Author's response to reviews

Title: Strategies for Recruiting Hispanic Women into a Prospective Cohort Study of Modifiable Risk Factors for Gestational Diabetes Mellitus

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Author's response to reviews: see over
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Anastasios Koutsos, PhD.
Scientific Editor
BMC-series Journals
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London, WC1X 8HL

Dear Dr. Koutsos:

Thank you for considering our manuscript "Strategies for Recruiting Hispanic Women into a Prospective Cohort Study of Modifiable Risk Factors for Gestational Diabetes Mellitus," MS: 1794711649294902 for publication. We have altered the manuscript in accordance with reviewers’ comments; changes are underlined. Below, please find our point-by-point response. We would also like to thank the editor and reviewers for their helpful comments on our manuscript.

Sincerely,

Lisa Chasan-Taber, ScD
Associate Professor of Epidemiology
Title: Strategies for Recruiting Hispanic Women into a Prospective Cohort Study of Modifiable Risk Factors for Gestational Diabetes Mellitus

Referee 1

General comments
This is an important paper which focuses on optimising recruitment of a population of women who are underrepresented in research on pregnancy and childbirth despite experiencing a greater burden of disease. Facilitating recruitment of minority women into pregnancy and childbirth studies would increase the generalisability of research findings and could influence the uptake of evidence into practice particularly in minority communities. However, in its current iteration, the manuscript lacks some information needed for readers to determine whether the strategies outlined for optimizing recruitment are worth pursuing by other researchers:

Major compulsory revisions

1. There is no clear indication of how successful the recruitment strategy package actually was. The predicted or target recruitment goal is not reported and it is difficult to assess from the available information in the paper whether recruitment of 9.8\% of all pregnant women in the Baystate Health system was considered a good outcome when according to the paper approximately 57\% of the population served by the Baystate Health system are Hispanic. Furthermore, by reporting recruitment rates (percentage recruited) with a denominator of all potential women rather than potentially eligible women, both recruitment rate and refusal rate are difficult to interpret. For example, 8.8\% of all potential women refused to participate, however, 45.5\% of all potential women were never even approached to participate and of those who were approached 35.9\% were ineligible. In fact 47.6\% of eligible women who were approached refused and 52.4\% of eligible women who were approached agreed.

The authors should:
a) state the recruitment target and comment on the success of the strategy in relation to this.
b) report more detail about the recruitment and refusal rates and explain why they have chosen to use the denominator they have used. Reporting in both ways may be preferable.

The reviewer raises an excellent point. We have revised the manuscript to now state the recruitment target (Methods page 4, last para) and comment on the success of the strategy in relation to this target (Discussion page 12, para. 2). In addition, we agree with the reviewer that reporting recruitment rates with a denominator of all potential women rather than eligible women makes the recruitment and refusal rates difficult to interpret. The reviewer’s suggestion is also consistent with recent recommendations by Galea et al. in a review article on “Participation Rates in Epidemiologic Studies” (Ann Epidemiol 2007). Therefore, we have revised Table 1 as well as the Results section (page 10, para. 1) to now calculate the recruitment and refusal rates among eligible women.
c) on p.13 of the discussion the authors do discuss difficulties in accessing patients to request study participation. This discussion could be expanded in light of the comments above about the number of potential participants who were never approached for participation and its effect on the applicability and generalisability of the study findings.

We agree with the reviewer and have expanded the discussion of the difficulty in accessing patients and now also address the applicability and generalizability of the study findings (page 12, last para; page 13, para. 2; page 15, para. 1).

d) A comment on p.11 about the use of pre-screening could be expanded.

We have expanded this comment on pre-screening (page 11, para. 2).

2. By virtue of its design as a prospective cohort study it is not possible to determine whether this intensive recruitment strategy would be more effective than a less intensive strategy. It would be good if the authors acknowledged that a randomised trial of these recruitment strategies comparing this intensive package and a less intensive package would assist future researchers. Also, some follow-up qualitative research to understand why some strategies were effective may also be warranted.

This is an excellent point. We have revised the manuscript to now acknowledge that a randomized trial of recruitment strategies would be required to test whether this intensive recruitment strategy would be more effective than a less intensive strategy. We also discuss the need for follow-up qualitative research to understand why some strategies were effective (page 15, last para).

Minor essential revisions
None

Discretionary revisions
1. the paper does not make a clear distinction between recruitment into the study and participation in the study. This may be a function of the study design, however, there are “recruitment” strategies described which are in fact about making participation in the study easier e.g. collection of study data from the medical record and administration of the study questionnaires by bilingual interviewers according to patient preference. It might be better to group these under a heading such as study design/protocol design.

We agree with the reviewer and have moved strategies which made participation in the study easier, such as collection of medical record data and the use of bilingual interviewers, to a new section titled, “Study Protocol” (page 8, last para; page 9 para. 1).

2. on p.5 the authors describe the study protocol and refer to a baseline interview using “structured scales”. Have these scales been previously validated? If not, what methods were used to ensure their validity for use in this study (I recognize that this is not the primary focus of this paper, however, it would make the reporting of the study more complete. If the authors have published this information elsewhere a comment to that effect would be sufficient.)
All of the structured scales used have been previously validated. We have added information on the validity of these scales to page 5, last para.

**Referee 2**

This manuscript clearly describes strategies that were undertaken to ensure appropriate recruitment methods for Hispanic women in a cohort study of gestational diabetes mellitus (GDM). As the authors note, Hispanic populations are often excluded from health research, even when, as in the case of GDM, the health issue particularly affects them. The manuscript achieves its aim in providing other researchers with helpful information about the sorts of strategies that are needed to ensure successful recruitment of Hispanic women.

**Minor Essential Revisions**

Please define ‘potential participants’. Are they all prenatal patients at the clinics, or all Hispanic patients?

We have revised the Methods section (page 7, last para) to define potential participants.Briefly, potential participants were defined as pregnant women who were, based on the hospital database, estimated to be between ages 16 and 40 years and early in pregnancy (<20 weeks gestation). The ‘ethnicity’ field in the hospital database was deemed inadequately reliable to use to identify Hispanic participants.

On page 9 and in Table 1 the category 'temporarily refused' is used. This seems not a very useful distinction, given that none of them is included in the total finally enrolled, which seems to suggest that none of them was subsequently re-approached to invite participation. This needs clarification.

We agree with the reviewer that the category ‘temporarily refused’ is not useful and have revised Results section (page 10, 1st para.) and Table 1 to now use an overall ‘Refused’ category.

It would also be useful to indicate the proportion of ‘approached and eligible’ women who were finally enrolled, not just the proportion of all potential participants.

Please see our response to Referee #1, comment #1 above who also made this suggestion. We have revised Table 1 and the Results section (page 10, para. 1) to now indicate the proportion of eligible women enrolled.

On page 10, please provide the actual percentages in the second sentence: ie, the % of the women who preferred to speak English; and the % born in the US, given percentages are presented for the other sample characteristics.

We have revised the manuscript to now provide the actual percentages for these characteristics on page 10, para. 2.