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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.*

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.

Date: Aug 18, 2022
To: "Torri Derback Metz" [redacted]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-22-1427

RE: Manuscript Number ONG-22-1427

Association Between Giving Birth During the Early COVID-19 Pandemic and Serious Maternal Morbidity

Dear Dr. Metz:

Thank you for sending us your updated manuscript for consideration for publication in Obstetrics & Gynecology. Your manuscript has been reviewed by the Statistical Editor. When you submit your revision, please address his comments below.

STATISTICAL EDITOR COMMENTS:

lines 7-8, 272-273 et al: Although the composite endpoint includes both morbidity and mortality, there were no mortalities reported in this series. One cannot generalize from these data whether there was any change in mortality associated with Covid-19. Language should be added to precis, results and discussion to clarify that this study's results cannot be extrapolated to state that Covid-19 was or was not associated with increased mortality. There is insufficient stats power, a much larger sample would be required to conclude that.

lines 270-271: What are the criteria for establishing whether a RR ≥ 1.15 would be clinically meaningful? Although a minority of patients, that represents ~ 1.3% absolute increase in proportion of women with composite morbidity, or ~ 160 women out of the N = 12,133 cohort. Does not seem trivial.

EDITOR'S COMMENTS:

Please revise manuscript, beyond the discussion, to reflect that differences in mortality cannot be determined when there are none in either group.

EDITORIAL OFFICE COMMENTS:

1. If your article is accepted, the journal will publish a copy of this revision letter and your point-by-point responses as supplemental digital content to the published article online. You may opt out by writing separately to the Editorial Office at em@greenjournal.org, and only the revision letter will be posted.

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:
* Funding information (ie, grant numbers or industry support statements) should be disclosed on the title page and at the end of the abstract. For industry-sponsored studies, describe on the title page how the funder was or was not involved in the study.
* 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's Copyright Transfer Agreement (CTA) must be completed by all authors. When you uploaded your manuscript, each coauthor received an email with the subject, "Please verify your authorship for a submission to Obstetrics & Gynecology." Please ask your coauthor(s) to complete this form, and confirm the disclosures listed in their CTA are included on the manuscript's title page. If they did not receive the email, they should check their spam/junk folder. Requests to resend the CTA may be sent to em@greenjournal.org.

4. ACOG uses person-first language. Please review your submission to make sure to center the person before anything else. Examples include: "People with disabilities" or "women with disabilities" instead of "disabled people" or "disabled women"; "patients with HIV" or "women with HIV" instead of "HIV-positive patients" or "HIV-positive women"; and "people who are blind" or "women who are blind" instead of "blind people" or "blind women."

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6. Responsible reporting of research studies, which includes a complete, transparent, accurate and timely account of what was done and what was found during a research study, is an integral part of good research and publication practice and not an optional extra. Obstetrics & Gynecology supports initiatives aimed at improving the reporting of health research, and we ask authors to follow specific guidelines:

STROBE: observational studies

Include the appropriate checklist for your manuscript type upon submission, if applicable, and indicate in your cover letter which guideline you have followed. Please write or insert the page numbers where each item appears in the margin of the checklist. Further information and links to the checklists are available at www.equator-network.org/.

7. Make sure your manuscript meets the following word limit. The word limit includes the manuscript body text only (for example, the Introduction through the Discussion in Original Research manuscripts), and excludes the title page, précis, abstract, tables, boxes, and figure legends, reference list, and supplemental digital content. Figures are not included in the word count.

Original Research: 3,000 words

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* 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 or indicate whether the meeting was held virtually).
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* Do not use only authors' initials in the acknowledgement or Financial Disclosure; spell out their names the way they appear in the byline.

9. Be sure that each statement and any data in the abstract are also stated in the body of your manuscript, tables, or figures. Statements and data that appear in the abstract must also appear in the body text for consistency. Make 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 manuscript.

In addition, the abstract length should follow journal guidelines. Please provide a word count.

Original Research: 300 words

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Please make sure your references are numbered in order of appearance in the text.

12. Figures: The current figure files may be resubmitted as-is, unless there are requested changes from the Statistical Editor.

13. 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.

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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.

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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 a point-by-point response to each of the received comments in this letter. Do not omit your responses to the EDITOR COMMENTS (if applicable), the REVIEWER COMMENTS, the STATISTICAL EDITOR COMMENTS (if applicable), or the EDITORIAL OFFICE COMMENTS.

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

Again, your manuscript will be maintained in active status for 21 days from the date of this letter. If we have not heard from you by Sep 08, 2022, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

Ebony B. Carter, MD, MPH
Associate Editor, Equity

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Dear Dr. Carter,

Thank you for your ongoing consideration of our submission for publication in *Obstetrics and Gynecology*. Please see responses to the statistical editor and editor comments below.

Sincerely,

Torri Metz, MD

STATISTICAL EDITOR COMMENTS:

lines 7-8, 272-273 et al: Although the composite endpoint includes both morbidity and mortality, there were no mortalities reported in this series. One cannot generalize from these data whether there was any change in mortality associated with Covid-19. Language should be added to precis, results and discussion to clarify that this study's results cannot be extrapolated to state that Covid-19 was or was not associated with increased mortality. There is insufficient stats power, a much larger sample would be required to conclude that.

Response: We understand the lack of ability to discern a difference in maternal death. However, this was part of our primary composite outcome. We have kept it as part of the primary composite outcome as registered on clinicaltrials.gov. We have removed maternal death from the precis and from the conclusions of the abstract. We have also added specifically in the abstract that there were no maternal deaths observed in our cohort.

"No maternal deaths were observed."

The finding of no maternal deaths was included in the prior manuscript version (both as text on p.14 of the results and in Table 2 in which no RR is reported as we recognize that no comparison can be made). We added verbiage stating more specifically that the lack of maternal deaths precluded comparison for this component of the primary outcome on p. 14:

"There were no maternal deaths in either group which precluded comparison for this component of the primary outcome."

We have also added a reference to a study that did show a difference in maternal deaths during the pandemic, and now have a full paragraph that addresses this issue in the Discussion on p. 16:

"Notably, there were no maternal deaths in our cohort on the randomly selected delivery dates through 42 days postpartum. Given that maternal death is a rare outcome, we did not have a sufficient sample size to examine this component of the composite individually. Larger studies are required to examine maternal mortality at the population level, as there are initial concerning findings for an increase in maternal mortality during the pandemic. Our study also does not examine pregnancy-related deaths through 1 year postpartum as recommended by the Centers for Disease Control and Prevention, as there are cases in which pregnancy initiates a chain of events resulting in death later than our examined window of 42 days postpartum."

lines 270-271: What are the criteria for establishing whether a RR ≥ 1.15 would be clinically meaningful? Although a minority of patients, that represents ~ 1.3% absolute increase in proportion of women with composite morbidity, or ~ 160 women out of the N = 12,133 cohort. Does not seem trivial.

Response: Thank you for raising this issue. We have removed the language about a clinically meaningful difference given the statistical editor's concerns, and now just have the previously requested post hoc power calculation. We will allow the reader to determine if they consider this to be a clinically meaningful difference since this is subjective rather than making that judgment ourselves.

EDITOR'S COMMENTS:

Please revise manuscript, beyond the discussion, to reflect that differences in mortality cannot be determined when there are none in either group.

Response: Please see responses to the statistical editor above. This information appears in the abstract, results text, and table 2 (RR not calculated in table 2 for that component of the primary outcome as it is not possible to calculate it). There is also a new paragraph in the discussion that focuses on maternal mortality.

EDITORIAL OFFICE:

Response: All bullets points were reviewed. We opt in to publishing our point by point responses to the reviewers' comments. A STROBE checklist was uploaded with this revision. Additional minor, "track changes" edits were made to reduce the length of the manuscript to 3000 words. Abstract length was edited to reduce length to 300 words. If accepted, we plan to use the standard publishing route (not open access).