Reviewer's report

Title: A study protocol to evaluate the relationship between outdoor air pollution and pregnancy outcomes

Version: 2 Date: 2 September 2010

Reviewer: Denis Zmirou-Navier

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Major Compulsory Revisions

The authors have answered several of the questions raised in my previous review. However, they overlook the issue of short term (maybe 10-12 weeks) time dependence of the study outcome on air pollution. Their main hypothesis is that long term differences in exposure of women prior to and during pregnancy will result in effects on pregnancy outcomes. This is a reasonable assumption. But, as already stated in my review, air pollution contrasts between the study locations might be smaller than the seasonal (winter/summer) variations. Therefore, because the lack of appropriate time resolution of the exposure metric might induce a high degree of misclassification. For this reason, it is important that additional information be provided on the relative contrasts of air quality at the spatial and seasonal scales within the study area. Data from the previous studies conducted by the same authors should be used to provide this information. They should also discuss this issue more deeply.

Minor Essential Revisions

- p9 (Statistical power): “The study has statistical power of 80% to detect a difference of 4% at the significance level of 0.05 (95% confidence level) between pregnant exposed to outdoor air pollution and pregnant not exposed to outdoor air pollution”. What does “exposed and not exposed” mean? What is the contrast of air pollution that is expected to yield a 4% difference in the outcome rates (low birth weight and premature birth)? Please provide estimates of the baseline outcome rate so that the reader can assess what the declared 4% expected difference represents in regards to these rates.

- P 12 (Methods, first line): Please explain how both night and day-time addresses of mothers during pregnancy are incorporated to construct the personal exposure variable.

- p 13 (Selection bias section, last sentence): do the authors plan to collect information about the study outcome on non participating mothers so as to evaluate whether participation relates to the outcome?

Minor revisions

5th line before the end: correct the sentence: "... since no Quercus suber trees were not available for analysis"
**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Acceptable

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

'I declare that I have no competing interests’