

# 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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**Date:** Jan 07, 2022  
**To:** [REDACTED]  
**From:** "The Green Journal" em@greenjournal.org  
**Subject:** Your Submission ONG-21-2404

RE: Manuscript Number ONG-21-2404

Development and Validation of a Model to Predict Post-Discharge Opioid Use after Cesarean Birth

Dear Dr. Osmundson:

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.

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 21 days from the date of this letter. If we have not heard from you by Jan 28, 2022, we will assume you wish to withdraw the manuscript from further consideration.

#### REVIEWER COMMENTS:

Reviewer #1:

Obstetrics and Gynecology  
Manuscript # ONG-21-2404  
"Development and validation of a model to predict post-discharge opioid use after cesarean birth"

#### GENERAL

The submitted manuscript is a prospective randomized trial of standardization of post-cesarean opioid discharge prescription amounts with determination of pre-discharge predictors to estimate post-discharge utilization.

1. The final study analysis included 389 patients, of whom 279 filled the exact study prescription (lines 178-179); these 279 patients were subsequently utilized (exclusively) for model construction. Recognizing the authors' analysis is predicated on an intent-to-treat basis, would it be reasonable to focus only on this homogenous group, and exclude these 108 patients prescribed a non-study opioid volume from consideration?
2. Consider including morphine equivalents (5 MME) of each tablet of the study medication (hydrocodone-acetaminophen) for clarity.
3. Were any of the patients treated with any other medications following discharge (ex: NSAIDs, antiretroviral therapy) that may have influenced postpartum opioid analgesic requirements?
4. Line 127: Is the "all sources" intended to refer to directly questioning patients? (as inferred in Lines 197-198)
5. Have the study findings impacted clinical practice at the authors' institution?
6. Consider converting Figure 2 into a simpler (perhaps internet-based) calculator to improve adoption into clinical practice.

## Reviewer #2:

General comment: This is a prospective cohort study which examined factors associated with outpatient opiate use after cesarean delivery in order to create a model to predict use and tailor prescriptions. Thank you for your dedication to research in women's health.

Abstract and précis- Succinct and well written.

Introduction- Well organized.

Methods- Well written and organized. Lines 67-69 consider rewording.

Statistical analysis- comprehensive and appropriate analysis

Results- the analyses benefit from a well characterized cohort, and I particularly likes the use of the pared down model which improves generalizability.

Discussion- A minor limitation of this study is the potential for bias in the measurement of outpatient opiate use as this variable was self reported. A more objective way to perform this was to collect the remaining opiates. ( Description in lines 88-91). A multicenter study would also have increased generalizability, as this is a single Center and small study.

Reviewer #3: Very timely and interesting approach to modeling Csection opioid use.

Line 25 and 173 was the initial enrollment date 11/15/2019 or 11/15/2020. Discrepancy between these 2 lines.

Figure 2 Providing more clarity to nomogram and legend. Requires viewing a few times to absorb data compared to other tables and figured.

## STATISTICAL EDITOR COMMENTS:

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

Table 1: Rather than comparing the study cohort vs all (which includes the study cohort), should compare the study cohort vs the non-study cohort. Were there any statistical or clinical differences in those groups?

Table 2: The inpatient MME used is strongly associated with post-discharge MME use. What is the reduction in LR using in-pt opioid use alone vs the full model or vs the reduced model?

Table 3: Need to include CIs for the c-indices. They are all so numerically close that I suspect there is no statistical difference between the highest and the lowest nominal values.

## 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. For studies that report on the topic of race or include it as a variable, authors must provide an explanation in the manuscript of who classified individuals' race, ethnicity, or both, the classifications used, and whether the options were defined by the investigator or the participant. In addition, the reasons that race/ethnicity were assessed in the study also should be described (eg, in the Methods section and/or in table footnotes). Please put your use of race into context.

Race/ethnicity must have been collected in a formal or validated way. If it was not, it should be omitted. Authors must enumerate all missing data regarding race and ethnicity as in some cases, missing data may comprise a high enough proportion that it compromises statistical precision and bias of analyses by race.

Use "Black" and "White" (capitalized) when used to refer to racial categories. The nonspecific category of "Other" is a convenience grouping/label that should be avoided, unless it was a prespecified formal category in a database or research instrument. If you use "Other" in your study, please add detail to the manuscript to describe which patients were included in that category.

5. Because of space limitations, it is important that your revised manuscript adhere to the following length restrictions by manuscript type: Original Research reports should not exceed 5,500 words. 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. 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 Original Research articles is 300 words. Please provide a word count.

8. 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.

9. 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.

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. Line 246: 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](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](mailto:obgyn@greenjournal.org)). In most cases, if an ACOG document has been withdrawn, it should not be referenced in your manuscript.

14. Figures 1-2: Please upload as figure files on Editorial Manager.

15. Each supplemental file in your manuscript should be named an "Appendix," numbered, and ordered in the way they are first cited in the text. Do not order and number supplemental tables, figures, and text separately. References cited in appendixes should be added to a separate References list in the appendixes file.

16. 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>.

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If you choose to revise your manuscript, please submit your revision through Editorial Manager at <http://ong.editorialmanager.com>. Your manuscript should be uploaded as a Microsoft Word document. Your revision's cover letter should include 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 Jan 28, 2022, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

Jason D. Wright, MD  
Editor-in-Chief

2020 IMPACT FACTOR: 7.661

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

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VANDERBILT UNIVERSITY



School of Medicine

*Department of Obstetrics & Gynecology*

November 29, 2021

Dwight J. Rouse, MD, MSPH  
Editor in Chief, *Obstetrics & Gynecology*

Dear Dr. Rouse:

We appreciate the opportunity to revise our manuscript titled, "Development and Validation of a Model to Predict Post-Discharge Opioid Use after Cesarean Birth" (Manuscript # ONG-21-2404) for publication in *Obstetrics & Gynecology*. Below, we detail point-by-point responses to the reviewers' feedback. We opt-in to publishing our point-by-point response letter attached.

Thank you for your time and consideration.

Sincerely,

A handwritten signature in black ink that reads "Sarah Osmundson".

Sarah S. Osmundson, MD, MS  
Associate Professor  
Division of Maternal-Fetal Medicine  
Department of Obstetrics & Gynecology  
Vanderbilt University Medical Center  
Nashville, TN

VANDERBILT UNIVERSITY MEDICAL CENTER  
1161 21<sup>st</sup> Avenue South  
B-1100 Medical Center North  
Nashville, TN 37232

## REVIEWER #1

The submitted manuscript is a prospective randomized trial of standardization of post-cesarean opioid discharge prescription amounts with determination of pre-discharge predictors to estimate post-discharge utilization.

1. The final study analysis included 389 patients, of whom 279 filled the exact study prescription (lines 178-179); these 279 patients were subsequently utilized (exclusively) for model construction. Recognizing the authors' analysis is predicated on an intent-to-treat basis, would it be reasonable to focus only on this homogenous group, and exclude these 108 patients prescribed a non-study opioid volume from consideration?
  - a. Response: For our primary analysis we examined outcomes and constructed the model only in patients who received the study opioid ("intent-to-treat"). We anticipated that some patients inevitably would receive non-study opioids and we enrolled patients until we achieved the sample size for which we were powered. However, we feel that the 108 patients who received non-study opioids also provide valuable data, which is why we examined how the model performed in this quasi-real-world population where the amount of discharge opioid was not controlled by the study.
  - b. Location in manuscript: Lines 101-105
  - c. Textual Response: No change to manuscript
  
2. Consider including morphine equivalents (5 MME) of each tablet of the study medication (hydrocodone-acetaminophen) for clarity.
  - a. Response: We have added MME next to tablet number where applicable in the manuscript.
  - b. Location in manuscript: Lines 84, 103, 189, 190
  - c. Textual Response:
    - *Line 84*: "Standardized prescriptions at discharge included 30 tablets of ibuprofen 600mg and 30 tablets of hydrocodone 5mg-acetaminophen 325mg (150 MME)."
    - *Line 103* "For our primary model we examined participants who were confirmed via CMSD to have received only the prescribed study opioid (30 tablets of hydrocodone 5mg-acetaminophen 325mg or 150 MME)."
    - *Line 189* "Among the entire population (n=387), participants spent a median 2.8 days in the hospital and used the median equivalent of 7 tablets of hydrocodone 5 mg-acetaminophen 325 mg during their hospital stay (35 MME)."
    - *Line 190* After discharge, they used a median of 8 tablets or 40 MME (IQR 1-18) for a median of 8 (IQR 3-11) days. A majority (53%, 207/387) used some opioid while 24% (91/387) used no opioid and 23% (89/387) used all opioids.
  
3. Were any of the patients treated with any other medications following discharge (ex: NSAIDs, antiretroviral therapy) that may have influenced postpartum opioid analgesic requirements?
  - a. Response: All participants in the study received 30 tablets of ibuprofen 600mg. We did not specifically analyze ibuprofen use as it was not the primary aim of the study. However, those data are available. No participants in our study received antiretroviral therapy or other medications that we anticipate would influence analgesic response.
  - b. Location in manuscript: Lines 83-84
  - c. Textual Response: No change to manuscript



4. Line 127: Is the "all sources" intended to refer to directly questioning patients? (as inferred in Lines 197-198)
  - a. Response: "All sources" includes patient survey data in addition to data gathered from ICD10 codes. We have clarified this in the manuscript.
  - b. Location in manuscript: Lines 125-129
  - c. Textual Response: "Additionally, given concerns about under-reporting depression/anxiety in the EHR, we asked women about personal history of anxiety/depression or antidepressant use to compare information obtained from the EHR only (EHR depression/anxiety) versus information from all sources including patient-reported outcomes (All depression/anxiety)."
5. Have the study findings impacted clinical practice at the authors' institution?
  - a. Response: We plan to implement this model at our institution pending build of a clinical decision support tool to assist clinicians with individualized opioid prescribing. We are concerned that present circumstances require substantial clinician time to gather data on inpatient opioid use, depression/anxiety, and tobacco use, which could limit implementation.
  - b. Location in manuscript: not applicable
  - c. Textual Response: not applicable
6. Consider converting Figure 2 into a simpler (perhaps internet-based) calculator to improve adoption into clinical practice.
  - a. Response: We now present an internet-based calculator for estimating outpatient opioid use based on inpatient characteristics. We caution that the current model requires external validation and should not be used clinically until that validation process is successful
  - b. Location in manuscript: Lines 229-232
  - c. Textual Response: "A nomogram based on the final reduced model estimates with these three predictors was constructed and is presented in Figure 2 and a web-based calculator that estimates patients' mean MME usage after hospital discharge can be found at [https://vumc-chp-halvorson.shinyapps.io/OpioidUseAfterCes\\_app/](https://vumc-chp-halvorson.shinyapps.io/OpioidUseAfterCes_app/)."

## REVIEWER #2

This is a prospective cohort study which examined factors associated with outpatient opiate use after cesarean delivery in order to create a model to predict use and tailor prescriptions. Thank you for your dedication to research in women's health.

1. Abstract and précis- Succinct and well written.
  - a. Response: Thank you for the positive feedback
  - b. Location in manuscript: not applicable
  - c. Textual response: not applicable
2. Introduction- Well organized.
  - a. Response: Thank you for the positive feedback
  - b. Location in manuscript: not applicable
  - c. Textual response: not applicable
3. Methods- Well written and organized. Lines 67-69 consider rewording.
  - a. Response: We have clarified these lines
  - b. Location in manuscript: Lines 67-69

- c. Textual response: “The study followed TRIPOD guidelines for the transparent reporting of a multivariable prediction models for individual prognosis or diagnosis<sup>18</sup>.”
- 4. Statistical analysis- comprehensive and appropriate analysis
  - a. Response: Thank you for the positive feedback
  - b. Location in manuscript: not applicable
  - c. Textual response: not applicable
- 5. Results- the analyses benefit from a well characterized cohort, and I particularly like the use of the pared down model which improves generalizability.
  - a. Response: Thank you for the positive feedback
  - b. Location in manuscript: not applicable
  - c. Textual response: not applicable
- 6. Discussion- A minor limitation of this study is the potential for bias in the measurement of outpatient opiate use as this variable was self-reported. A more objective way to perform this was to collect the remaining opiates. (Description in lines 88-91). A multicenter study would also have increased generalizability, as this is a single Center and small study.
  - a. Response: We agree with this statement and have added this to the limitation section of the Discussion. We have used electronic smart caps in the past to assess correlation between patient-reported use and smart cap-reported use. Because we found a high correlation in this prior study and because of the rising expense of using these smart caps, we did not use them in this study. A multicenter study to externally validate the model is planned.
  - b. Location in manuscript: Lines 321-325
  - c. Textual response: “We also acknowledge that patient-reported opioid use could be inaccurate, however our prior study in this population found high correlation between patient-reported opioid use and data gathered from real-time electronic medication caps that record when a pill bottle is accessed.<sup>21</sup>”

### REVIEWER #3

- 1. Very timely and interesting approach to modeling C-section opioid use.
  - a. Response: Thank you for the positive feedback
  - b. Location in manuscript: not applicable
  - c. Textual response: not applicable
- 2. Line 25 and 173 was the initial enrollment date 11/15/2019 or 11/15/2020. Discrepancy between these 2 lines.
  - a. Response: Thank you for catching this error. The initial date of enrollment was 11/15/2019
  - b. Location in manuscript: Line 175
  - c. Textual response: “Between 11/15/2019 and 1/15/2021, 459 of 552 (83.2%) eligible patients enrolled”
- 3. Figure 2 Providing more clarity to nomogram and legend. Requires viewing a few times to absorb data compared to other tables and figured.
  - a. Response: This point was raised by another reviewer, and we now present an internet-based calculator for estimating outpatient opioid use based on inpatient characteristics.
  - b. Location in manuscript: Lines 229-232

- c. Textual Response: “A nomogram based on the final reduced model estimates with these three predictors was constructed and is presented in Figure 2 and a web-based calculator that estimates patients’ mean MME usage after hospital discharge can be found at [https://vumc-chp-halvorson.shinyapps.io/OpioidUseAfterCes\\_app/](https://vumc-chp-halvorson.shinyapps.io/OpioidUseAfterCes_app/).”

## STATISTICAL EDITOR

1. Table 1: Rather than comparing the study cohort vs all (which includes the study cohort), should compare the study cohort vs the non-study cohort. Were there any statistical or clinical differences in those groups?
  - a. Response: Thank you for this suggestion. We have modified Table 1 to reflect a comparison between patients who received Study and non-Study prescriptions.
  - b. Location in manuscript: Table 1, Lines 187-190
  - c. Textual response: “These patients had a shorter length of stay, which may have contributed to not receiving the study prescription. They also reported higher inpatient pain scores but used less opioid per hour of inpatient admission. Other demographic and clinical characteristics were similar (Table 1).”
2. Table 2: The inpatient MME used is strongly associated with post-discharge MME use. What is the reduction in LR using inpatient opioid use alone vs the full model or vs the reduced model?
  - a. Response: The LR  $\chi^2$  was 164 for the full model, 152 for the reduced model, and 110 for the model with inpatient opioid use alone. These data were presented in Table 3
  - b. Location in manuscript: Table 3
  - c. Textual response: not applicable
3. Table 3: Need to include CIs for the c-indices. They are all so numerically close that I suspect there is no statistical difference between the highest and the lowest nominal values.
  - a. Response: Table 3 now includes confidence intervals for the C-indices
  - b. Location in manuscript: Table 3
  - c. Textual response: Table 3

## EDITOR'S 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:
  - ➔ We have opted-in to publishing the point-by-point response letter, which is noted in the cover letter above
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).

- *The manuscript has been updated*
- ➔ 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.
    - *The manuscript has been updated*
  - ➔ Include clinical trial registration numbers, PROSPERO registration numbers, or URLs at the end of the abstract (if applicable).
    - *The manuscript has been updated*
  - ➔ Name the IRB or Ethics Committee institution in the Methods section (if applicable).
    - *The manuscript has been updated*
  - ➔ 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.
- ➔ We have confirmed with our co-authors that they received and completed this form
4. For studies that report on the topic of race or include it as a variable, authors must provide an explanation in the manuscript of who classified individuals' race, ethnicity, or both, the classifications used, and whether the options were defined by the investigator or the participant. In addition, the reasons that race/ethnicity were assessed in the study also should be described (eg, in the Methods section and/or in table footnotes). Please put your use of race into context. Race/ethnicity must have been collected in a formal or validated way. If it was not, it should be omitted. Authors must enumerate all missing data regarding race and ethnicity as in some cases, missing data may comprise a high enough proportion that it compromises statistical precision and bias of analyses by race. Use "Black" and "White" (capitalized) when used to refer to racial categories. The nonspecific category of "Other" is a convenience grouping/label that should be avoided, unless it was a prespecified formal category in a database or research instrument. If you use "Other" in your study, please add detail to the manuscript to describe which patients were included in that category.
- ➔ Explanations for how individual's race/ethnicity were classified are described in Lines 101-104
5. Because of space limitations, it is important that your revised manuscript adhere to the following length restrictions by manuscript type: Original Research reports should not exceed 5,500 words. Stated word limits include the title page, précis, abstract, text, tables, boxes, and figure legends, but exclude references.
- ➔ Our manuscript is 4,834 words in length excluding 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]."

- ➔ These rules have been followed

7. 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 Original Research articles is 300 words. Please provide a word count.

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