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- Comments from the reviewers and editors (email to author requesting revisions)
- Response from the author (cover letter submitted with revised manuscript)*

*The corresponding author has opted to make this information publicly available.

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Questions about these materials may be directed to the Obstetrics & Gynecology editorial office:

obgyn@greenjournal.org.
RE: Manuscript Number ONG-21-2357

Association between Social Vulnerability and Achieving Glycemic Control among Pregnant Women with Pregestational Diabetes

Dear Dr. Venkatesh:

Your manuscript has been reviewed by the Editorial Board and by special expert referees. Although it is judged not acceptable for publication in Obstetrics & Gynecology in its present form, we would be willing to give further consideration to a revised version.

If you wish to consider revising your manuscript, you will first need to study carefully the enclosed reports submitted by the referees and editors. Each point raised requires a response, by either revising your manuscript or making a clear and convincing argument as to why no revision is needed. To facilitate our review, we prefer that the cover letter include the comments made by the reviewers and the editor followed by your response. The revised manuscript should indicate the position of all changes made. We suggest that you use the "track changes" feature in your word processing software to do so (rather than strikethrough or underline formatting).

Please be sure to address the Editor comments (see "EDITOR COMMENTS" below) in your point-by-point response.

Your paper will be maintained in active status for 21 days from the date of this letter. If we have not heard from you by Jan 25, 2022, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1: The authors' objective as to evaluate the association between community-level social vulnerability and achieving glycemic control (defined as hemoglobin A1c [HbA1c] <6.0% or <6.5%) among women with pregestational diabetes. To do this they conducted a retrospective cohort of women with pregestational diabetes with singleton gestations from 2012-2016 at a tertiary care center. Addresses were geocoded using ArcGIS, and then linked at the census tract to the Center for Disease Control and Prevention's (CDC) 2018 Social Vulnerability Index (SVI), which incorporates 15 census variables to produce a composite score and 4 scores across thematic domains (socioeconomic status, household composition and disability, minority status and language, and housing type and transportation). The primary outcome was a HbA1c <6.0%, and secondarily, HbA1c <6.5%, in the second or third trimesters. They found that women with a higher SVI were less likely to achieve a HbA1c <6.0% versus those with a lower SVI: for each 0.1-unit increase in SVI, the risk of achieving a HbA1c <6.0% decreased by nearly 50%, and by over 30% for a HbA1c <6.5%. With regard to specific SVI domains, those who scored higher on socioeconomic status as well as on household composition and disability were less likely to achieve a HbA1c <6.0%. They conclude that pregnant women with pregestational diabetes living in an area with higher social vulnerability were less likely to achieve glycemic control, as measured by HgbA1c levels.

Below are my comments and questions:

1. Can the authors discuss the reason for using a cohort that dates as far back as a decade for this study?

2. The authors appropriately comment on the fact that patients may have changed locations or resided at other locations than their primary address. The misascertainment of the exposure and resultant differential misclassification are appropriately highlighted in the limitations section.

3. The inability to establish causation is also appropriately commented on.

4. Can the authors expand some more on the potential effect on their results of excluding a fifth of the original sample due to absent HbA1c data?

5. Can the authors comment more on the differential frequencies of HgbA1c level testing in the cohort?

6. Can the authors comment more on whether and how the frequency of HgbA1c testing was incorporated in their analysis?
7. Can the authors comment more on whether and how the number of prenatal visits was incorporated in their analysis?

8. Can the authors comment on whether and how the gestational age at first initiation of prenatal care was incorporated in their analysis?

9. Lines 217-220: saying "higher socioeconomic status .." in here seems misleading as I think the authors mean "higher score for socioeconomic status domain" - which is defined as "unemployment, high school education, poverty" (Table 2).

10. The authors may want to use current guidance around gender-based language.

Reviewer #2: First of all, I think this is a fantastic article. It is a timely and important topic and addresses a significant challenge in caring for patients with diabetes. It is well thought out and the design is appropriate for the subject. In my review of the literature I find some studies that touch on this subject but none that address it with the rigor or quality of this article.

I do take some issue with the authors' definition of pregestational diabetes. Within their study group they have patients with 1) a prior documented diagnosis before pregnancy 2) "a 1-hour, 50-gram glucose challenge test ≥200 mg/dL" and 3) "2 elevated values on a 3-hour, 100-gram glucose tolerance test at less than 20 weeks' gestation." (presumably the patients with the elevated 50g were also prior to 20 weeks, but the wording is a bit vague). For the latter two groups, this is a frequent approach providers use in guiding care, but strictly speaking isn't the most rigorous definition. The annual ADA publication on standards of care for diabetes states that to establish a diagnosis of preexisting diabetes in pregnancy, "test women with risk factors for type 2 diabetes at their initial prenatal visit, using standard diagnostic criteria [that would be] used outside of pregnancy." ACOG (which the authors cite) states "if diabetes is diagnosed in the first trimester or early second trimester with the standard diagnostic criteria of a hemoglobin A1C (HbA1C ) of 6.5% or greater, a fasting plasma glucose of 126 mg/dL or greater, or a 2-hour glucose of 200 mg/dL or greater on a 75-g oral glucose tolerance test, it is considered pregestational diabetes." A 3-hour GTT isn't one of the criteria used by either organization.

Many of the patients included in this study would therefore be most strictly classified as gestational diabetes (early onset), and it is conceivable that many likely have prediabetes. It would be beneficial for the authors to report the basis on which patients qualified for the study (if that data is available)

I suspect the use of this definition doesn't invalidate the results - if anything it may even dilute the association the authors have identified, as I would speculate that many of the patients diagnosed based on the 3-hour probably have lesser degrees of hyperglycemia than patients with more clearly established diagnoses. The authors data would seem to support my conclusion that the findings are robust, based on the sensitivity analysis (patients with established diabetes are probably more likely to have periconceptional A1c).

Reviewer #3: This is a retrospective study of GDM patients looking at the social vulnerability index (SVI) provided by the CDC and its relationship with glycemic control. The authors found that higher scores of SVI related to lower likelihood of achieving glycemic control. They found socioeconomic status and household composition/disability domain scores to be most significant for their population. This manuscript uses a tool (SVI) that can be viewed and compared across the country, making it an important tool for researchers. It is well written with the exception of a few minor revision requests, described below.

Introduction:

line 95-96: Include an additional sentence to discuss importance of using SVI. It is accessible to all researchers and numbers are able to be compared across the country.

Methods:

Provide a clarifying statement about when prenatal care is initiated and if this is uniform across the study population

Statistical analysis

Line 162: Include the actual value of SVI used for 75th percentile for study population.

Line 177: The use of the periconception hgba1c is more accurately described as a subgroup analysis (sensitivity analysis #1). Sensitivity analysis #2 is a sensitivity analysis. They had a set of secondary analyses which assessed if there is a
synergistic effect between SVI and certain variables (line 181). Are there more subgroups that they looked at besides diabetes and insurance status? If not, they should include the data in the supplementary file. If they looked at other subgroups, they should elaborate. They should also make this a different paragraph, separate from the information about the sensitivity analysis.

Results:

Line 232: This sentence is confusing in terms of what the y variable is. Instead, they could write "when further adjusting the third trimester hbA1c with the periconception HgbA1c, the above results held..."

Line 236: clarify subgroup analyses as described above

STATISTICAL EDITOR COMMENTS:

The Statistical Editor makes the following points that need to be addressed:

Table 1 and General: This Table cites the characteristics for patients in the highest quartile vs the lower 3 quartiles, while other comparisons were based on actual SVI scores, ranging from 0-1. Need to relate the two measures of SVI. Should include a table comparing characteristics across 4 quartiles. Should include the mean and range of SVIs in each quartile, also.

Table 2: Since CIs are included, the identification (*) of p-values < 0.05 is redundant and should be omitted. Need to state in footnote that the RR and aRR are based on increments of 0.1 SVI (lines 40-43). The slope shown in Fig 1 does not appear to coincide with the ORs of this Table. If the Risk ratio were a factor of ~ 0.5 for each 0.1 unit decrease in SVI, then how did the probability of HbA1c < 6.0% change from ~ 35% at the highest values in Fig 1 to ~ 50% at the lowest values?

Fig 1: Need a legend to explain the figure. Should include in the legend or on the figure itself the slope, intercept and r² for the line of best fit. The x-axis shows scores from 0-1 (lines 33-34), which are not percentiles. If these represent SVI scores, should clarify. Should include another graph which shows the final HbA1c on the y-axis vs the SVI scores on the x-axis. The figure appears to show a statistically significant association, but one that has wide CIs for an individual case.

General: I presume that the inference threshold was p < 0.05, but need to state in Methods.

EDITOR COMMENTS:

1. The Editors of Obstetrics & Gynecology have increased transparency around its peer-review process, in line with efforts to do so in international biomedical peer review publishing. If your article is accepted, we will be posting this revision letter as supplemental digital content to the published article online. Additionally, unless you choose to opt out, we will also be including your point-by-point response to the revision letter. If you opt out of including your response, only the revision letter will be posted. Please reply to this letter with one of two responses:

A. OPT-IN: Yes, please publish my point-by-point response letter.
B. OPT-OUT: No, please do not publish my point-by-point response letter.

2. When you submit your revised manuscript, please make the following edits to ensure your submission contains the required information that was previously omitted for the initial double-blind peer review:
   * Include your title page information in the main manuscript file. The title page should appear as the first page of the document. Add any previously omitted Acknowledgements (ie, meeting presentations, preprint DOIs, assistance from non-byline authors).
   * Funding information (ie, grant numbers or industry support statements) should be disclosed on the title page and in the body text. For industry-sponsored studies, the Role of the Funding Source section should be included in the body text of the manuscript.
   * Include clinical trial registration numbers, PROSPERO registration numbers, or URLs at the end of the abstract (if applicable).
   * Name the IRB or Ethics Committee institution in the Methods section (if applicable).
   * Add any information about the specific location of the study (ie, city, state, or country), if necessary for context.

3. Obstetrics & Gynecology uses an "electronic Copyright Transfer Agreement" (eCTA), which must be completed by all authors. When you uploaded your manuscript, each co-author received an email with the subject, "Please verify your
4. For studies that report on the topic of race or include it as a variable, authors must provide an explanation in the manuscript of who classified individuals’ race, ethnicity, or both, the classifications used, and whether the options were defined by the investigator or the participant. In addition, the reasons that race/ethnicity were assessed in the study also should be described (eg, in the Methods section and/or in table footnotes). Race/ethnicity must have been collected in a formal or validated way. If it was not, it should be omitted. Authors must enumerate all missing data regarding race and ethnicity as in some cases, missing data may comprise a high enough proportion that it compromises statistical precision and bias of analyses by race.

Use "Black" and "White" (capitalized) when used to refer to racial categories. The nonspecific category of "Other" is a convenience grouping/label that should be avoided, unless it was a prespecified formal category in a database or research instrument. If you use "Other" in your study, please add detail to the manuscript to describe which patients were included in that category.

5. Please submit a completed STROBE checklist to accompany the revision.

6. Standard obstetric and gynecology data definitions have been developed through the reVITALize initiative, which was convened by the American College of Obstetricians and Gynecologists and the members of the Women's Health Registry Alliance. Obstetrics & Gynecology has adopted the use of the reVITALize definitions. Please access the obstetric data definitions at https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-obstetrics-data-definitions and the gynecology data definitions at https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-gynecology-data-definitions. If use of the reVITALize definitions is problematic, please discuss this in your point-by-point response to this letter.

7. Because of space limitations, it is important that your revised manuscript adhere to the following length restrictions by manuscript type: Original Research reports should not exceed 5,500 words. Stated word limits include the title page, précis, abstract, text, tables, boxes, and figure legends, but exclude references.

8. Specific rules govern the use of acknowledgments in the journal. Please note the following guidelines:

* All financial support of the study must be acknowledged.
* Any and all manuscript preparation assistance, including but not limited to topic development, data collection, analysis, writing, or editorial assistance, must be disclosed in the acknowledgments. Such acknowledgments must identify the entities that provided and paid for this assistance, whether directly or indirectly.
* All persons who contributed to the work reported in the manuscript, but not sufficiently to be authors, must be acknowledged. Written permission must be obtained from all individuals named in the acknowledgments, as readers may infer their endorsement of the data and conclusions. Please note that your response in the journal's electronic author form verifies that permission has been obtained from all named persons.
* If all or part of the paper was presented at the Annual Clinical and Scientific Meeting of the American College of Obstetricians and Gynecologists or at any other organizational meeting, that presentation should be noted (include the exact dates and location of the meeting).
* If your manuscript was uploaded to a preprint server prior to submitting your manuscript to Obstetrics & Gynecology, add the following statement to your title page: "Before submission to Obstetrics & Gynecology, this article was posted to a preprint server at: [URL]."

9. The most common deficiency in revised manuscripts involves the abstract. Be sure there are no inconsistencies between the Abstract and the manuscript, and that the Abstract has a clear conclusion statement based on the results found in the paper. Make sure that the abstract does not contain information that does not appear in the body text. If you submit a revision, please check the abstract carefully.

In addition, the abstract length should follow journal guidelines. The word limit for Original Research articles is 300 words. Please provide a word count.

10. Only standard abbreviations and acronyms are allowed. A selected list is available online at http://edmgr.ovid.com/ong/accounts/abbreviations.pdf. Abbreviations and acronyms cannot be used in the title or précis. Abbreviations and acronyms must be spelled out the first time they are used in the abstract and again in the body of the manuscript.

11. The journal does not use the virgule symbol (/) in sentences with words. Please rephrase your text to avoid using "and/or," or similar constructions throughout the text. You may retain this symbol if you are using it to express data or a measurement.

12. ACOG avoids using "provider." Please replace "provider" throughout your paper with either a specific term that defines the group to which are referring (for example, "physicians," "nurses," etc.), or use "health care professional" if a specific term is not applicable.

13. In your Abstract, manuscript Results sections, and tables, the preferred citation should be in terms of an effect size,
such as odds ratio or relative risk or the mean difference of a variable between two groups, expressed with appropriate confidence intervals. When such syntax is used, the P value has only secondary importance and often can be omitted or noted as footnotes in a Table format. Putting the results in the form of an effect size makes the result of the statistical test more clinically relevant and gives better context than citing P values alone.

Please standardize the presentation of your data throughout the manuscript submission. For P values, do not exceed three decimal places (for example, "P = .001"). For percentages, do not exceed one decimal place (for example, 11.1%).

14. Please review the journal's Table Checklist to make sure that your tables conform to journal style. The Table Checklist is available online here: http://edmgr.ovid.com/ong/accounts/table_checklist.pdf.

15. Please review examples of our current reference style at http://ong.editorialmanager.com (click on the Home button in the Menu bar and then "Reference Formatting Instructions" document under "Files and Resources). Include the digital object identifier (DOI) with any journal article references and an accessed date with website references. Unpublished data, in-press items, personal communications, letters to the editor, theses, package inserts, submissions, meeting presentations, and abstracts may be included in the text but not in the reference list.

In addition, the American College of Obstetricians and Gynecologists' (ACOG) documents are frequently updated. These documents may be withdrawn and replaced with newer, revised versions. If you cite ACOG documents in your manuscript, be sure the references you are citing are still current and available. Check the Clinical Guidance page at https://www.acog.org/clinical (click on "Clinical Guidance" at the top). If the reference is still available on the site and isn't listed as "Withdrawn," it's still a current document.

If the reference you are citing has been updated and replaced by a newer version, please ensure that the new version supports whatever statement you are making in your manuscript and then update your reference list accordingly (exceptions could include manuscripts that address items of historical interest). If the reference you are citing has been withdrawn with no clear replacement, please contact the editorial office for assistance (obgyn@greenjournal.org). In most cases, if an ACOG document has been withdrawn, it should not be referenced in your manuscript.

16. Figure 1 may be resubmitted with the revision.

17. Each supplemental file in your manuscript should be named an "Appendix," numbered, and ordered in the way they are first cited in the text. Do not order and number supplemental tables, figures, and text separately. References cited in appendixes should be added to a separate References list in the appendixes file.

18. Authors whose manuscripts have been accepted for publication have the option to pay an article processing charge and publish open access. With this choice, articles are made freely available online immediately upon publication. An information sheet is available at http://links.lww.com/LWW-ES/A48. The cost for publishing an article as open access can be found at https://wkauthorservices.editage.com/open-access/hybrid.html.

If your article is accepted, you will receive an email from the editorial office asking you to choose a publication route (traditional or open access). Please keep an eye out for that future email and be sure to respond to it promptly.

If you choose open access, you will receive an Open Access Publication Charge letter from the Journal's Publisher, Wolters Kluwer, and instructions on how to submit any open access charges. The email will be from publicationservices@copyright.com with the subject line, "Please Submit Your Open Access Article Publication Charge(s)." Please complete payment of the Open Access charges within 48 hours of receipt.

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If you choose to revise your manuscript, please submit your revision through Editorial Manager at http://ong.editorialmanager.com. Your manuscript should be uploaded as a Microsoft Word document. Your revision's cover letter should include the following:
* A confirmation that you have read the Instructions for Authors (http://edmgr.ovid.com/ong/accounts/authors.pdf), and
* A point-by-point response to each of the received comments in this letter. Do not omit your responses to the Editorial Office or Editors' comments.

If you submit a revision, we will assume that it has been developed in consultation with your co-authors and that each author has given approval to the final form of the revision.

Again, your paper will be maintained in active status for 21 days from the date of this letter. If we have not heard from you by Jan 25, 2022, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

Jason D. Wright, MD
Editor-in-Chief

2020 IMPACT FACTOR: 7.661
2020 IMPACT FACTOR RANKING: 3rd out of 83 ob/gyn journals

In compliance with data protection regulations, you may request that we remove your personal registration details at any time. (Use the following URL: https://www.editorialmanager.com/ong/login.asp?a=r). Please contact the publication office if you have any questions.
RE: Manuscript Number ONG-21-2357R1

Association between Social Vulnerability and Achieving Glycemic Control among Pregnant Women with Pregestational Diabetes

Dear Dr. Venkatesh:

Thank you for resubmitting your revised manuscript. We appreciate your responsiveness to our prior comments. Your manuscript was discussed among the Editors and the Statistical Editor, and we had a few additional suggestions. Please respond to these queries at your earliest convenience.

Your paper will be maintained in active status for 7 days from the date of this letter. If we have not heard from you by Jan 18, 2022, we will assume you wish to withdraw the manuscript from further consideration.

STATISTICAL EDITOR:

First, I want to thank the Authors for their additional work on this paper.

Table 1: See comments re: Appendix, Table 1.

Appendix, Table 1: I think that this is more informative than the present Table 1 and would suggest making Appendix Table 1 the Table 1 in main text. As with the original Table 1, should compare statistically the differences in baseline characteristics across the SVI categories.

Appendices Table 2,3: Should include SD for the values in the Table, which I assume are mean values.

Appendix Table 5: Should include the "n" for each row category entry. Should include a column of unadjusted RR to contrast with the aRRs.

I think that the Appendix Fig 2 is important enough to be included in main text. However, I would urge including the actual individual entries (x,y) as well as the fitted model. Although statistically significant and important for groups, there remains much individual variability. I believe that format would convey that message as well as the "big picture". Also, please format the R² as usual in decimal form, rather than as %, lest it somehow were confused by the reader as referring to HbA1c levels.

Fig 1 in main text: Should format the R² in decimal format, not as %.

Sincerely,

Jason D. Wright, MD
Editor-in-Chief

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2020 IMPACT FACTOR RANKING: 3rd out of 83 ob/gyn journals

In compliance with data protection regulations, you may request that we remove your personal registration details at any time. (Use the following URL: https://www.editorialmanager.com/ong/login.asp?a=r). Please contact the publication office if you have any questions.
First, I want to thank the Authors for their additional work on this paper.

Thank you for this favorable review of our revision. We have accepted the prior version of edits made in bold in revision version #1, and the additional edits made below for revision #2 now appear in tracked changes format in the manuscript.

Table 1: See comments re: Appendix, Table 1.

We have made the requested edits below.

Appendix, Table 1: I think that this is more informative than the present Table 1 and would suggest making Appendix Table 1 the Table 1 in main text. As with the original Table 1, should compare statistically the differences in baseline characteristics across the SVI categories.

We have made the Appendix Table 1 the primary Table 1, and have removed the current Table 1 from the manuscript. We have added the statistical tests for comparison to Table 1 across quartiles. The text in the methods and results that describes these results across all four quartiles has been appropriately amended.

Please see revised paragraph describing these results in the manuscript (lines 251 to 263): “Individuals at a higher SVI quartile were more likely to have Medicaid insurance (≥75th percentile: 68% vs. <25th percentile: 21%; overall p<0.001), and be of minority race and ethnicity (for example, non-Hispanic Black ≥75th percentile: 50% vs. <25th percentile: 9%; overall p<0.001) compared to those at a lower SVI quartile (Table 1). Those at a higher SVI quartile were more likely to have type 2 diabetes (≥75th percentile: 81% vs. <25th percentile: 53%; overall p<0.001), and were less likely to be nulliparous (≥75th percentile: 34% vs. <25th percentile: 50%; overall p<0.001). Mean HbA1c in the second or third trimester increased with SVI quartile (75th percentile: 6.6% vs. <25th percentile: 6.2%; overall p<0.01), but not mean HbA1c in the periconception period. Age, tobacco use, chronic hypertension, and baseline hemoglobin varied by SVI quartile (overall p<0.05 for all). Albeit not significant, individuals with higher SVI scores had less severe diabetes as assessed by White classification. BMI, diabetes pharmacotherapy, and gestational age at delivery and at HbA1c assessment did not differ by SVI quartile.”

Appendices Table 2,3: Should include SD for the values in the Table, which I assume are mean values.

Yes, we have added that these values are means in the labels within both tables, and have also added standard deviations. For comparison, we also provide the overall (not stratified by HgbA1C) SVI scores.

Appendix Table 5: Should include the "n" for each row category entry. Should include a column of unadjusted RR to contrast with the aRRs.
We have added the “n” for each row category entry, and we have also included a separate column for the unadjusted RR.

I think that the Appendix Fig 2 is important enough to be included in main text. However, I would urge including the actual individual entries (x,y) as well as the fitted model. Although statistically significant and important for groups, there remains much individual variability. I believe that format would convey that message as well as the "big picture". Also, please format the R² as usual in decimal form, rather than as %, lest it somehow were confused by the reader as referring to HbA1c levels.

We have included Appendix Figure 2 as Figure 1b now in the manuscript. R² is listed in decimal form. We have added individual entries for the x and y at each 0.1 value of x (so total of 10 entries) for both figures 1a and figure 1b to be consistent. This can be reformatted by the editorial staff to further facilitate visual presentation.

Fig 1 in main text: Should format the R² in decimal format, not as %.

R² is listed in decimal form.