

OBSTETRICS & GYNECOLOGY



NOTICE: This document contains comments from the reviewers and editors generated during peer review of the initial manuscript submission and sent to the author via email.

Questions about these materials may be directed to the *Obstetrics & Gynecology* editorial office:
obgyn@greenjournal.org.

Date: Apr 25, 2022
To: "Angela Rose Seasely" [REDACTED]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-22-607

RE: Manuscript Number ONG-22-607

Maternal and Perinatal Outcomes Associated With The Omicron Variant of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Disease

Dear Dr. Seasely:

Thank you for your submission to Obstetrics & Gynecology. The Editors reviewed your manuscript and believe that it will be acceptable for publication if you can address the comments below. Given the public health importance of your work, we would like to include your article as a fast track publication that is immediately available to our readership. As such, I would ask if you could resubmit your revisions within 7 days.

If you wish to revise your manuscript, please read the following comments submitted by the reviewers and Editors. Each point raised requires a response, by either revising your manuscript or making a clear argument as to why no revision is needed in the cover letter.

To facilitate our review, we prefer that the cover letter you submit with your revised manuscript include each reviewer and Editor comment below, followed by your response. That is, a point-by-point response is required to each of the EDITOR COMMENTS (if applicable), REVIEWER COMMENTS, STATISTICAL EDITOR COMMENTS (if applicable), and EDITORIAL OFFICE COMMENTS below. Your manuscript will be returned to you if a point-by-point response to each of these sections is not included.

The revised manuscript should indicate the position of all changes made. Please use the "track changes" feature in your document (do not use strikethrough or underline formatting).

Your submission will be maintained in active status for 7 days from the date of this letter. If we have not heard from you by May 02, 2022, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1: The authors of this research letter state that they previously published early findings of serious morbidity and adverse perinatal outcomes associated with the delta variant in pregnancy, and now seek to report differences in perinatal outcomes between the three main variants to date: patients were categorized as pre-delta (3/22/2020-5/31/2021), delta (7/1/2021-12/15/2021) or omicron (12/16/21-2/26/22). Their findings indicate that severe acute respiratory syndrome coronavirus 2 (SARS-Cov-2) omicron variant was associated with a lower frequency of critical illness and adverse perinatal outcomes compared to pre-delta and delta variants.

The following are my questions and comments for the authors:

1. It may be helpful for the reader to state whether patients were categorized based on timeline or on sequencing, or both? How was discordancy, if any, handled between timeline and sequencing?
2. The authors describe a peak We peak of pregnant patients with COVID-19 infection in January 2022 when the omicron variant was predominant. It may be helpful to the reader for the authors to explain the possible reasons for this finding?
3. The authors state that overall, 50% of cases were diagnosed on routine pre-procedure screening (i.e. asymptomatic) during the pre-delta and omicron waves whereas only 15% of the delta variant were diagnosed on routine screening (i.e. the remainder were symptomatic). In the Discussion section, can the authors offer the reader their thoughts on the reason for this pattern?
4. The authors state that when considering only unvaccinated patients in the omicron wave compared with delta and pre-delta cohorts, findings were consistent with the overall analysis (data not shown). In the Discussion section, can the authors offer the reader their thoughts on the reason for this pattern in the unvaccinated cohorts?

5. Addressing #3 would further strengthen the concluding statement: "Given our large number of vaccinated omicron patients experiencing mild illness, we encourage pregnant patients to follow guidelines for booster vaccinations. We continue to emphasize the importance of vaccinating all pregnant patients to mitigate severe perinatal morbidity and mortality due to unknown risks of adverse outcomes associated with new and future viral variants."

Reviewer #2:

Introduction:

#11

Did the authors mean 2020?

Methods:

#20-21

"Based on the subsets of pregnant patients who underwent viral genome": what proportion of patients did not undergo sequencing? i.e., got excluded?

#23

I'm not sure the author can comment on the hospital presentation rate based on the provided data. Too many variables could interfere with the hospital presentation rate (e.g., availability of home testing kits, vaccination status, evolving health literacy over time within the population).

Results:

#30-34

Please see the last comment from Methods.

42-44

There is no mention of these outcomes in your Methods.

#47-49

I'm not sure I understand this phrase. Please consider rephrasing.

Discussion:

The discussion should be focused on your primary objective: " seek to report differences in perinatal outcomes between the three main variants to date."

Alternatively, please provide additional data regarding the outcomes in vaccinated/ unvaccinated, including within the delta variant, so that the discussion can be congruent with your objective/ analysis.

STATISTICAL EDITOR COMMENTS:

lines 10-14: How many of the cases in this series had sequencing done to confirm the variant, or were the dates cited based on community definitions of predominant strain?

lines 31-34: Since the criteria for screening differed during the three time periods, one can report, but not compare, rates of asymptomatic/symptomatic or serious requiring hospitalization or ICU admission. Those results would be statistically biased due to differential ascertainment of all cases.

lines 34-38: Differential rates of escalated care and evolving treatments during Covid also complicates direct comparison of rates of ICU admission, treatments or outcomes.

45-49: Should include those data in supplemental material. As noted by the Authors, vaccination had a profound effect on probability of severe disease. Should include a summary in main text, with complete data in supplemental material. Additionally, no data are provided re: history of prior Covid infection or titers from infections. With each successive wave, the virus was more transmissible, but also a larger proportion of the community would have been infected and potentially have some measure of acquired immunity, again complicating comparison of successive waves.

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: "Patients with obesity" instead of "obese patients," "Women with disabilities" instead of "disabled women," "women with HIV" instead of "HIV-positive women," "women who are blind" instead of "blind women."

5. Please add whether you received IRB or Ethics Committee approval or exemption to your Methods. Include the name of the IRB or Ethics Committee. If you received an exemption, explain why in this section.

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. 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.

8. 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.

Research Letters: 600 words (do not include more than two figures and/or tables [2 items total])

9. Specific rules govern the use of acknowledgments in the journal. Please review the following guidelines and edit your title page as needed:

- * 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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10. 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.

Research Letter: 125 words

11. 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.

12. The journal does not use the virgule symbol (/) in sentences with words, except with ratios. 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.

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").

Express all percentages to one decimal place (for example, 11.1%). Do not use whole numbers for percentages.

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

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

16. Figure 1: Please upload as a figure file on Editorial Manager.

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<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 7 days from the date of this letter. If we have not heard from you by May 02, 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

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