

OBSTETRICS & GYNECOLOGY



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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.

Date: Nov 18, 2021
To: "Malavika Prabhu" [REDACTED]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-21-2271

RE: Manuscript Number ONG-21-2271

The impact of gestational age at COVID-19 mRNA vaccination and prior history of COVID-19 on maternal and umbilical cord antibody levels at delivery

Dear Dr. Prabhu:

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 for possible fast-track publication

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 7 days from the date of this letter. If we have not heard from you by Nov 25, 2021, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1:

The authors report via a research letter their data on SARS-Co-V2 vaccination during pregnancy and antibody levels at delivery.

1. Your introduction could be more of a general introduction to why you believe gestational age might be important information with respect to IgG antibody transfer. Even stating that time to generate IgG so it can cause the placenta would be useful information here.
2. Did you obtain IRB approval to use their samples? Were they de-identified? How many women declined to participate? Were any patients lacking antibodies? Did any women have an active infection at the time of admission?
3. What was the date range of vaccinations prior to delivery for this cohort?
4. If this an expected result?

Reviewer #2:

The authors present a Research Letter regarding maternal serum and umbilical cord Covid IgG levels, based on the timing of vaccination. I have a few comments/questions for the authors:

1. do the authors have access to which vaccine the patients received? if so, this would be worth including in the data
2. are the authors able to assess if any other factors (age, BMI, for example) significantly interact with their results
3. as a research letter, this would be improved by making the figures more simple. i would suggest including one table that lists mean (or median) levels based on trimester of vaccination, including p-values.
4. curious why this was submitted as a research letter and not original research

EDITOR COMMENTS:

Please expand to a short original research article. Break up the figure. Add a table. Tell us a little more about your methodology. Bring more nuance to the discussion about the fact that there also needs to be prioritization of maternal protection against SARS-CoV-2 and that optimizing neonatal antibody levels is not the only consideration in vaccination timing (and really should be secondary to just protecting the mother).

EDITORIAL OFFICE 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 authorship for a submission to Obstetrics & Gynecology." Please check with your coauthors to confirm that they received and completed this form, and that the disclosures listed in their eCTA are included on the manuscript's title page.

4. 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 for reporting randomized controlled trials (ie, CONSORT), observational studies (ie, STROBE), observational studies using ICD-10 data (ie, RECORD), meta-analyses and systematic reviews of randomized controlled trials (ie, PRISMA), harms in systematic reviews (ie, PRISMA for harms), studies of diagnostic accuracy (ie, STARD), meta-analyses and systematic reviews of observational studies (ie, MOOSE), economic evaluations of health interventions (ie, CHEERS), quality improvement in health care studies (ie, SQUIRE 2.0), and studies reporting results of Internet e-surveys (CHERRIES). Include the appropriate checklist for your manuscript type upon submission. 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 <http://ong.editorialmanager.com>. In your cover letter, be sure to indicate that you have followed the CONSORT, MOOSE, PRISMA, PRISMA for harms, STARD, STROBE, RECORD, CHEERS, SQUIRE 2.0, or CHERRIES guidelines, as appropriate.

5. 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.

6. Because of space limitations, it is important that your revised manuscript adhere to the following length restrictions by manuscript type: Research Letters should not exceed 600 words and may include no more than two figures and/or tables (2 items total). Stated word limits include the title page, *précis*, abstract, text, tables, boxes, and figure legends, but exclude references.

7. 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]."

8. Provide a short title of no more than 45 characters (40 characters for case reports), including spaces, for use as a running foot.

9. 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.

10. 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.

11. 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%).

12. 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.

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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.

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 Nov 25, 2021, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,
Dwight J. Rouse, 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.

Dear Dr Rouse,

Thank you for the opportunity to revise our manuscript. We have made the following key changes to address the reviewers' and editorial suggestions:

1. We have expanded it to Original Research manuscript
2. We increased the sample size as we captured a few more deliveries, including many boosted women, in the interval since our submission last week.
3. We included the placental transfer ratio, as part of the expansion of the manuscript.
4. We included data on women with Johnson & Johnson vaccination in our cohort, in order to describe the maternal and umbilical cord blood responses after this vaccine type.

As previously noted in our initial cover letter, the 122 third trimester vaccinated women previously published in this journal are not included in this current study. We would like to have made mention of this in our methods section, but due to the need to remain blinded, we did not do so. Please let us know if you would like for this fact to be added to the methods section.

We also would like to add 2 authors to this manuscript.

Zhen Zhao, PhD. Dr. Zhao contributed to anti-N assay validation, and was inadvertently omitted from the first iteration of the manuscript.

Iman Mohammed, BA. Iman contributed to sample capture and sample processing, including the new data now included in this paper, and was inadvertently omitted from the first iteration of the manuscript.

Below is our point by point response to the reviewer comments. Given the breadth of the changes, we are submitted a track changes version of the manuscript as well as a clean copy of the manuscript. The line numbers below refer to changes in the clean copy for clarity. We also now include a STROBE checklist.

Sincerely,
Malavika Prabhu

REVIEWER COMMENTS:

Reviewer #1:

The authors report via a research letter their data on SARS-CoV-2 vaccination during pregnancy and antibody levels at delivery.

1. Your introduction could be more of a general introduction to why you believe gestational age might be important information with respect to IgG antibody transfer. Even stating that time to generate IgG so it can cause the placenta would be useful information here.

Thank you for these comments. We have now updated our introduction to review more the published literature on COVID-19 vaccination in pregnancy, as well as COVID-19 in pregnancy, and the impact of timing of vaccination or infection on antibody levels at delivery.

2. Did you obtain IRB approval to use their samples? Were they de-identified? How many women

declined to participate? Were any patients lacking antibodies? Did any women have an active infection at the time of admission?

This study is IRB approved. This is noted in line 139.

All samples were de-identified. This is noted in line 105.

Given the use of leftover clinical samples, a waiver of consent was granted by our IRB. Consequently, we did not prospectively approach vaccinated women for informed consent. Some women were not included due to lack of sample capture and this limitation is noted in line 237.

All women who were fully vaccinated at the time of delivery had a detectable antibody response by time of birth. Individual results are purposefully represented in Figure 1 to allow all readers to accurately see all data points.

At the time of admission for delivery, all women are screened for SARS-CoV-2 via a PCR test, and no woman in this study was positive. This is noted in line 145.

3. What was the date range of vaccinations prior to delivery for this cohort?

The date ranges of the first vaccine dose are December 16, 2020 and September 1, 2021, and of the second vaccine dose are January 5, 2021 and September 22, 2021. This is noted in line 146-147.

4. If this an expected result?

We do believe our findings are consistent with what we expected, based on the data presented for COVID-19 vaccination for non-pregnant adults. Maternal antibody levels peak at the point at which women are considered fully vaccinated (2 weeks after dose #2), thus the peak maternal antibody response is noted with vaccine initiation around 34 weeks gestation, given our median gestational age at delivery of 39.3 weeks. Based on our prior work, we expected a correlation between maternal and umbilical cord antibody levels. We also expected a more significant antibody response with vaccination after a prior SARS-CoV-2 infection, and suspected that antibody levels after boosting may resemble antibody levels with primary vaccination after a SARS-CoV-2 infection.

Reviewer #2:

The authors present a Research Letter regarding maternal serum and umbilical cord Covid IgG levels, based on the timing of vaccination. I have a few comments/questions for the authors:

1. do the authors have access to which vaccine the patients received? if so, this would be worth including in the data

We have now included specific data on which vaccine patients received – Pfizer, Moderna, or Johnson & Johnson. All data are included in Table 2 as well as discussed in our manuscript.

2. are the authors able to assess if any other factors (age, BMI, for example) significantly interact with their results

Thank you for this comment, this is an excellent point. At this time we have not been able to evaluate the impact of clinical characteristics and comorbidities on antibody levels, as this requires additional manual abstraction from the electronic medical record. We plan to evaluate this in a forthcoming analysis. We have now included patient demographics on our cohort of 1359 women (Table 1) to describe our cohort in greater detail.

3. as a research letter, this would be improved by making the figures more simple. i would suggest including one table that lists mean (or median) levels based on trimester of vaccination, including p-values.

Thank you for these comments. We have now included Table 2 which summarizes the data in a simple format and lists the mean anti-S IgG levels, by vaccine type and trimester of vaccination, with p-values.

We have maintained the approach to presenting our figures the same, but did so due to the following considerations:

-Figure 1 allows us to visually display maternal and umbilical anti-S individual results to accurately depict the antibody response of the population (along with population variability) which would have been lost with a summary figure. In addition Figure 1 allows us to demonstrate additional layers of information such as the breakdown of fully vaccinated to not fully vaccinated women over time in our cohort.

-Figure 2 allows us to concurrently sub stratify the cohort in different ways and conduct multiple statistical analyses on the substratifications. Comparisons between the different sub-cohorts would be lost if the figure were broken up. In addition, in attempting to do so during this review process, we have found that these multiple comparisons are difficult to summarize in a clear and cohesive tabular format.

As we expanded to an Original Research article, with more space in the results, we more precisely describe each aspect of the figures in order to improve the clarity of what we want to show, and have also expanded on the discussion of the implication of our findings in the discussion.

We continue to be open to suggestions or ongoing discussions on additional ways to present the data.

4. curious why this was submitted as a research letter and not original research

We have now expanded our manuscript.

EDITOR COMMENTS:

Please expand to a short original research article. Break up the figure. Add a table. Tell us a little more about your methodology. Bring more nuance to the discussion about the fact that there also needs to be prioritization of maternal protection against SARS-CoV-2 and that optimizing neonatal antibody levels is not the only consideration in vaccination timing (and really should be secondary to just protecting the mother).

We have now expanded to original research. As above (see reviewer 2, comment 3), we did leave the figure representation of the data the same but are open to suggestion on additional ways to present the data. The important messages we wanted to demonstrate with the Figure 1 are (1) maternal anti-S levels are present at delivery regardless of gestational age of vaccine initiation (or pre-pregnancy

vaccination) – which supports the importance of maternal vaccination for maternal protection throughout pregnancy; (2) umbilical cord anti-S levels mirror the maternal trend, albeit with a peak with early third trimester vaccination, however the placental transfer ratio findings (newly added to this version) argue for maternal immunization regardless of gestational age, with similar placental transfer of vaccine induced antibodies until the late third trimester. The presentation of the figure as allows us to represent variability in the cohort. Our attempts to summarize and simplify the figure led to loss of these important findings. In figure 2, we wish to demonstrate (1) the importance of being fully vaccinated both for maternal and neonatal reasons, (2) prior SARS-CoV-2 infection results in higher antibody levels than vaccination without prior antigen exposure, suggesting the overall benefit of boosting, and (3) boosting in the third trimester results in high maternal and umbilical cord antibody levels at delivery. The comprehensive data presentation allows us to be able to compare different cohorts directly. Attempts to simplify and breakdown the figure led to loss of the ability to make direct comparisons, and attempts to summarize the data in tabular format actually led to more confusion with all the different tables that would have been necessary to demonstrate the same conclusions.

In this version, we added 2 tables, one with demographic, clinical, and vaccine characteristics of the cohort, and another with mean antibody levels by vaccine type (Pfizer, Moderna, J&J) and trimester of vaccine initiation.

We have expanded the methods section to clearly explain how the vaccinated pregnant women were identified, samples captured and deidentified, clinical data abstracted, and analyses performed.

We have also expanded the discussion and agree that our prior discussion did not give justice to the importance of maternal vaccination regardless of gestational age. We have now edited our discussion section significantly.

EDITORIAL OFFICE COMMENTS:

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OPT-IN.

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:

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* 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.

We have made these changes.

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 authorship for a submission to Obstetrics & Gynecology." Please check with your coauthors to confirm that they received and completed this form, and that the disclosures listed in their eCTA are included on the manuscript's title page.

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We are including the STROBE checklist with the revision

5. 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.

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7. 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]."

8. Provide a short title of no more than 45 characters (40 characters for case reports), including spaces, for use as a running foot.

Short title: COVID19 vaccination and boosting in pregnancy

9. 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.

10. 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.

11. 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.

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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.

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- * 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 Nov 25, 2021, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,
Dwight J. Rouse, MD
Editor-in-Chief