NOTICE: This document contains correspondence generated during peer review and subsequent revisions but before transmittal to production for composition and copyediting:

- 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.

Personal or nonessential information may be redacted at the editor’s discretion.

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

obgyn@greenjournal.org.
RE: Manuscript Number ONG-19-2050

Adverse Outcomes Among Low-Risk Term Pregnancies Stratified by Race and Ethnicity

Dear Dr. Parchem:

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).

Your paper will be maintained in active status for 14 days from the date of this letter. If we have not heard from you by Dec 19, 2019, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1:

Overall impression: I thought that this was a nicely written manuscript that focused on an important topic. The study approach is appropriate and there are some interesting findings. My main concern is with the use of the data source; i.e. that it may be suboptimal for evaluating many exposures and outcomes. I believe this manuscript would be strengthened by focusing on the neonatal outcomes which would be a more appropriate use of the data.

Introduction

The introduction is generally well written but is a little bit long and I have two specific comments:

First, I generally don’t think that the best lead in for these types of analyses is the assertion that non-white women are at higher risk for adverse outcomes than white women. While this is technically true (as risk among black women and neonates is particularly high), comparisons between white women and Hispanic and Asian women (the second and fourth largest racial/ethnic groups) generally show modest differentials with risk sometimes higher and sometimes lower among white women. It would be better and more accurate just to say that black women are at higher risk than everyone else. The authors get to this later in the introduction, but it would be cleaner just to focus on that from the start.

Second, while attribution of racial disparities to implicit bias is common in obstetric literature, data from social psychology increasingly points to implicit bias as not being a major predictor of behavior and outcomes. A recent meta-analysis found implicit bias accounted for only 2% of discriminatory behavior (PMID 27109866) and performed less well than measures of explicit bias. Given the current state of the IAT literature, it probably makes sense be more conservative in ascribing outcomes to implicit bias.

Methods

I am worried about using this data source for ascertainment of inclusion criteria in the study. Specifically, it’s not clear how well maternal conditions are captured in the birth certificate data. A better approach to ascertain maternal conditions would be to analyze linked discharge-birth certificate data.

Similarly, there are concerns with many of the study outcomes (particularly maternal) that may be under-ascertained using birth certificate data. Many birth certificate fields are relatively high quality (such as gestational age), but the inferences from this study depend on many variables that may be poor quality.

I like that this study used Poisson models to estimate relative risk.
Results
The most interesting results of this analysis are the neonatal outcomes including differentials in LBW and neonatal and infant death rates.

The maternal outcome differentials, however, aren't particularly believable. They don't line up with clinical and administrative data. This could be because this is a low-risk cohort, but another possibility is that this is just a poor data source for evaluating these outcomes.

Discussion
I found this study interesting in part because many of the findings were counterintuitive. I disagree with the authors that the adjusted RR for the neonatal composite for black compared to white women (1.07) represents a meaningful disparity given the effect size and that this is administrative data and there were many factors that could not be accounted for. Black women were at higher risk for SGA, low Apgars, and infant death.

The differentials between white women and Hispanic and Asian women were interesting - it is unclear why Hispanic women in particular were at much lower risk for many outcomes. I was also surprised that low Apgars and seizures were higher among white compared to black women.

Page 13 line 209-226 - I think it’s hard to make inferences with the maternal data. The birth certificates are just not a great source of maternal data.

A major takeaway from this analysis for me was that how race relates to neonatal outcomes is more complicated than maternal disparities wherein black women experience consistently worse outcomes across a broad range of clinical circumstances. I think that the discussion would be improved by focusing more on this, rather than on inferences from the maternal disparities analysis.

Reviewer #2: This population-based cohort study effectively examines the differences in maternal and neonatal outcomes based on maternal race and ethnicity.

Specific Comments:
Line 93: Appreciate the use of a nationwide database to improve the generalizability of the study
Line 97: Why include only women who labor?
Line 111: STROBE guidelines followed
Line 225: I am unclear why transfusion needs to be excluded.

Reviewer #3: Thank you for your work. Specific comments:
Title: I was expecting to hear about maternal outcomes based on this title. I would note that you look at infant and maternal outcomes.
Precis: This reads a bit awkwardly. Need to mention maternal outcomes too as based on this I would believe the article is about neonatal outcomes only.
Abstract: The only comment is that I would include the fact that you look at neonatal and maternal outcomes in the objective sentence.
Introduction: lines 83-9 In this paragraph I believe you are making the claim for doing your study, however I am not sure I believe that there is a larger lack of data in this group, as most studies I have read of maternal health disparities account/control for preterm birth and maternal comorbidities, and many do the analysis on patient's without comorbidities as well.
Methods: The glaring question is why you did not look at maternal mortality as this is known to be different among different racial groups in the US. With data on 9million+ women, you should be able to study this outcome.
Is there information available on the accuracy of this data set? What level of error in data entry and attribution is known to exist?

How much data was missing and categorized as "unknown"?

As you divide out neonatal and infant mortality in results, please put here what definitions you used (even if they are "standard")

When you did the adjusted model, how did you test what factors were significant and stayed in the model? Did you just include all?

Results:
Line 144-5 I would mention here what % were excluded due to unknown race.

Line 159: remove interestingly

You give us results as adjusted RR but only in the legend of table 3 do you note what was adjusted for, this should be mentioned here or in methods.

Discussion:
Lines 217-20: this assumption has been disproven in other studies which show even after adjusting for these factors black women have higher rates of adverse outcomes. Why does your data differ?

STATISTICAL EDITOR COMMENTS:

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

lines 92-93: Should provide a reference or link to the data base. Why were data from 2018 not included?

lines 95-101: Should include a flow diagram with inclusion/exclusion groups.

Table 2: Need to identify the counts of the adverse outcomes for the various groups, so that the RRs and aRRs can be put into context. I would suggest either including the material in Table 1 or including Supplemental Table 1 as a Table in main text. The rates per 10,000 births should also include CIs.

Table 3: Similar comment re: the counts for adverse maternal outcomes and including this material in main text. Need to include CIs for the rates per 10,000.

Table 4: Need to include CIs for the rates per 10,000.

Figs 2, 3: Probably not needed after inclusion of supplemental Tables, but if were to include, should include a concise description of the stats and need to include CIs to the histograms.

EDITOR COMMENTS:

1. The Editors of Obstetrics & Gynecology are seeking to increase 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. As of December 17, 2018, Obstetrics & Gynecology has implemented an "electronic Copyright Transfer Agreement" (eCTA) and will no longer be collecting author agreement forms. When you are ready to revise your manuscript, you will be prompted in Editorial Manager (EM) to click on "Revise Submission." Doing so will launch the resubmission process, and you will be walked through the various questions that comprise the eCTA. Each of your coauthors will receive an email from the system requesting that they review and electronically sign the eCTA.

Please check with your coauthors to confirm that the disclosures listed in their eCTA forms are correctly disclosed on the
3. Please submit a STROBE statement that includes the page numbers where each item appears. You may write this in the margin.

4. 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 and gynecology data definitions at https://www.acog.org/About-ACOG/ACOG-Departments/Patient-Safety-and-Quality-Improvement/reVITALize. If use of the reVITALize definitions is problematic, please discuss this in your point-by-point response to this letter.

5. 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 22 typed, double-spaced pages (5,500 words). Stated page limits include all numbered pages in a manuscript (i.e., title page, précis, abstract, text, references, tables, boxes, figure legends, and print appendixes) but exclude references.

6. 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).

7. 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 limits for different article types are as follows:

- Original Research articles, 300 words. Please provide a word count.

8. 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.

9. 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.

10. 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.

If appropriate, please include number needed to treat for benefits (NNTb) or harm (NNTh). When comparing two procedures, please express the outcome of the comparison in U.S. dollar amounts.

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%)

11. 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.

12. 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 reference you are citing is still current and available. If the reference you are citing has been updated (i.e., 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 (exceptions could include manuscripts that address items of historical interest). All ACOG documents (eg, Committee Opinions and Practice Bulletins) may be found via the Clinical Guidance & Publications page at https://www.acog.org/Clinical-Guidance-and-Publications/Search-Clinical-Guidance.

13. Figures 1–3: Please upload as separate figure files on Editorial Manager. If possible, please upload the original figure file (eps, tiff, jpeg), rather than pasting into a Word document.

14. 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 http://edmgr.ovid.com/acd/accounts/ifauth.htm.

Please note that 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.

15. If you choose to revise your manuscript, please submit your revision through Editorial Manager at http://ong.editorialmanager.com. Your manuscript should be uploaded in a word processing format such as Microsoft Word. 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.

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 14 days from the date of this letter. If we have not heard from you by Dec 19, 2019, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

Nancy C. Chescheir, MD
Editor-in-Chief

2018 IMPACT FACTOR: 4.965
2018 IMPACT FACTOR RANKING: 7th 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.
December 16, 2019

Nancy C. Chescheir, MD
Editor-in-Chief
Obstetrics & Gynecology

Re: ONG-19-2050 - Revised submission of manuscript, “Adverse Outcomes Among Low-Risk Term Pregnancies Stratified by Race and Ethnicity”

Dear Dr. Chescheir,

Thank you for the opportunity to revise our manuscript. We appreciate the constructive comments from the reviewers and editors. The comments are addressed in a point-by-point response below. Relevant changes in the text are highlighted in the document using “track changes” and referenced in the response using the line numbers of the revised manuscript. We have also attached the STROBE guidelines as requested.

As the lead author, I have read the Instructions for Authors and I affirm that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned have been explained.

All authors have approved this revision. We hope the revised version is suitable for publication in Obstetrics & Gynecology. Thank you for your consideration.

Sincerely,

Jacqueline G. Parchem, MD
Response to *Obstetrics & Gynecology* Decision Letter for Manuscript Number ONG-19-2050

**REVIEWER COMMENTS:**

**Reviewer #1:**

1. Overall impression: I thought that this was a nicely written manuscript that focused on an important topic. The study approach is appropriate and there are some interesting findings. My main concern is with the use of the data source; i.e. that it may be suboptimal for evaluating many exposures and outcomes. I believe this manuscript would be strengthened by focusing on the neonatal outcomes which would be a more appropriate use of the data.

**Response:** We appreciate the reviewer’s compliment and concerns. While the accuracy of some of the outcomes may not be optimally reliable, prior reports have utilized similar adverse outcomes (e.g. Chen et al, *Obstet Gynecol* 2019, doi: 10.1097/AOG.0000000000003372). Importantly, as exemplified by the ARRIVE study (Grobman et al, *N Engl J Med* 2018, doi: 10.1056/NEJMoa1800566), population-based analyses provide directionality of untoward outcomes, which may be confirmed in randomized trials. We address the limitations of the data source in the revised Discussion (lines 246-256).

**Introduction**

The introduction is generally well written but is a little bit long and I have two specific comments:

2. First, I generally don’t think that the best lead in for these types of analyses is the assertion that non-white women are at higher risk for adverse outcomes that white women. While this is technically true (as risk among black women and neonates is particularly high), comparisons between white women and Hispanic and Asian women (the second and fourth largest racial/ethnic groups) generally show modest differentials with risk sometimes higher and sometimes lower among white women. It would be better and more accurate just to say that black women are at higher risk than everyone else. The authors get to this later in the introduction, but it would cleaner just to focus on that from the start.

**Response:** We appreciate this feedback and have revised the Introduction to incorporate this suggestion (lines 65-67): “In the U.S., the rate of pregnancy-related death for black mothers exceeds rates for all other racial and ethnic groups.”

3. Second, while attribution of racial disparities to implicit bias is common in obstetric literature, data from social psychology increasingly points to implicit bias as not being a major predictor of behavior and outcomes. A recent meta-analysis found implicit bias accounted for only 2% of discriminatory behavior (PMID 27109866) and performed less well than measures of explicit bias. Given the current state of the IAT literature, it probably makes sense be more conservative in ascribing outcomes to implicit bias.

**Response:** Thank you for this comment. We list implicit bias as a potential contributor to racial disparities, and do not mean to imply that it is a major contributor or that we know the extent to which it influences health disparities in maternal care. We have revised the Introduction to clearly state that the relative contribution of potential causes of disparities is uncertain. In lines 78-79, we state: “The extent to which each of these factors impacts pregnancy outcome is uncertain.”
Nonetheless, there are many examples in the medical literature supporting the notion that implicit bias impacts patients and the care they receive (e.g. Cooper et al, *Am J Public Health* 2012, doi: 10.2105/AJPH.2011.300558; Hoffman et al, *Proc Natl Acad Sci* 2016, doi: 10.1073/pnas.1516047113; Institute of Medicine 2003, doi:10.17226/12875). Importantly, implicit bias manifests in multiple ways, making it difficult to recognize and measure (Williams et al, *JAMA* 2015, doi:10.1001/jama.2015.9260). Indeed, the meta-analysis cited by the reviewer suggests that outcome measures used in implicit bias research are not reliable measures of discrimination, and may not be reliable for assessing the predictive ability of the Implicit Association Test (IAT), which is weakly correlated with discrimination (Carlsson et al, *Scand J Psychol* 2016, doi: 10.1111/sjop.12288). This meta-analysis does not refute the claim that implicit bias may be an important factor, but rather focuses on the deficiencies of the current tools used for measuring bias and reporting its impact.

Methods

4. I am worried about using this data source for ascertainment of inclusion criteria in the study. Specifically, it’s not clear how well maternal conditions are captured in the birth certificate data. A better approach to ascertain maternal conditions would be to analyze linked discharge-birth certificate data.

**Response:** We appreciate the reviewer’s comment regarding the validity of the study outcomes, particularly with respect to maternal outcomes, and have included additional references on this topic. We acknowledge the limitations of the National Vital Statistics System birth certificate data in the revised Discussion (lines 246-254):

“This analysis was limited to the variables reported in the U.S. vital statistics data sets, which lack detailed clinical information. Since some clinical variables and outcomes are likely underreported in the data set, the credibility of analyses using birth certificate data has been disputed. However, studies of birth certificate data have consistently shown that maternal demographic data and certain clinical details (e.g. mode of delivery and birth weight) are collected with a high degree of completeness and accuracy, although research assessing the validity of maternal outcomes is lacking. Nevertheless, the American College of Obstetricians and Gynecologists (ACOG) recognizes the importance of the vital statistics data as an integral tool for quality improvement and measurements of quality of care.”

As the CDC does not have discharge data, it was not possible to link discharge and birth certificate data in this study.

5. Similarly, there are concerns with many of the study outcomes (particularly maternal) that may be under-ascertained using birth certificate data. Many birth certificate fields are relatively high quality (such as gestational age), but the inferences from this study depend on many variables that may be poor quality.

**Response:** See response to Point 4 above.

6. I like that this study used Poisson models to estimate relative risk.

**Response:** Thank you. We appreciate the compliment.
Results

7. The most interesting results of this analysis are the neonatal outcomes including differentials in LBW and neonatal and infant death rates.

Response: Thank you for the compliment. These results are highlighted in the Discussion (lines 207-227).

8. The maternal outcome differentials, however, aren't particularly believable. They don't line up with clinical and administrative data. This could be because this is a low-risk cohort, but another possibility is that this is just a poor data source for evaluating these outcomes.

Response: We agree that our study results may be due in part to the low-risk cohort. Studies using administrative databases to identify maternal morbidities based on ICD9-CM codes also have limitations, as these data are gathered for billing and other administrative purposes and do not provide detailed, patient-level clinical information. We acknowledge the limitations of the vital statistics data in the revised Discussion (lines 246-254). Please also see response to Point 4 above.

Discussion

9. I found this study interesting in part because many of the findings were counterintuitive. I disagree with the authors that the adjusted RR for the neonatal composite for black compared to white women (1.07) represents a meaningful disparity given the effect size and that this is administrative data and there were many factors that could not be accounted for. Black women were at higher risk for SGA, low Apgars, and infant death.

Response: We agree that the effect size is small. However, the relative risk points in the direction of increased risk, even among low-risk pregnancies. Of course, we need more population-based studies to reinforce these findings. We have revised the Discussion to incorporate the reviewer’s points (lines 207-214):

“Our findings reporting the trend of adverse neonatal outcomes and infant mortality are consistent with prior reports showing that infants of black women are at higher risk for mortality and complications associated with low birth weight, although the magnitude of the risk increase for the composite neonatal outcome was relatively small after adjustment for confounders. In our cohort, infants of black women had the highest rates of SGA (16.9% vs. 8.1% for white) and early term deliveries (29.1% vs. 21.8% for white), both of which are known risk factors for adverse neonatal outcomes43,44 and may in part explain the observed disparity.”

10. The differentials between white women and Hispanic and Asian women were interesting - it is unclear why Hispanic women in particular were at much lower risk for many outcomes. I was also surprised that low Apgars and seizures were higher among white compared to black women.

Response: We also found these results interesting. The finding of lower risk for Hispanic women is consistent with prior studies as cited in the manuscript (references 17, 29, and 35).

11. Page 13 line 209-226 - I think it's hard to make inferences with the maternal data. The birth certificates are just not a great source of maternal data.
Response: We acknowledge the limitations of birth certificate data. Please see response to Point 4 above. With limited data resources available for the study of maternal morbidity, particularly from a population-based perspective, our study provides valuable information for future research on this topic.

12. A major takeaway from this analysis for me was that how race relates to neonatal outcomes is more complicated than maternal disparities wherein black women experience consistently worse outcomes across a broad range of clinical circumstances. I think that the discussion would be improved by focusing more on this, rather than on inferences from the maternal disparities analysis.

Response: Thank you. We agree and have emphasized the neonatal outcomes in the Discussion (lines 207-227). We also discuss in more depth the limitations of using these data for maternal morbidity (246-258).

Reviewer #2:

This population-based cohort study effectively examines the differences in maternal and neonatal outcomes based on maternal race and ethnicity.

Specific Comments:

1. Line 93: Appreciate the use of a nationwide database to improve the generalizability of the study

Response: Thank you. This is a major strength of the vital statistics data.

2. Line 97: Why include only women who labor?

Response: The primary reason we included only women who labored was that we wanted to be consistent with recent studies of low-risk term pregnancies (e.g. Chen et al, Obstet Gynecol 2019, doi: 10.1097/AOG.0000000000003372; Grobman et al, N Engl J Med 2018, doi: 10.1056/NEJMoa1800566), which excluded planned cesarean deliveries. Additionally, women who labor are a discrete group of low-risk pregnancies which makes the comparison with prior publications more meaningful.

3. Line 111: STROBE guidelines followed

Response: Yes, STROBE guidelines were followed.

4. Line 225: I am unclear why transfusion needs to be excluded.

Response: We conducted a sensitivity analysis to ascertain whether the associations of composite maternal adverse outcome persisted after excluding transfusion due to caveats associated with this outcome variable: 1) We did not have information regarding the number of units transfused; 2) transfusion of 1-2 units may be falsely recorded (Main et al, Am J Obstet Gynecol 2015, doi: 10.1016/j.ajog.2015.11.004); 3) previous research has demonstrated large variability in transfusions based on physician practice, therefore, transfusion of < 4 units may not represent severe morbidity (Callaghan et al, Obstet Gynecol 2014, doi: 10.1097/AOG.0000000000000218; Kilpatrick et al, Obstet Gynecol 2014, doi: 10.1097/AOG.0000000000000397). In addition, we wanted to be congruent with other
publications on the topic (Chen et al, Obstet Gynecol 2019, doi: 10.1097/AOG.0000000000003372). This is clarified in the revised Methods (lines 144-148):

“Due to missing details about blood transfusion, such as number of units transfused and indication, and the reported limitations of transfusion as a measure of severe maternal morbidity, we also performed a sensitivity analysis to examine the association between race and composite maternal adverse outcome without blood transfusion.”

Reviewer #3:

Thank you for your work. Specific comments:

1. Title: I was expecting to hear about maternal outcomes based on this title. I would note that you look at infant and maternal outcomes.

Response: The title has been modified to, “Adverse Infant and Maternal Outcomes Among Low-Risk Term Pregnancies Stratified by Race and Ethnicity”.

2. Precis: This reads a bit awkwardly. Need to mention maternal outcomes too as based on this I would believe the article is about neonatal outcomes only.

Response: The Precis has been revised: “Among low-risk term deliveries, infants of black women were more likely to experience adverse outcomes; Asian women were at highest risk for maternal adverse outcomes.”

Abstract:

3. The only comment is that I would include the fact that you look at neonatal and maternal outcomes in the objective sentence.

Response: We appreciate the reviewer’s comment and have revised the objective (lines 36-37): “To assess whether racial and ethnic disparities in adverse infant and maternal outcomes exist among low-risk term pregnancies.”

4. Introduction: lines 83-9 In this paragraph I believe you are making the claim for doing your study, however I am not sure I believe that there is a larger lack of data in this group, as most studies I have read of maternal health disparities account/control for preterm birth and maternal comorbidities, and many do the analysis on patients without comorbidities as well.

Response: We agree that most studies on maternal health disparities have included high-risk pregnancies and report results from adjusted analyses, which is different than our approach of straightforwardly analyzing population data to obtain contemporary estimates for adverse outcomes among low-risk pregnancies by race.

Methods:

5. The glaring question is why you did not look at maternal mortality as this is known to be different among different racial groups in the US. With data on 9million+ women, you should be able to study this outcome.
Response: We appreciate this comment and agree that maternal mortality is an important and germane outcome. Unfortunately, maternal mortality is not included in the birth certificate data and currently it is not feasible to link the birth certificate data with other data sources.

6. Is there information available on the accuracy of this data set? What level of error in data entry and attribution is known to exist?


7. How much data was missing and categorized as "unknown"?

Response: Please see Figure 1 for details about women who were excluded (3.9% excluded for “other” or “unknown” race and ethnicity). Table 1 details the number of women for whom the demographic and clinical variables were unknown (ranged from 0-3%).

8. As you divide out neonatal and infant mortality in results, please put here what definitions you used (even if they are "standard")

Response: Thank you for identifying this oversight. Our study follows the CDC definitions for neonatal and infant mortality (https://www.cdc.gov/nchs/products/databriefs/db326.htm), which are included in the revised Methods (lines 123 and 126).

9. When you did the adjusted model, how did you test what factors were significant and stayed in the model? Did you just include all?

Response: We first examined the association between individual maternal characteristics and race/ethnicity (Table 1) Then, based on prior literature and clinical knowledge and to avoid over-adjustment, we selected potential confounders to include in the multivariable model. This has been clarified in the revised Methods (lines 143-144): “Selection of potential confounders was based upon differences in maternal characteristics, as well as prior literature and clinical knowledge.”

Results:

10. Line 144-5 I would mention here what % were excluded due to unknown race.

Response: Done.

11. Line 159: remove interestingly

Response: Done.

12. You give us results as adjusted RR but only in the legend of table 3 do you note what was adjusted for, this should be mentioned here or in methods.

Response: This information was provided in the Methods of the initial submission of the manuscript (lines 132-142 of the revision).
Discussion:

13. Lines 217-20: this assumption has been disproven in other studies which show even after adjusting for these factors black women have higher rates of adverse outcomes. Why does your data differ?

Response: In the adjusted analysis, the risk for the composite maternal adverse outcome was not significantly increased among Black mothers. The reasons for this finding are uncertain. We speculate that this might be due to inclusion of only low-risk women. In addition, as we state in the Discussion and in the responses here, the vital statistics data are limited with respect to maternal outcomes. Severe morbidities, such as postpartum hemorrhage and peripartum infection, are not captured, therefore, differences from prior studies may also be related to differences in data source and definitions of composite maternal morbidity.

STATISTICAL EDITOR COMMENTS:

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

1. lines 92-93: Should provide a reference or link to the data base. Why were data from 2018 not included?

Response: We have included a link to the database in the Methods (line 101). The Period Linked Birth-Infant Death Data File is only available through 2017; the 2018 data have not been released yet.

2. lines 95-101: Should include a flow diagram with inclusion/exclusion groups.

Response: The flow diagram is presented in Figure 1.

3. Table 2: Need to identify the counts of the adverse outcomes for the various groups, so that the RRs and aRRs can be put into context. I would suggest either including the material in Table 1 or including Supplemental Table 1 as a Table in main text. The rates per 10,000 births should also include CIs.

Response: The revised Tables now include the counts, CIs and rates per 10,000 as suggested (revised Tables 2, 3, and 4).

4. Table 3: Similar comment re: the counts for adverse maternal outcomes and including this material in main text. Need to include CIs for the rates per 10,000.

Response: Please see response to Point 3 above.

5. Table 4: Need to include CIs for the rates per 10,000.

Response: Done.

6. Figs 2, 3: Probably not needed after inclusion of supplemental Tables, but if were to include, should include a concise description of the stats and need to include CIs to the histograms.

Response: We agree. The Tables have been revised as suggested above. We have removed Figures 2 and 3 in the revision.
EDITOR COMMENTS:

1. The Editors of Obstetrics & Gynecology are seeking to increase 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.

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Response: OPT-IN

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3. Please submit a STROBE statement that includes the page numbers where each item appears. You may write this in the margin.

4. 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 and gynecology data definitions at https://urldefense.proofpoint.com/v2/url?u=https-3A__www.acog.org_About-2DACOG_ACOG-2DDepartments_Patient-2DSafety-2Dand-2DQuality-2DImprovement_reVITALize&d=DwIGaQ&c=bKRySV-ouEg_AT-w2QWsTdd9X___KYh9Eq2fdmQDVZgw&r=Gn01jcBpFgl70VQJduxmj3EyMa9d2S1eBrjv2CThv8Y&m=sPyyV9Q-vp0lyW0CL5NhdgAkJ81ZSlQcZVIYaSxY07U&s=8bc9W_Wv6KtJ5oZMVZNZf9KkoTQfJxxKYLP4Ne SU&e=. If use of the reVITALize definitions is problematic, please discuss this in your point-by-point response to this letter.

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