

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.*

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: Sep 07, 2021
To: "Richard Michael Burwick" [REDACTED]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-21-1750

RE: Manuscript Number ONG-21-1750

Use of Casirivimab and Imdevimab in Pregnant Individuals with Moderate Coronavirus Disease 2019

Dear Dr. Burwick:

Your manuscript has been reviewed by the Editorial Board and by special expert referees. The Editors are interested in potentially publishing your revised manuscript in a timely manner. In order to have this considered quickly, we need to have your revision documents submitted to us as soon as you are able. I am tentatively setting your due date to September 13, 2021, but please let me know if you need additional time.

The standard revision letter text follows.

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).

REVIEWER COMMENTS:

Reviewer #1: The authors present a case report of two patients who underwent monoclonal antibody treatment in pregnancy. There is currently very limited data regarding the use of this therapy in pregnancy and this contributes to the limited literature. I would be curious if the authors have additional patients since the initial manuscript to strengthen the paper.

Introduction:

Although the information is true and important, the information on the vaccine and CDC recommendations is likely not needed. Additionally monoclonal antibodies are also being used in vaccinated individuals who are IGG negative and therefore this information is useful for both populations.

Case 1 is delivery data available? Was any additional monitoring for the mother or fetus obtained?

Case 2-

line 119- what were the neonates "respiratory signs" was there concern for infection?

Do you have the BMI for these patients?

Discussion:

Line 163- is there data to approximate the "relative low rates" of unvaccinated pregnant individuals?

Reviewer #2: This case reports the use of monoclonal antibodies in patients with moderate COVID-19 in pregnancy.

Title: Consider rewording to "Use of monoclonal antibodies...." as readership may not be aware of the generic names of these antibodies yet.

Abstract:

Line 17-19 Would add a qualifier, "While investigational" or "Under an EUA". Would also recommend calling for prospective collection to determine safety and effectiveness in pregnancy.

Introduction:

Line 33-37 Consider adding numbers here (e.g. XX-times more likely than nonpregnant patients....) to justify the use of an investigational drug.

Line 48 add quotes "pandemic of the unvaccinated."

Line 50-57 Consider clarifying that treatment with monoclonal antibodies is approved under an "emergency use authorization" from the F.D.A. and is considered investigational in the introduction, and that safety and effectiveness are still being evaluated (see below).

Please define what is meant by mild, moderate and severe COVID-19 in pregnancy in the introduction. What about postexposure prophylaxis in pregnant patients?

Line 51-52 Make clear that this is a co-formulated product. Include other eligibility criteria for MAB here, (e.g. timing, severity of disease, hospitalized versus non-hospitalized, unvaccinated OR who are not expected to mount an adequate immune response, etc). See comments below.

Line 94 Use units for RR and HR here and throughout

Line 97-98 Was she admitted and if so, for what indication?

Line 100-109 Why was the patient not offered REGEN COV during the first evaluation? This may be confusing as she was eligible. If she was not, please explain this.

Line 108 Add dose and how administered.

Discussion

Line 128-136 Consider moving this to the introduction.

Discuss why authors waited until 2nd presentation to offer REGEN-COV.

Recommend discussing use of REGEN COV in postexposure prophylaxis in pregnancy.

Recommend authors discuss how to develop a process for administration of REGEN COV in the readers' own institutions/hospitals and any anticipated or real barriers. Also, expand on shared decision making and what factors the readers should consider and discuss with the patient.

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: Case Reports should not exceed 2,000 words. Stated word limits include the title page, précis, abstract, text, tables, boxes, and figure legends, but exclude references.

6. Titles in Obstetrics & Gynecology are limited to 100 characters (including spaces). Do not structure the title as a declarative statement or a question. Introductory phrases such as "A study of..." or "Comprehensive investigations into..." or "A discussion of..." should be avoided in titles. Abbreviations, jargon, trade names, formulas, and obsolete terminology also should not be used in the title. Titles should include "A Randomized Controlled Trial," "A Meta-Analysis," or "A Systematic Review," as appropriate, in a subtitle. Otherwise, do not specify the type of manuscript in the title.

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. The most common deficiency in revised manuscripts involves the abstract. Be sure there are no inconsistencies between the Abstract and the manuscript, and that the Abstract has a clear conclusion statement based on the results found in the paper. Make sure that the abstract does not contain information that does not appear in the body text. If you submit a revision, please check the abstract carefully.

In addition, the abstract length should follow journal guidelines. The word limit for Case Reports is 125 words. Please provide a word count.

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. 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.

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. Please convert Figure 1 to Box 1.

It appears to be modified from an FDA document. Please provide a full reference in the legend.

<https://www.fda.gov/media/145611/download>

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.

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 Sep 13, 2021, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

Dwight J. Rouse, MD, MSPH
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.

September 13, 2021

Re: **ONG-21-1750**

Dear Editors,

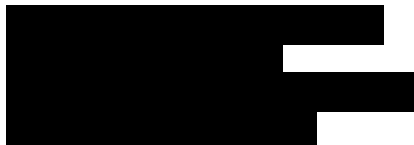
We wish to submit our revised manuscript ONG-21-1750, “Monoclonal Antibodies Casirivimab and Imdevimab in Pregnant People with Coronavirus Disease 2019” for consideration by *Obstetrics & Gynecology*. We appreciate the thoughtful comments and suggestions of the reviewers and the editor. We have provided detailed replies below, and we have uploaded the revised manuscript with tracked changes, incorporating reviewer suggestions.

We confirm that this work is original and has not been published, nor it is under consideration for publication elsewhere. We intend to submit solely to *Obstetrics & Gynecology*, and it will not be submitted elsewhere unless a final negative decision is made by the Editors of *Obstetrics & Gynecology*. As the senior and corresponding author, I confirm that this report is an honest, accurate, and transparent account of the cases being reported; that no important aspects of the case have been omitted. Case series of 3 or less patients are IRB-exempt at Cedars-Sinai IRB, but patient consent is required for publication. Both of our patients consented to the write-up of this case report, and their consent forms have been uploaded.

Thank you for considering this report, and please let us know if you have additional questions or concerns.

Sincerely,

Richard M. Burwick, MD, MPH
Cedars-Sinai Medical Center



REVIEWER COMMENTS:

Reviewer #1: The authors present a case report of two patients who underwent monoclonal antibody treatment in pregnancy. There is currently very limited data regarding the use of this therapy in pregnancy and this contributes to the limited literature. I would be curious if the authors have additional patients since the initial manuscript to strengthen the paper.

Author Reply: Thank you for the comment. Unfortunately, we don't have additional pregnancy cases to add to the current report without submitting a new IRB application. However, by presenting these two cases we hope to shed light on the importance of monoclonal antibodies in unvaccinated pregnant individuals, and we added text to emphasize the need for prospective data collection to evaluate safety and effectiveness (lines 191-192).

Introduction:

Although the information is true and important, the information on the vaccine and CDC recommendations is likely not needed. Additionally monoclonal antibodies are also being used in vaccinated individuals who are IGG negative and therefore this information is useful for both populations.

Author Reply: Thank you for the comment. While we agree that this text is optional in the introduction, we would like to keep it to emphasize that COVID19 vaccination is the first line option in pregnant individuals. We wanted to make a clear contrast between vaccinated and unvaccinated individuals, to help reader understand why monoclonal antibodies are particularly useful in unvaccinated group. Our 2 cases were in unvaccinated pregnant individuals with symptomatic COVID19, thus we focused primarily on that area in the paper. However, we agree that some vaccinated pregnant individuals may be immunocompromised and meet criteria for use of monoclonal antibodies, and some unvaccinated pregnant individuals may opt for postexposure prophylaxis even in the absence of COVID19 infection. Thus, we added text to the discussion to include these points (lines 166-169)

Case 1 is delivery data available? Was any additional monitoring for the mother or fetus obtained?

Author Reply: This patient was seen and treated at 19 weeks gestation. Currently she is 25 weeks gestation and remains undelivered. We reported that she was recovered from her COVID illness during follow up at 2 weeks, but we don't have additional fetal or maternal updates to report aside from routine prenatal care (lines 97-99).

Case 2-

line 119- what were the neonates "respiratory signs" was there concern for infection?

Author Reply: For clarity we added more details regarding the neonate's respiratory signs and work up for infection as person under investigation (PUI). The text was updated on lines 132-136.

Do you have the BMI for these patients?

Author Reply: The BMI for patient one was 24 kg/m² and is listed on line 84. The BMI for patient two was also 24 kg/m² and we added this to line 105.

Discussion:

Line 163- is there data to approximate the "relative low rates" of unvaccinated pregnant individuals?

Author Reply: Yes, we updated our citation to link this data to the CDC report (Reference #6). The data shows that only 24% of pregnant individuals have received at least one dose of the COVID-19 vaccine through August 28, 2021. We provided the specific number in the introduction (lines 56-59), so we did not repeat it in the discussion to avoid redundancy.

Reviewer #2: This case reports the use of monoclonal antibodies in patients with moderate COVID-19 in pregnancy.

Title: Consider rewording to "Use of monoclonal antibodies....." as readership may not be aware of the generic names of these antibodies yet.

Author Reply: We updated the title to add the term "monoclonal antibodies". However, since the term "monoclonal antibodies" is non-specific, we prefer to keep the generic names in the title as well if possible.

Revised title: "Monoclonal Antibodies Casirivimab and Imdevimab in Pregnant People with Coronavirus Disease 2019"

Abstract:

Line 17-19 Would add a qualifier, "While investigational" or "Under an EUA". Would also recommend calling for prospective collection to determine safety and effectiveness in pregnancy.

Author Reply: Thank you for the suggestion. We updated the abstract (lines 39-40), and discussion (lines 149-151) accordingly.

Introduction:

Line 33-37 Consider adding numbers here (e.g. XX-times more likely than nonpregnant patients...) to justify the use of an investigational drug.

Author Reply: Numbers were added in this section, including 3-4x higher risk of hospitalization and severe disease, and 13x higher risk of death (lines 46-49).

Line 48 add quotes "pandemic of the unvaccinated."

Author Reply: Quotations added.

Line 50-57 Consider clarifying that treatment with monoclonal antibodies is approved under an "emergency use authorization" from the F.D.A. and is considered investigational in the introduction, and that safety and effectiveness are still being evaluated (see below).

Author Reply: Moved information on FDA emergency use authorization from discussion to introduction (lines 66-69). Added notation regarding safety and effectiveness in the discussion (lines 150-151; 191-192).

Please define what is meant by mild, moderate and severe COVID-19 in pregnancy in the introduction.

Author Reply: Added this information in Box 1.

What about postexposure prophylaxis in pregnant patients?

Author Reply: Thank you for this question. REGEN-COV is approved for use as postexposure prophylaxis but since our cases were focused on patients with +SARS-CoV-2 infection, we did not discuss this point in detail. However, we added text in the discussion to note that the FDA-EUA also includes this group (lines 166-169)

Line 51-52 Make clear that this is a co-formulated product. Include other eligibility criteria for MAB here, (e.g. timing, severity of disease, hospitalized versus non-hospitalized, unvaccinated OR who are not expected to mount an adequate immune response, etc). See comments below.

Author Reply: We added text stating that REGEN-COV is a co-formulated product (line 66; Box 1). We added a note that it is indicated for mild and moderate disease and we added Box 1 to include additional criteria, with emphasis that it is not recommended in those who are hospitalized or with severe disease due to COVID-19 (Box 1). We did not add additional criteria because they are too lengthy, but we did add text in the discussion

to note that monoclonal antibodies may be considered in vaccinated patients who are not expected to mount an adequate immune response to complete SARS-CoV-2 vaccination (Lines 167-169).

Line 94 Use units for RR and HR here and throughout

Author reply- Units added throughout.

Line 97-98 Was she admitted and if so, for what indication?

Author reply- We revised the text to clarify that she did not require hospital admission during this initial evaluation (lines 112-113).

Line 100-109 Why was the patient not offered REGEN COV during the first evaluation? This may be confusing as she was eligible. If she was not, please explain this.

Author reply – We added a comment that REGEN-COV was initially declined due to mild nature of her symptoms (line 113-114)

Line 108 Add dose and how administered.

Author reply – We revised the text to add dose and administration (line 123-124)

Discussion

Line 128-136 Consider moving this to the introduction.

Author reply. Thank you for the suggestion, we moved this information to Introduction, Lines 66-69.

Discuss why authors waited until 2nd presentation to offer REGEN-COV.

Author reply – We added a comment that REGEN-COV was initially declined due to mild nature of her symptoms (line 113-114).

Recommend discussing use of REGEN COV in postexposure prophylaxis in pregnancy.

Author reply. We agree that REGEN-COV is approved for use as postexposure prophylaxis, but since our cases in this report focused on those with +SARS-CoV-2 infection, we did not discuss this point in detail. However, we added a few lines in the discussion to note that the FDA-EUA also includes this group (lines 167-171).

Recommend authors discuss how to develop a process for administration of REGEN COV in the readers' own institutions/hospitals and any anticipated or real barriers.

Author reply. We added lines in the discussion to emphasize the need to establish a process for administration of monoclonal antibodies and the need to identify and reduce barriers to care (lines 192-194)

Also, expand on shared decision making and what factors the readers should consider and discuss with the patient.

Author reply. Text added to expand on potential risks-benefits to discuss with the patient (lines 176-184)

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:

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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.

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://urldefense.com/v3/_https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-obstetrics-data-definitions_!!K0mnBZxC8_2BBQ!nEj2d5M63KSzaKsDOfPr1OjU_zhBX7ksK7zoE2rz8zyBLQfv2omX8vW8oUC-XGEI1eY\\$](https://urldefense.com/v3/_https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-obstetrics-data-definitions_!!K0mnBZxC8_2BBQ!nEj2d5M63KSzaKsDOfPr1OjU_zhBX7ksK7zoE2rz8zyBLQfv2omX8vW8oUC-XGEI1eY$) and the gynecology data definitions at [https://urldefense.com/v3/_https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-gynecology-data-definitions_!!K0mnBZxC8_2BBQ!nEj2d5M63KSzaKsDOfPr1OjU_zhBX7ksK7zoE2rz8zyBLQfv2omX8vW8oUC-In3u0II\\$](https://urldefense.com/v3/_https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-gynecology-data-definitions_!!K0mnBZxC8_2BBQ!nEj2d5M63KSzaKsDOfPr1OjU_zhBX7ksK7zoE2rz8zyBLQfv2omX8vW8oUC-In3u0II$). 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: Case Reports should not exceed 2,000 words. Stated word limits include the title page, précis, abstract, text, tables, boxes, and figure legends, but exclude references.

Author reply: Word count 1999

6. Titles in Obstetrics & Gynecology are limited to 100 characters (including spaces). Do not structure the title as a declarative statement or a question. Introductory phrases such as "A study of..." or "Comprehensive investigations into..." or "A discussion of..." should be avoided in titles. Abbreviations, jargon, trade names, formulas, and obsolete terminology also should not be used in the title. Titles should include "A Randomized Controlled Trial," "A Meta-Analysis," or "A Systematic Review," as appropriate, in a subtitle. Otherwise, do not specify the type of manuscript in the title.

Author reply: Title 96 characters (with spaces)

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).

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8. The most common deficiency in revised manuscripts involves the abstract. Be sure there are no inconsistencies between the Abstract and the manuscript, and that the Abstract has a clear conclusion statement based on the results found in the paper. Make sure that the abstract does not contain information that does not appear in the body text. If you submit a revision, please check the abstract carefully.

In addition, the abstract length should follow journal guidelines. The word limit for Case Reports is 125 words. Please provide a word count.

Author reply: Abstract 125 words

9. Only standard abbreviations and acronyms are allowed. A selected list is available online at [https://urldefense.com/v3/_http://edmgr.ovid.com/ong/accounts/abbreviations.pdf_!!K0mnBZxC8_2BBQ!nEj2d5M63KSzaKsDOfPr1OjU_zhBX7ksK7zoE2rz8zyBLQfv2omX8vW8oUC-tR2V9v0\\$](https://urldefense.com/v3/_http://edmgr.ovid.com/ong/accounts/abbreviations.pdf_!!K0mnBZxC8_2BBQ!nEj2d5M63KSzaKsDOfPr1OjU_zhBX7ksK7zoE2rz8zyBLQfv2omX8vW8oUC-tR2V9v0$). 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.

Author reply: text revised

11. 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.

Author reply: text revised

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:

[https://urldefense.com/v3/_http://edmgr.ovid.com/ong/accounts/table_checklist.pdf_!!K0mnBZxC8_2BBQ!nEj2d5M63KSzaKsDOfPr1OjU_zhBX7ksK7zoE2rz8zyBLQfv2omX8vW8oUC-9_awbEM\\$](https://urldefense.com/v3/_http://edmgr.ovid.com/ong/accounts/table_checklist.pdf_!!K0mnBZxC8_2BBQ!nEj2d5M63KSzaKsDOfPr1OjU_zhBX7ksK7zoE2rz8zyBLQfv2omX8vW8oUC-9_awbEM$)

13. Please review examples of our current reference style at

[https://urldefense.com/v3/_http://ong.editorialmanager.com_!!K0mnBZxC8_2BBQ!nEj2d5M63KSzaKsDOfPr1OjU_zhBX7ksK7zoE2rz8zyBLQfv2omX8vW8oUC-dc2s1R8\\$](https://urldefense.com/v3/_http://ong.editorialmanager.com_!!K0mnBZxC8_2BBQ!nEj2d5M63KSzaKsDOfPr1OjU_zhBX7ksK7zoE2rz8zyBLQfv2omX8vW8oUC-dc2s1R8$) (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://urldefense.com/v3/_https://www.acog.org/clinical_!!K0mnBZxC8_2BBQ!nEj2d5M63KSzaKsDOfPr1OjU_zhBX7ksK7zoE2rz8zyBLQfv2omX8vW8oUC-zdiTUsk\\$](https://urldefense.com/v3/_https://www.acog.org/clinical_!!K0mnBZxC8_2BBQ!nEj2d5M63KSzaKsDOfPr1OjU_zhBX7ksK7zoE2rz8zyBLQfv2omX8vW8oUC-zdiTUsk$) (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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14. Please convert Figure 1 to Box 1.

It appears to be modified from an FDA document. Please provide a full reference in the legend.

Author Reply: Based on reviewer and editor feedback we removed Figure 1 and replaced with Box 1 and included information on disease spectrum (mild-moderate-severe) and indication for use of monoclonal antibody. We included a citation reference in the legend.

[https://urldefense.com/v3/_https://www.fda.gov/media/145611/download_!!K0mnBZxC8_2BBQ!nEj2d5M63KSzaKsDOFPr1OjU_zhBX7ksK7zoE2rz8zyBLQfv2omX8vW8oUC-xS2JNTU\\$](https://urldefense.com/v3/_https://www.fda.gov/media/145611/download_!!K0mnBZxC8_2BBQ!nEj2d5M63KSzaKsDOFPr1OjU_zhBX7ksK7zoE2rz8zyBLQfv2omX8vW8oUC-xS2JNTU$)

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