Of n=60,747, ..." Please explain what that means.

Response: The number 10,213 has been corrected to 10,218. A footnote has been added to clarify that the remaining numbers do not add up to 10,218 because some women were excluded for more than one reason. Thank you for noticing the formatting error; it has been corrected.

Figure 2) This is a very nice and informative figure. If I understand the x-axis correct each number (1-20) represents a quarter. If that is correct, the intervals for Tips 2012 and Tips 2013 should be adjusted/moved to represent the correct intervals of the campaigns. Footnote b) Please state what statistical test you used, and not just the command used in SAS.

Response: We originally had adjusted the quarters slightly to align with the beginning and end of Tips 2012, but we realize that this may confuse readers. We have modified the figure to depict the calendar quarters and have moved the lines accordingly.

Table 1) Footnote c) Please state what statistical test you used, and not just the command used in SAS.

Response: The footnote has been revised.

Reviewer: 4

Reviewer Name: Dr Johnson George

An interesting paper and the authors have to be appreciated for undertaking such a study; however, the findings have to be interpreted with extreme caution given the high stakes policy implications, not

just locally, but internationally. I personally won't be surprised if the authors' statement about confounding in the limitations section is actually the case. The trend reported in Kentucky supports this possibility. Pregnant women who are still smoking in second trimester is a very challenging group and it often requires very complex interventions to achieve cessation. A mass media campaign, that too not targeting pregnant women, may not be that effective in the absence of other motivating factors. The statement in the second last paragraph about a general campaign being more cost effective than one targeting pregnant women is not evidence-based and has to be removed.

Response: The reviewer's comment regarding caution is valid, and we did endeavor to temper the interpretation of our findings. We agree that it cannot yet be concluded that a general campaign is more cost effective than one targeting pregnant women, and we raised this as a possibility rather than stating it as a conclusion. To address the reviewer's concern, we've rephrased the sentence to emphasize the need to determine whether this is so (page 16).

I have a number of questions about the study design and potential bias, which are listed below:

1. Have you measured exposure to smoking cessation treatments that are gaining popularity among smokers, including pregnant women, due to more safety data on nicotine replacement therapy? Can you adjust for this based on sales data?

Response: To our knowledge, there is not a growing perception in the US that NRT is more acceptable for use during pregnancy; recommendations from the FDA and from ACOG have not changed in recent years and NRT is not recommended as a first line cessation treatment in pregnancy. Unfortunately, sales data in the US would not be specific for pregnant women, and because NRT isn't routinely recommended for use in pregnant smokers in the U.S., we would not be able to generalize from sales data to this specific population.

2. Have you measured and adjusted for e-cigarette use in these states?

Response: Unfortunately, we do not have data at this time on e-cigarette use in pregnant women in the US. The rise in e-cigarette use in US adults occurred gradually during the study period, and preceded the Tips campaign. If e-cigarettes were contributing substantially to quit rates (and there aren't data to support that is happening in US adults), we would expect that quit rates would mirror the increase in e-cigarette use, and we would see a more linear increase in cessation, beginning in 2011. Instead, we observed a sharp and sustained increase beginning in early 2012 that corresponded to the beginning of the 2012 campaign.

3. It is not clear why a random selection of states or combinations was not attempted.

Response: We agree that a random selection of states would be ideal. However, acquiring the state-based data needed for this analysis (we required date of birth which is not publically available), necessitates separate requests and approval processes for each state. For efficiency, we selected states with high smoking prevalence in pregnant women and a high number of births. This information is stated on page 5.

4. Multiple testing and lack of objective measures of exposure and outcomes are major limitations. Can you perform at least some interviews on a random sample to confirm the exposure and outcomes?

Response: Although there are multiple statistical comparisons in the manuscript, our main hypothesis (that cessation rates increased with the airing of the Tips campaign) is addressed with few comparisons—the trend analysis, the comparison of cessation rates between exposed and unexposed women (found in Table 2), and the generation of an odds ratio for cessation with adjustment for confounders. All of these findings were statistically significant. We agree that the ecological study design is a limitation. We know that about 80% of smokers report seeing at least one Tips campaign ad, but we do not have exposure data at the individual level. Unfortunately, it is not feasible to trace women using the birth certificate to conduct interviews. We did attempt to determine whether there could have been a difference in the accuracy of cessation reporting (such as, if more women who continued to smoke failed to disclose their smoking in late pregnancy) by examining birth weight in quitters, and found no evidence of an increase in non-disclosure among smokers.

5. The design of the study automatically excludes women who had a poor outcome potentially due to smoking (e.g. foetal death or miscarriage)

Response: The reviewer is correct. In the US, most states do not routinely collect information on pregnancies ending in fetal death or miscarriage. Unfortunately, this is a limitation of most population-based studies of pregnancy outcomes in the U.S. We are not able to overcome this limitation, but did state it in the limitations section (page 15).

6. Why smoking status during 2nd trimester was not used as an outcome? Or a combined second-third trimester smoking status as the outcome? Many women give up smoking as they find out that they are pregnant. Also on page 8 it is stated that women who were only exposed to Tips 2012 during third trimester were excluded. Why can't the authors undertake a sensitivity analysis rather than excluding them completely from the analysis?

Response: Any woman who smoked in the three months before pregnancy and who did not smoke in the third trimester of pregnancy was categorized as a quitter, regardless of when she quit. For example, someone who quit in the second trimester would be counted as a quitter as long as she did not relapse and smoke in the third trimester. We decided to limit our analysis to cessation by the end of pregnancy rather than looking at cessation earlier on as a separate outcome because many women who quit relapse before the end of pregnancy, and because cessation by the third trimester has clear and established benefits.

We decided a priori to exclude women who were only exposed during the third trimester from the association analyses. There is a possibility that these women might not have been exposed to the campaign until very late in pregnancy, and if these women quit in mid or late third trimester, this might not be captured in the birth certificate record (which only notes whether a woman smoked in the third trimester). For example, a woman who quit smoking in response to seeing the campaign very late in pregnancy (or who quit then for other reasons) might still have smoked earlier in the third trimester, and she would not be captured as a quitter. In addition, the benefits of cessation late in the third trimester are unclear.

In contrast to the association analyses in which we attempted to categorize women as exposed or unexposed, all smokers and quitters are included in the trend analysis, regardless of when they were exposed to the tips campaign.

7. Tobacco prices are always going up and it is one of the motivating factors to quit. Has this been accounted for?

Response: There were no increases in tobacco prices in any of these 3 states near the time the Tips

campaign aired.

8. Smoking status of partner is another potential confounder that was not adjusted for.

Response: We do not have data on partner smoking, but agree this would be interesting to examine. There is a possibility that the Tips campaign could benefit pregnant smokers indirectly through effects on partners. This would be an interesting question to explore in future research.

9. Changes in cigarette types available (e.g. menthol cigarettes) and restrictions on tobacco sales may have contributed to changes in smoking patterns (more light smokers). This may have contributed to the higher proportions smoking less than 21 cigarettes in the exposed group in Table 1. They may be more willing to quit.

Response: We agree that changes in smoking intensity could have contributed to quit rates. We attempted to account for this by adjusting for pre-pregnancy smoking. As stated in the paper, we were unable to identify any other large-scale tobacco control interventions in the study period in any of the 3 states that contributed data to our analysis.

Minor comments

It will be useful to know what times of the day/night these campaigns were used and what proportion of the pregnant women actually had exposure or not (e.g. due to work status).

Response: We do not have individual level exposure and are limited to an ecological study design. We do not have employment status of women during pregnancy. However, we do know that approximately 80% of smokers did see at least one ad from the Tips campaign.

Tips ads were delivered via TV, radio, print (magazines), outdoor (billboards and others), theater, and digital media. TV ads aired both during the day and evening/prime time, with tagging for 1-800-QUIT-NOW and CDC.gov/Tips as appropriate.

Why work status was not used as a covariate in the regression model?

Response: Unfortunately, occupation and employment status are not included in the birth certificate.

It is possible that there was an increase in self-reported abstinence rates by pregnant women (rather than actual abstinence) due to social desirability bias.

Response: We agree and we attempted to address this by examining birth weight among quitters and found no sign of increased non-disclosure as evidenced by a reduction in birth weight in this group (please see page 13).

Is the magnitude of change reported in the manuscript regarded as of public health significance in light of all the limitations and potential confounding?

Response: There are perhaps two different issues here—does the magnitude of the change we found in the study accurately reflect the real change resulting from the campaign (which is related to confounding, etc.), and does that magnitude have public health implications? With respect to the latter, the magnitude of the change needs to be weighed against the resources required to achieve it. Because Tips has already been demonstrated to be cost-effective, any added benefit of cessation to this subgroup of women only strengthens the argument in support of the national campaign, and it is possible that a general campaign could become one of the standard tools known to be effective to

increase cessation in pregnant women.

We've tried to address the possibility that the results are due to confounding or other factors in the discussion of the manuscript. It is important to attempt to replicate the findings with additional research.

Figure 1 has multiple typographical errors (e.g. Tips 2102)

VERSION 2 – REVIEW

REVIEWER	Stephen T. Higgins University of Vermont, USA
REVIEW RETURNED	17-Jul-2017

GENERAL COMMENTS	This is an outstanding study and contribution to this area of public health research for which I commend the authors.
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REVIEWER	Dr Johnson George Monash University, Australia
REVIEW RETURNED	06-Jul-2017

GENERAL COMMENTS	The authors have satisfactorily addressed the issues and/or questions raised by the reviewers.
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