OBSTETRICS & GYNECOLOGY

**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.

**Date:** Dec 17, 2021
**To:** "Ravindra Ganesh"[redacted]
**From:** "The Green Journal" em@greenjournal.org
**Subject:** Your Submission ONG-21-2334

RE: Manuscript Number ONG-21-2334

Outcomes of Anti-Spike Monoclonal Antibody Therapy in Pregnant Women with Mild to Moderate COVID-19

Dear Dr. Ganesh:

The Editors of Obstetrics & Gynecology have evaluated your manuscript and our interested in considering it further for publication. Given that the study reports a series of patients without a control group, we ask that you modify the submission to a Research Letter. Formatting guidelines for Research Letters can be found in the Instructions for Authors.

***Given the timeliness and public health importance of your work we are interested in fast track publication of your findings online. To facilitate fast track publication we ask that you provide responses to the reviewers as soon as possible (before December 21, if possible). If you cannot meet this deadline, please respond to this message with your anticipated submission date.***

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 Dec 21, 2021, we will assume you wish to withdraw the manuscript from further consideration. Again, thank you for allow us the opportunity to evaluate your work.

REVIEWER COMMENTS:

Reviewer #1: The authors present a case series of 51 patients experiencing mild to moderate covid-19 in pregnancy and treated with anti-spike monoclonal antibody therapy. Currently the use of monoclonal antibodies for treatment of covid-19 has increased among pregnant women and there is a lack of literature to support safety and efficacy. This case series is clinically relevant as a large series of pregnant women. However the manuscript can benefit from some edits and additional details.

Abstract:
Line 14 in results, the 29 healthy babies and then 21 uncomplicated pregnancies is confusing. Please rewrite in a clear fashion.

Line 17- the conclusion that this was well-tolerated in women "considered at high-risk for complications of covid-19 " implies that these women had additional risk factors and should be edited.

Introduction:
Line 39- in this ob journal "high risk" implies high risk pregnancy. Please use the same wording as the prior sentence and state that these are comordbities with increased risk of severe disease.

Line 48- some information in this paragraph is repeated from the first and can be cut down.

Line 58- did the FDA recommend the antibody in pregnancy (as it was a high-risk condition) prior to May? This line may be clearer earlier in the introduction.

Methods:

Did the clinic have any contraindications to receiving mAB infusions? Were they offered to every patient meeting criteria (including pregnant patients)?

Line 77- for how long were patients followed by the remote monitoring program?

Line 81- Did all pregnant patients remain in the system and delivery at the same hospital? How was missing information identified? What was the follow up time? What information was obtained regarding pregnancy outcomes?

Results:
Table 1: - was data collected regarding pregnancy co-morbidities? Please include this as well, please list gestational age in weeks.

Was information regarding vaccination obtained?

Line 102- did monitoring include fetal monitoring?

Line 105- what time period did they seek care in the ED? Was this during pregnancy, for one week after? How did the investigators ensure the patients returned to the ED in the same system as the antibodies?

Line 109- At what time were these four patients admitted to the hospital? During pregnancy? Postpartum? Delivery?

Line 113- the information on the fetal demise from hydrops and congenital heart disease is likely too detailed. However do the authors have information on the presence of hydrops prior to infusion?

Line 118- again how long were patients followed and what was the complications evaluated.

Line 119- Did the program include a method for follow up of the fetus to evaluate for adverse outcomes?

Line 121- for this obstetric journal please include more delivery information and gestational age at delivery data in weeks.

The authors state the objective is to evaluate efficacy and safety of this medication in pregnancy. Please define the endpoints used to evaluate these two points. Currently the authors simply state "no adverse reactions" and "healthy pregnancy" however these are vague. The manuscript would also be strengthened by including pregnancy outcome data for the 21 (almost 50% of the patients) ongoing pregnancies.

Discussion:
The first paragraph repeats the results in detail and can be cut down to only summarize.

Reviewer #2: This is a very timely case series and it's understandable that the authors desire to publish this pregnancy-focused information sooner rather than later, especially to highlight the safety of the infusion during pregnancy. However, there are elements of interest to readers that are absent from this report that limit its value. While the initial follow-up of patients receiving MAb seems to be complete for the study period, follow-up through the initial post-partum period for all receiving therapy is incomplete; no information about the undelivered patients in the treatment group is presented beyond initially receiving their infusions. In addition, was there a search for pregnant patients testing positive for Covid-19 who may have had mild/moderate symptoms but did not receive MAb therapy? Such a comparison could provide more information about the value of timely providing the MAb treatment intervention.

Line 50 - Subject verb agreement needed. The word "data" requires a plural verb here.

Line 93 - Is it possible to order the cases by weeks gestation rather than trimester? Would doing so make any difference?

Line 97 - Can you list the clinical elements included in the FDA definition of mild to moderate covid ?

Line 105 - Spell check may be the problem, but the acronym for monoclonal antibody infusion is shown as MAb and Mab. Are both acceptable or should it preferably be one or the other?

Lines 131-133 - Should these be two separate sentences?

Line 150 - Does this statement need a citation?

Line 155 - Please see note for Line 50.

Can you speculate about the generalizability of your findings to a broader population? Can you include a little more detail about the strengths and limitations of your data collection and analysis? What about the long term clinical and public health implications of your findings and conclusions?

Reviewer #3: This is a retrospective case series summarizes the experience of 51 pregnant persons who received monoclonal antibodies for treatment of mild-moderate COVID-19.

* Despite the stated objective (lines 5-6), there are too few participants to make meaningful conclusions about safety or efficacy. This report would be strengthened by including a matched control group which did not receive monoclonal antibodies.

* Lines 33-35: The evidence is now quite consistent that pregnancy is a risk factor for severe disease, not just among women with other underlying conditions.

* Lines 54-56: Suggest including the NIH treatment guidelines here as well as ACOG and SMFM.

* Details about the overall monoclonal program could be condensed to focus just on the pregnant patients.

* Information about the 27 patients infused postpartum might be an interesting addition to this brief report.

* Lines 170-171: These results should be presented in results section.

* Please add a limitations section.

* Please add an updated systematic review to document that there are no other published case series.

* Table 2 can be deleted or combined with table 1.

STATISTICAL EDITOR COMMENTS:

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

Table 1: Need to indicate the total "N" for the series and enumerate any missing data. Ned units for age, BMI. Gravity and parity can only have integer values, so should format as median(range or IQR) or as categories.

General: Although it is true that there were no major complications among the 29 delivered or the 21 still pregnant patients that were attributable to MAb treatment, those zero rates have CIs of [0%-13%] and [0%-18%], respectively. Even if the calculation were based on 0 events in 51 pregnancies, the upper boundary of that estimate is 7%. That is, one cannot be certain at a $p < 0.05$ threshold of an adverse event could not occur.

It is therefore prudent both to report these data as a descriptive series and to highlight the limitations of determining safety based on a limited sample, esp when stratified by several formulations.

EDITOR COMMENTS:

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

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

2. When you submit your revised manuscript, please make the following edits to ensure your submission contains the required information that was previously omitted for the initial double-blind peer review:
* Include your title page information in the main manuscript file. The title page should appear as the first page of the document. Add any previously omitted Acknowledgements (ie, meeting presentations, preprint DOIs, assistance from non-byline authors).
* Funding information (ie, grant numbers or industry support statements) should be disclosed on the title page and in

the body text. For industry-sponsored studies, the Role of the Funding Source section should be included in the body text of the manuscript.
* Include clinical trial registration numbers, PROSPERO registration numbers, or URLs at the end of the abstract (if applicable).
* Name the IRB or Ethics Committee institution in the Methods section (if applicable).
* Add any information about the specific location of the study (ie, city, state, or country), if necessary for context.

3. Obstetrics & Gynecology uses an "electronic Copyright Transfer Agreement" (eCTA), which must be completed by all authors. When you uploaded your manuscript, each co-author received an email with the subject, "Please verify your 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. 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.

5. 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.

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).
* 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]."

7. 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.

8. 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.

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

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.

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. Lien 124: Your manuscript contains a priority claim. We discourage claims of first reports since they are often difficult to prove. How do you know this is the first report? If this is based on a systematic search of the literature, that search should be described in the text (search engine, search terms, date range of search, and languages encompassed by the search). If it is not based on a systematic search but only on your level of awareness, it is not a claim we permit.

12. 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.

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

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

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

14. Figure 1: Should the box “27 infused post pregnancy” be moved down next to “51 infused during pregnancy”

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

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

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

***

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.

Sincerely,
Jason Wright, MD
Editor-in-Chief, Elect

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

---

REVIEWER COMMENTS:

Reviewer #1: The authors present a case series of 51 patients experiencing mild to moderate covid-19 in pregnancy and treated with anti-spike monoclonal antibody therapy. Currently the use of monoclonal antibodies for treatment of covid-19 has increased among pregnant women and there is a lack of literature to support safety and efficacy. This case series is clinically relevant as a large series of pregnant women. However the manuscript can benefit from some edits and additional details.

Abstract:
Line 14 in results, the 29 healthy babies and then 21 uncomplicated pregnancies is confusing. Please rewrite in a clear fashion.

- *This has been removed as resubmitted as a research letter.*

Line 17- the conclusion that this was well-tolerated in women "considered at high-risk for complications of covid-19 " implies that these women had additional risk factors and should be edited.

- *This has been removed as resubmitted as a research letter.*

Introduction:
Line 39- in this ob journal "high risk" implies high risk pregnancy. Please use the same wording as the prior sentence and state that these are comordbities with increased risk of severe disease.

- *This language has been removed as resubmitted as a research letter.*

Line 48- some information in this paragraph is repeated from the first and can be cut down.

- *This language has been removed as resubmitted as a research letter.*

Line 58- did the FDA recommend the antibody in pregnancy (as it was a high-risk condition) prior to May? This line may be clearer earlier in the introduction.

- *Monoclonal antibodies were not recommended for pregnancy explicitly in the initial EUA. Language has been revised to make it clear that the May 2021 expansion of criteria "now include" pregnancy.*

Methods:
Did the clinic have any contraindications to receiving mAB infusions? Were they offered to every patient meeting criteria (including pregnant patients)?

- *No contraindications to receiving MAb. They were offered to all eligible patients. Patients were assessed on arrival to the infusion center and if they had progressed to severe disease, they were sent to the Emergency Department and treatment withheld. This was not included in the research letter due to word limit.*

Line 77- for how long were patients followed by the remote monitoring program?

- *Generally 20 days but patients with persistent symptoms were followed until symptom resolution or MD terminating the program (up to 40 days).*

Line 81- Did all pregnant patients remain in the system and delivery at the same hospital? How was missing information identified? What was the follow up time? What information was obtained regarding pregnancy outcomes?

- *All of our patients remained within our system, and this was identified through chart review. Follow up time varied but Ob/Gyn generally checked in the week after the infusion and routine follow up thereafter. Information regarding pregnancy outcomes was extracted from the delivery note, so birth weight, Apgars, and complications. Infant chart was reviewed for any medical concerns.*

Results:

Table 1: - was data collected regarding pregnancy co-morbidities? Please include this as well, please list gestational age in weeks.

- *Thank you for the feedback. This has been done.*

Was information regarding vaccination obtained?

- *This was not collected.*

Line 102- did monitoring include fetal monitoring?

- *Immediate post-infusion monitoring did not include fetal monitoring. Patients were followed by Ob/Gyn within a week as above.*

Line 105- what time period did they seek care in the ED? Was this during pregnancy, for one week after? How did the investigators ensure the patients returned to the ED in the same system as the antibodies?

- *We counted ED visits during the 28 days post infusion and all admissions during pregnancy. This has been clarified in the research letter.*

Line 109- At what time were these four patients admitted to the hospital? During pregnancy? Postpartum? Delivery?

- *We counted ED visits during the 28 days post infusion and all admissions during pregnancy. This has been clarified in the research letter.*

Line 113- the information on the fetal demise from hydrops and congenital heart disease is likely too detailed. However do the authors have information on the presence of hydrops prior to infusion?

- *This has been removed due to research letter word limits. However, we do not have information on presence of hydrops prior to the infusion. This patient was referred to us from an external physician who had documented fetal bradycardia. COVID test prior to being seen was positive so she was infused with MAb. US was done ten days later when she could come on campus and Epstein anomaly was noted.*

Line 118- again how long were patients followed and what was the complications evaluated.

- *We counted ED visits during the 28 days post infusion and all admissions during pregnancy. This has been clarified in the research letter.*

Line 119- Did the program include a method for follow up of the fetus to evaluate for adverse outcomes?

- *Patients were followed up by Ob/Gyn within a week of infusion.*

Line 121- for this obstetric journal please include more delivery information and gestational age at delivery data in weeks.

- *Additional delivery information was not added due to research letter format and word limits. Gestational age at delivery has been added.*

The authors state the objective is to evaluate efficacy and safety of this medication in pregnancy. Please define the endpoints used to evaluate these two points. Currently the authors simply state "no adverse reactions" and "healthy pregnancy" however these are vague. The manuscript would also be strengthened by including pregnancy outcome data for the 21 (almost 50% of the patients) ongoing pregnancies.

- *Thank you for this feedback. This has not been addressed due to resubmission as a research letter. We will incorporate this data into potential future submissions.*

Discussion:
The first paragraph repeats the results in detail and can be cut down to only summarize.

- *This has been removed as resubmitted as a research letter.*

Reviewer #2: This is a very timely case series and it's understandable that the authors desire to publish this pregnancy-focused information sooner rather than later, especially to highlight the safety of the infusion during pregnancy. However, there are elements of interest to readers that are absent from this report that limit its value. While the initial follow-up of patients receiving MAb seems to be complete for the study period, follow-up through the initial post-partum period for all receiving therapy is incomplete; no information about the undelivered patients in the treatment group is presented beyond initially receiving their infusions. In addition, was there a search for pregnant patients testing positive for Covid-19 who may have had mild/moderate symptoms but did not receive MAb therapy? Such a comparison could provide more information about the value of timely providing the MAb treatment intervention.

Line 50 - Subject verb agreement needed. The word "data" requires a plural verb here.

- *Thank you for the feedback. This has been done.*

Line 93 - Is it possible to order the cases by weeks gestation rather than trimester? Would doing so make any difference?

- *This has been removed as resubmitted as a research letter.*

Line 97 - Can you list the clinical elements included in the FDA definition of mild to moderate covid ?

- *This has been removed as resubmitted as a research letter. This was defined as patients being symptomatic, but not requiring admission due to hemodynamic instability or hypoxia (spO2 <94%)*

Line 105 - Spell check may be the problem, but the acronym for monoclonal antibody infusion is shown as MAb and Mab. Are both acceptable or should it preferably be one or the other?

- *Thank you for the feedback. This has been reviewed and corrected.*

Lines 131-133 - Should these be two separate sentences?

- *Thank you for the feedback. This has been reviewed and corrected.*

Line 150 - Does this statement need a citation?

- *Thank you for the feedback. This has been reviewed and corrected.*

Line 155 - Please see note for Line 50.

- *Thank you for the feedback. This has been reviewed and corrected.*

Can you speculate about the generalizability of your findings to a broader population? Can you include a little more detail about the strengths and limitations of your data collection and analysis? What about the long term clinical and public health implications of your findings and conclusions?

- *Thank you for this feedback and this would greatly improve the manuscript. As we are resubmitting as a research letter, this was not included.*

Reviewer #3: This is a retrospective case series summarizes the experience of 51 pregnant persons who received monoclonal antibodies for treatment of mild-moderate COVID-19.

* Despite the stated objective (lines 5-6), there are too few participants to make meaningful conclusions about safety or efficacy. This report would be strengthened by including a matched control group which did not receive monoclonal antibodies.
  - *Thank you for this feedback and this would greatly improve the manuscript. As we are resubmitting as a research letter, this was not included.*

* Lines 33-35: The evidence is now quite consistent that pregnancy is a risk factor for severe disease, not just among women with other underlying conditions.
  - *Thank you for the feedback. This has been reviewed and corrected.*

* Lines 54-56: Suggest including the NIH treatment guidelines here as well as ACOG and SMFM.
  - *Thank you for the feedback. This has been reviewed and corrected.*

* Details about the overall monoclonal program could be condensed to focus just on the pregnant patients.
    - *Thank you for the feedback. This has been reviewed and corrected.*

* Information about the 27 patients infused postpartum might be an interesting addition to this brief report.
    - *Thank you for this feedback and this would greatly improve the manuscript. As we are resubmitting as a research letter, this was not included.*

* Lines 170-171: These results should be presented in results section.
    - *Thank you for the feedback. This has been reviewed and corrected.*

* Please add a limitations section.
    - *Thank you for this feedback and this would greatly improve the manuscript. As we are resubmitting as a research letter, this was not included.*

* Please add an updated systematic review to document that there are no other published case series.
    - *Thank you for this feedback and this would greatly improve the manuscript. As we are resubmitting as a research letter, this was not included.*

* Table 2 can be deleted or combined with table 1.
- *Thank you for the feedback. This has been reviewed and corrected.*

STATISTICAL EDITOR COMMENTS:

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

Table 1: Need to indicate the total "N" for the series and enumerate any missing data. Ned units for age, BMI. Gravity and parity can only have integer values, so should format as median(range or IQR) or as categories.
- *Thank you for the feedback. This has been reviewed and corrected.*

General: Although it is true that there were no major complications among the 29 delivered or the 21 still pregnant patients that were attributable to MAb treatment, those zero rates have CIs of [0%-13%] and [0%-18%], respectively. Even if the calculation were based on 0 events in 51 pregnancies, the upper boundary of that estimate is 7%. That is, one cannot be certain at a $p < 0.05$ threshold of an adverse event could not occur.

It is therefore prudent both to report these data as a descriptive series and to highlight the limitations of determining safety based on a limited sample, esp when stratified by several formulations.

- *Thank you for the feedback. We completely agree with this assessment and have tried to make it clear that these are reassuring preliminary data.*

EDITOR COMMENTS:

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

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

- *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:

* 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.

- *Thank you for the feedback. This has been reviewed and corrected.*

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.

- *We have sent a reminder email to all authors to fill out the eCTA.*

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 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.

- *These have been reviewed.*

5. 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.

- *Thank you for the instructions. The article has been rewritten to fit these constraints.*

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).
* 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]."

- *Thank you for the feedback. The article has been reviewed with these changes.*

7. 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.

- *These have been reviewed.*

8. 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.

- *Thank you for the feedback. The article has been reviewed with these changes.*

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

- *Thank you for the feedback. The article has been reviewed with these changes. There is one mention of "providers" in the references that we cannot remove.*

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.

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%").

- *Thank you for the feedback. The article has been reviewed with these changes.*

11. Lien 124: Your manuscript contains a priority claim. We discourage claims of first reports since they are often difficult to prove. How do you know this is the first report? If this is based on a systematic search of the literature, that search should be described in the text (search engine, search terms, date range of search, and languages encompassed by the search). If it is not based on a systematic search but only on your level of awareness, it is not a claim we permit.

- *Thank you for the feedback. The article has been reviewed and this claim has been removed.*

12. 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.

- *Thank you for the feedback. The article has been reviewed with these changes.*

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

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

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

- *Thank you for the feedback. The article has been reviewed with these changes.*

14. Figure 1: Should the box “27 infused post pregnancy” be moved down next to “51 infused during pregnancy”

- *Thank you for the feedback. The article has been reviewed with these changes.*