

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 03, 2020
To: "Jade M Shorter"
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-20-2131

RE: Manuscript Number ONG-20-2131

Racial Disparities in Mental Health Outcomes Among Women with Early Pregnancy Loss

Dear Dr. Shorter:

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).

Your revision will be due in Editorial Manager by September 24, 2020.

REVIEWER COMMENTS:

Reviewer #1: Shorter et al performed a planned secondary analysis from a randomized trial on medical management of early pregnancy loss (EPL). Primary aim was to determine the odds of major depression 30 days after EPL treatment in Black compared with non-Black participants. Secondary aim was high perceived stress 30 days after medical management of miscarriage.

Precis:

22 As the CES-D a screening tool that aids in identifying individuals at risk for clinical depression, recommend authors be precise in stating that race/ACE is associated with "risk for" MDD throughout the article. A positive screen for MDD versus diagnosis of MDD is conflated throughout the article.

Abstract:

Authors clearly define their objective. Methods for collection of data are clearly defined in the abstract. Results are clearly stated. Conclusions are appropriate for this manuscript.

41-44, 45 Please clarify that this is "risk for" MDD as above.

Introduction:

66 Is this the correct reference (25) that supports a disaggregation of race from pregnancy-related morbidity?

70 Recommend changing to "around the time of" instead of "at the time of".

72 Recommend adding "risk for" major depression....

Materials and Methods:

Study design is appropriate to study associations between EPL, race and MDD. Study was IRB approved. Power analysis was not included. Recommend defining inclusion/exclusion criteria.

77-78 The authors define the study population.

105 Is the PSS scale validated and for what population?

113-114 Recommend authors describe that this screening tool was only validated for White and affluent population in this part of manuscript, and leave explanation to discussion section.

123-127 Authors describe statistical analyses for their data that appears appropriate.

125-127 Primary and secondary outcomes well defined.

136-136 Did the authors control for treatment method as one of the baseline characteristics and if not, why? As the results were found to be statistically significant in the original article, it may be prudent to make sure this is explained.

Results:

162-168 Recommend adding participants "who met criteria for" or "higher risk for" MDD as above

Discussion:

189, 190, 191, 196, 200, 204, 206, 207, 210, 212 "risk for" (major/baseline) depression

207-208 Recommend authors also suggest that in addition to lack of statistical power, the lack of effect may be due to using a screening tool that was intended for affluent, Caucasian women.

218-222 Recommend including data on response rate, missing data (in addition to tables), racial/geographic diversity in methods and/or results if items are listed as strengths to the study.

226 "risk for" depression

Conclusions:

243-247 Suggest removing these sentences from conclusion; not focus of study.

249-251 Would also suggest removing this sentence as it suggests ACE plays a role as risk for MDD after EPL, yet the results of the study did not confirm this.

Figures and Tables:

Table 1 - Recommend including treatment modality for EPL.

Table 2 - Consider renaming "Association between race and risk for..."

References: Appropriate for study.

Reviewer #2: This is a secondary analysis of a randomized clinical trial on the relationship between race and the development of depressive symptoms in patients who are participating in a clinical trial of early pregnancy loss.

1) It would be interesting or perhaps pertinent to evaluate the factors, such as sociodemographics, pregnancy history, and what were the outcomes in "non-Black" participants. The danger is that there may be the development of stereotypes based on implicit biases in attributing symptoms to race rather than perhaps racism (as you outline in the limitations part of the paper).

2) on page 8, line 31, it can potentially be problematic to have as the main exposure as race, which cannot be changed. so that there is not a "blame the victim" view of such categorical variables.

3) Page 10, line 183 is a fragment after Table 2. Perhaps a semicolon would be appropriate so break up the next part of the sentence which is a fragment.

4) Why wasn't a power analysis done for the cohorts so that you know how many participants would be needed in each group to see the outcomes that the authors were looking for? The authors recognize the limitations of the small sample size.

5) Page 13, line 245, the authors should consider not using the word, "minority" rather than "minoritized," since "minority" implies less than so "minoritized populations" is preferably.

6) The authors may acknowledge/consider the importance of a cultural and structural competent workforce to address disparities in perinatal mental health in their future directions.

Reviewer #3:

The manuscript "Racial Disparities in Mental Health Outcomes Among Women with Early Pregnancy Loss" by Dr. Shorter et al studies an important and timely topic, very relevant to practicing physicians today which is maternal morbidity in the setting of racial inequities. The secondary analysis examines if Black participants have higher odds of major depression after EPL treatment when compared to non Black participants.

The strengths of the study are the number of participants recruited and the diverse population enrolled in the study. Additionally, utilizing a myriad of scales to examine depressive symptoms, including the ACE scale, provides for more information than just depressive symptoms but also trauma. The manuscript is concise, well written and I believe has pertinent information for Obstetric providers.

Abstract: I think it's important to define EPL and state what your gestational guidelines were for the original RCT (line 26).

Introduction: Include data on why Black women are more likely to experience EPL than other ethnic groups (line 59). The CES-D provides data on depressive symptoms, but as the authors point out, do not actually yield a clinical of MDD (line 72)? MDD is used throughout the paper, but this is misleading as these women are not being diagnosed with major depressive disorder, but rather, have higher scores on a scale of depressive symptomatology. Another concern is that since psychiatric diagnostic criteria are not evaluated in these women, is it possible that some of them, given early pregnancy loss, may be experiencing symptoms of either an adjustment disorder or other trauma-relevant psychopathology, that may be leading to higher CES-D scores without actually meeting diagnostic criteria for MDD, but instead a different psychiatric diagnosis?

Methods: In describing the methods, it would be helpful to include more information about where patients were recruited from: clinic vs hospital, suburban vs urban, in order to give the reader a better idea of what population was recruited in order to better interpret the findings (line 77). Was this based on previous literature? Upper tertile or quartile? It would be helpful to know more about the make up of the non-Black participants- do they include Latinx women, for example who may have similar rates of ACEs or baseline depression or stressors as black women? (line 124) Regarding the CES-D cutoff scores, it is unclear how the cutoff of , greater than 21 was reached to defined as "likely MDD" (line 101). Line 129 addresses the multivariable logistic analysis where ACE is used as a dichotomized variable. It is unclear why ACE is used as a categorical variable instead of as a continuous variable in the analysis to allow for the full variance in the data. Similarly, it would be helpful to know the overall mean scores for the ACE, CES-D, PSS variables instead of within each of the categories (and are there differences between Black and non-Black groups on these scales when not categorized?).

Results: Table 1- Both education and medical insurance are significantly different between the groups and should be considered as a covariate in the logistic regression analyses. They may serve as a proxy for SES, which is not accounted for in this analysis, and may play an important moderating or mediating effect.

STATISTICAL EDITOR COMMENTS:

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

General, lines 30-32: Since the primary outcome was major depressive disorder, with primary exposure as race and secondary exposure as high ACE, should separate more clearly those two results. That is, the primary exposure and outcome should be cited with more emphasis. The others, including associations with high perceived stress vs baseline stress are secondary.

lines 37-38: Should expand this section to include proportions of women of each race cohort who met criteria for major depressive disorder at 30 days

Table 1: The cohorts differ in many baseline characteristics, particularly completed education level, medical insurance etc which confounds comparisons.

Table 2: The strongest association was with baseline major depression. Should perform a sensitivity analysis by excluding all women with prior history of major depression to evaluate whether the association with race still holds.

Table 3: Given the numbers of women with high perceived stress, adjustment for two covariates may have resulted in over fitted models on the one hand and under powered analyses on the other.

EDITOR'S COMMENTS

We no longer require that authors adhere to the Green Journal format with the first submission of their papers. However, any revisions must do so. I strongly encourage you to read the instructions for authors (the general bits as well as those specific to the feature-type you are submitting). The instructions provide guidance regarding formatting, word and reference limits, authorship issues and other relevant topics. Adherence to these requirements with your revision will

avoid delays during the revision process by avoiding re-revisions on your part in order to comply with formatting.

Numbers below refer to line numbers.

56. The comparison group is women not pregnant within the preceding year and the patients included women with loss up to 28 weeks. The EGA alone makes this a less than perfect comparison to your population, which you describe as women with early pregnancy loss. Also, this reference is 23 years old. Are there more current data?

ACE should be spelled out throughout the manuscript. Similarly, EPL and PSS should be spelled out.

92. As noted by one of the reviewers your study has not included steps for making a diagnosis of major depression. The CED-D scale is "The CES-D scale is a brief self-report scale designed to measure self-reported symptoms associated with depression experienced in the past week", according to the Measurement Instrument Database for the Social Sciences. As such, throughout your paper you cannot say the participants were diagnosed with a major depression—you can only say that they had elevated depression symptom score. This is a very important distinction, that needs to be clear in the abstract, precis and manuscript. Similar to the PSS, the CES-D is "not a diagnostic instrument" (line 107.)

You state on line 125 that your primary outcome was "MDD 30 days after medical management". As noted, you have not made a diagnosis of MDD. So was it a score of 21 or more that was your primary outcome? Please clarify.

119. Should be "sexually transmitted infections".

P Values vs Effect Size and Confidence Intervals

While P values are a central part of inference testing in statistics, when cited alone, often the strength of the conclusion can be misunderstood. Whenever possible, 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.

This is true for the abstract as well as the manuscript, tables and figures.

Please provide absolute values for variables, in addition to assessment of statistical significance.

We ask that you provide crude OR's followed by adjusted OR's for all relevant variables. (For instance, see line 164)

162. Given there is only a one month difference in baseline to 30 day follow up, it should not be a surprise that there is such a high aOR here, do you think?

167. Here is an example of a place that requires editing re: "Baseline depression". You could say something like "elevated baseline CES-D score" here. Another example is line 189. I'm not being exhaustive pointing these out, but instead pointing out some examples of different ways you've phrased this to alert you to look for this throughout your paper.

220. As noted by one reviewer, you need to tell us in the methods about the racial and geographic diversity in the methods section.

214, 221 and perhaps later in the paper you recommend "future research". We consider that as a bit of a "throw away" phrase as every author could include such a statement given the non-definitive nature of research. Please remove such statements. If you wish to include a paragraph suggesting a particular study design with relevant questions that you think might further this research, that would perhaps be acceptable.

Line 251 seems to be referencing research to decrease ACE's in society in general and seems somewhat out of place here in which you are addressing a very specific question.

Table 1: Since the results are dichotomous for ACE scores (ie, they either had high or low scores), you only need to report either the high or the low ace scores—I'd recommend keeping the high ACE scores.

Please describe the CES-D scores as "likely not depressed", "likely mild/moderate depression". Etc. here and in other places in the tables and manuscript.

Table 4 could be moved to online material; you have 2 copies of figure 1 included in the manuscript. Is this an oversight or was there supposed to be a figure 2?

EDITORIAL OFFICE COMMENTS:

1. The Editors of Obstetrics & Gynecology are seeking to increase 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. Obstetrics & Gynecology uses an "electronic Copyright Transfer Agreement" (eCTA). When you are ready to revise your manuscript, you will be prompted in Editorial Manager (EM) to click on "Revise Submission." Doing so will launch the resubmission process, and you will be walked through the various questions that comprise the eCTA. Each of your coauthors will receive an email from the system requesting that they review and electronically sign the eCTA.

Please check with your coauthors to confirm that the disclosures listed in their eCTA forms are correctly disclosed on the manuscript's title page.

3. For studies that report on the topic of race, 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).

Use "Black" and "White" (capitalized) when used to refer to racial categories.

The category of "Other" is a 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.

4. Clinical trials submitted to the journal as of July 1, 2018, must include a data sharing statement. The statement should indicate 1) whether individual deidentified participant data (including data dictionaries) will be shared; 2) what data in particular will be shared; 3) whether additional, related documents will be available (eg, study protocol, statistical analysis plan, etc.); 4) when the data will become available and for how long; and 5) by what access criteria data will be shared (including with whom, for what types of analyses, and by what mechanism). Responses to the five bullet points should be provided in a box at the end of the article (after the References section).

5. Please submit a completed STROBE checklist.

Responsible reporting of research studies, which includes a complete, transparent, accurate and timely account of what was done and what was found during a research study, is an integral part of good research and publication practice and not an optional extra. Obstetrics & Gynecology supports initiatives aimed at improving the reporting of health research, and we ask authors to follow specific guidelines for reporting randomized controlled trials (ie, CONSORT), observational studies (ie, STROBE), observational studies using ICD-10 data (ie, RECORD), meta-analyses and systematic reviews of randomized controlled trials (ie, PRISMA), harms in systematic reviews (ie, PRISMA for harms), studies of diagnostic accuracy (ie, STARD), meta-analyses and systematic reviews of observational studies (ie, MOOSE), economic evaluations of health interventions (ie, CHEERS), quality improvement in health care studies (ie, SQUIRE 2.0), and studies reporting results of Internet e-surveys (CHERRIES). Include the appropriate checklist for your manuscript type upon submission. Please write or insert the page numbers where each item appears in the margin of the checklist. Further information and links to the checklists are available at <http://ong.editorialmanager.com>. In your cover letter, be sure to indicate that you have followed the CONSORT, MOOSE, PRISMA, PRISMA for harms, STARD, STROBE, RECORD, CHEERS, SQUIRE 2.0, or CHERRIES guidelines, as appropriate.

6. 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.

7. 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 22 typed, double-spaced pages (5,500 words). Stated page limits include all numbered pages in a manuscript (i.e., title page, précis, abstract, text, references, tables, boxes, figure legends, and print appendixes) but exclude references.

8. 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).

9. Precis: The Editors would like you to replace "Black participants" with "Black women."

10. 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.

11. Only standard abbreviations and acronyms are allowed. A selected list is available online at <http://edmgr.ovid.com/ong/accounts/abbreviations.pdf>. Abbreviations and acronyms cannot be used in the title or précis. Abbreviations and acronyms must be spelled out the first time they are used in the abstract and again in the body of the manuscript.

12. The journal does not use the virgule symbol (/) in sentences with words. Please rephrase your text to avoid using "and/or," or similar constructions throughout the text. You may retain this symbol if you are using it to express data or a measurement.

13. In your Abstract, manuscript Results sections, and tables, the preferred citation should be in terms of an effect size, such as odds ratio or relative risk or the mean difference of a variable between two groups, expressed with appropriate confidence intervals. When such syntax is used, the P value has only secondary importance and often can be omitted or noted as footnotes in a Table format. Putting the results in the form of an effect size makes the result of the statistical test more clinically relevant and gives better context than citing P values alone.

If appropriate, please include number needed to treat for benefits (NNT_b) or harm (NNT_h). When comparing two procedures, please express the outcome of the comparison in U.S. dollar amounts.

Please standardize the presentation of your data throughout the manuscript submission. For P values, do not exceed three decimal places (for example, "P = .001"). For percentages, do not exceed one decimal place (for example, 11.1%).

14. 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.

15. 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 reference you are citing is still current and available. If the reference you are citing has been updated (ie, 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 (exceptions could include manuscripts that address items of historical interest). All ACOG documents (eg, Committee Opinions and Practice Bulletins) may be found at the Clinical Guidance page at <https://www.acog.org/clinical> (click on "Clinical Guidance" at the top).

16. Figure 1 may be resubmitted with the revision as-is.

17. 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>.

Please note that 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 to revise your manuscript, please submit your revision through Editorial Manager at

<http://ong.editorialmanager.com>. Your manuscript should be uploaded in a word processing format such as Microsoft Word.
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.

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,

Nancy C. Chescheir, MD
Editor-in-Chief

2019 IMPACT FACTOR: 5.524

2019 IMPACT FACTOR RANKING: 6th out of 82 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.

01 October 2020

Dear Editors and Reviewers,

On behalf of my co-authors, I would like to thank you for considering our manuscript for publication in *Obstetrics & Gynecology*. We appreciate your thoughtful feedback and the opportunity to improve on our work. We hope the attached revised manuscript will meet the standard for publication. We are happy to continue to make further revisions as desired. Please see below for a point-by-point response to each of the reviewer and editor comments with descriptions of revisions made. We have read the Instructions for Authors.

I affirm that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned have been explained. STROBE guidelines were followed, and a checklist is enclosed.

Thank you for considering our work, and we look forward to hearing from you.

Sincerely on behalf of all authors,



Jade M. Shorter, MD, MSHP

REVIEWER COMMENTS:

Reviewer #1: Shorter et al performed a planned secondary analysis from a randomized trial on medical management of early pregnancy loss (EPL). Primary aim was to determine the odds of major depression 30 days after EPL treatment in Black compared with non-Black participants. Secondary aim was high perceived stress 30 days after medical management of miscarriage.

1. Precis:

22 As the CES-D a screening tool that aids in identifying individuals at risk for clinical depression, recommend authors be precise in stating that race/ACE is associated with "risk for" MDD throughout the article. A positive screen for MDD versus diagnosis of MDD is conflated throughout the article.

We made this edit as described. We will be using the phrase "risk for" throughout the manuscript.

Abstract:

Authors clearly define their objective. Methods for collection of data are clearly defined in the abstract. Results are clearly stated. Conclusions are appropriate for this manuscript.

2. 41-44, 45 Please clarify that this is "risk for" MDD as above.

We made these edits as described.

Introduction:

3. 66 Is this the correct reference (25) that supports a disaggregation of race from pregnancy-related morbidity?

We appreciate this concern. Reference 25 does not disaggregate race from pregnancy-related morbidity. This reference controls for race/ethnicity in their models looking at the association between ACEs and pregnancy outcomes. I have included an additional reference to this sentence (now reference 28) that explores race as a mediator of the relationship between ACEs and pregnancy outcomes and further supports this statement. We have adjusted the sentence to read: "Higher adverse childhood experience scores are associated with a greater likelihood of pregnancy loss, preterm birth, and perinatal depression,²⁵⁻²⁷ but the relationship between race, adverse childhood experience, and pregnancy-related morbidity has only recently been explored."

4. 70 Recommend changing to "around the time of" instead of "at the time of".
We made this edit as described.

5. 72 Recommend adding "risk for" major depression....
We made this edit as described.

Materials and Methods:

6. Study design is appropriate to study associations between EPL, race and MDD. Study was IRB approved. Power analysis was not included. Recommend defining inclusion/exclusion criteria.

A sample size calculation was not performed as this was a planned secondary analysis. We have included a sentence in the Methods section (line 136) that states we did not perform a sample size calculation. In this first paragraph of our methods section we refer to the inclusion criteria for the primary study. For our secondary data analysis, we included all participants from the primary study who completed the CES-D and PSS scales at 30 days after treatment. We do not have any exclusion criteria.

77-78 The authors define the study population.

7. 105 Is the PSS scale validated and for what population?

The 10-item PSS scale used in our study was validated with adequate internal consistency reliability ($\alpha = .78$). The original population was a large national sample of 2,387 American adults (60% Women; 82% of the participants identified as White, 8% Black, and 4% Hispanic). Income and education level were equally distributed among participants. Representative of age, ethnicity, sex and income. We have included that the PSS scale is “validated” in line 117.

8. 113-114 Recommend authors describe that this screening tool was only validated for White and affluent population in this part of manuscript, and leave explanation to discussion section.

We appreciate the reviewer’s suggestion. We have removed the statement “originally studied in a predominately White and affluent population”, as it may direct the focus away from the intent of this portion of the discussion. Our intention is not to question the validity of the ACE survey, but rather it is to highlight the potential benefit of using an expanded ACE scale in future research.

123-127 Authors describe statistical analyses for their data that appears appropriate.

125-127 Primary and secondary outcomes well defined.

9. 136-136 Did the authors control for treatment method as one of the baseline characteristics and if not, why? As the results were found to be statistically significant in the original article, it may be prudent to make sure this is explained.
We appreciate this comment. We have included treatment method in Table 1 and there is no significant difference by racial group; $p= 0.744$. We assessed treatment method for our model and we found that it did not confound the association between race and risk for major depression.

Results:

10. 162-168 Recommend adding participants "who met criteria for" or "higher risk for" MDD as above

We have made these edits as described.

Discussion:

11. 189, 190, 191, 196, 200, 204, 206, 207, 210, 212 "risk for" (major/baseline) depression

We have made these edits as described.

12. 207-208 Recommend authors also suggest that in addition to lack of statistical power, the lack of effect may be due to using a screening tool that was intended for affluent, Caucasian women.

We appreciate this suggestion. As we do not introduce the expanded ACE scale until after the suggested lines, we have included a statement ("This limitation may partially explain the lack of ACEs' effect on the relationship between Black race and the risk for post-treatment depression") at the end of the paragraph that introduces the expanded ACE scale.

13. 218-222 Recommend including data on response rate, missing data (in addition to tables), racial/geographic diversity in methods and/or results if items are listed as strengths to the study.

The 30-day survey response rate is described in the first line of the Results section. We have added a sentence that describes the response rates of the baseline CES-D and PSS surveys. We have also added a sentence that describes the racial diversity of our cohort. We added a sentence to the methods that describes the geographic diversity of the primary study.

14. 226 "risk for" depression

We made this edit as described.

Conclusions:

15. 243-247 Suggest removing these sentences from conclusion; not focus of study.

We have removed the sentences as suggested

16. 249-251 Would also suggest removing this sentence as it suggests ACE plays a role as risk for MDD after EPL, yet the results of the study did not confirm this.

We have removed these sentences as suggested.

Figures and Tables:

17. Table 1 - Recommend including treatment modality for EPL.

We have added treatment method to Table 1

18. Table 2 - Consider renaming "Association between race and risk for...."

We have made this edit as suggested.

References: Appropriate for study.

Reviewer #2: This is a secondary analysis of a randomized clinical trial on the relationship between race and the development of depressive symptoms in patients who are participating in a clinical trial of early pregnancy loss.

1. It would be interesting or perhaps pertinent to evaluate the factors, such as sociodemographics, pregnancy history, and what were the outcomes in "non-Black" participants. The danger is that there may be the development of stereotypes based on implicit biases in attributing symptoms to race rather than perhaps racism (as you outline in the limitations part of the paper).

We appreciate this comment. There is existing research that identifies the risk for depression among all women experiencing early pregnancy loss and this data was not disaggregated by race. Therefore, our objective was to research an understudied population and explore if women who self-identified as Black are high-risk for a treatable medical condition. We have expanded the discussion to caution readers against stigmatizing this population.

2. on page 8, line 31, it can potentially be problematic to have as the main exposure as race, which cannot be changed. so that there is not a "blame the victim" view of such categorical variables.

We appreciate the concern about having the main exposure as race. We have expanded the discussion section to address this concern. We aim to challenge readers to recognize the complex systemic factors, such as structural racism, that contribute to the disparate health outcomes among Black women.

3. Page 10, line 183 is a fragment after Table 2. Perhaps a semicolon would be appropriate so break up the next part of the sentence which is a fragment.

We have made this edit as described.

4. Why wasn't a power analysis done for the cohorts so that you know how many participants would be needed in each group to see the outcomes that the authors were looking for? The authors recognize the limitations of the small sample size.
A sample size calculation was not performed as this was a planned secondary analysis. We have included a sentence in the Methods section that states we did not perform a sample size calculation.

5. Page 13, line 245, the authors should consider not using the word, "minority" rather than "minoritized," since "minority" implies less than so "minoritized populations" is preferably.

We appreciate this suggestion. We have removed the entire sentence, as suggested by another reviewer.

6. The authors may acknowledge/consider the importance of a cultural and structural competent workforce to address disparities in perinatal mental health in their future directions.

We appreciate this comment. We have added the following sentence to our discussion section: "A structurally and culturally competent workforce, as well as appropriate mental health resources and intervention programs should therefore be prioritized in order to meet the needs of this high-risk population."

Reviewer #3:

The manuscript "Racial Disparities in Mental Health Outcomes Among Women with Early Pregnancy Loss" by Dr. Shorter et al studies an important and timely topic, very relevant to practicing physicians today which is maternal morbidity in the setting of racial inequities. The secondary analysis examines if Black participants have higher odds of major depression after EPL treatment when

compared to non Black participants.

The strengths of the study are the number of participants recruited and the diverse population enrolled in the study. Additionally, utilizing a myriad of scales to examine depressive symptoms, including the ACE scale, provides for more information than just depressive symptoms but also trauma. The manuscript is concise, well written and I believe has pertinent information for Obstetric providers.

1. Abstract: I think it's important to define EPL and state what your gestational guidelines were for the original RCT (line 26).

We have included the gestational guidelines for the original RCT in the results section of the abstract.

Introduction:

2. Include data on why Black women are more likely to experience EPL than other ethnic groups (line 59).

We appreciate this suggestion. The reason for Black women having an elevated risk of early pregnancy loss is unknown. The study that describes this disparity provides suggestions for plausible causal pathways, however, calls for further investigation.

3. The CES-D provides data on depressive symptoms, but as the authors point out, do not actually yield a clinical diagnosis of MDD (line 72)? MDD is used throughout the paper, but this is misleading as these women are not being diagnosed with major depressive disorder, but rather, have higher scores on a scale of depressive symptomatology.

We have replaced any implication of a clinical diagnosis throughout the paper with phrases such as "risk for major depression."

4. Another concern is that since psychiatric diagnostic criteria are not evaluated in these women, is it possible that some of them, given early pregnancy loss, may be experiencing symptoms of either an adjustment disorder or other trauma-relevant psychopathology, that may be leading to higher CES-D scores without actually meeting diagnostic criteria for MDD, but instead a different psychiatric diagnosis?

We appreciate this concern. As suggested, we have changed the language throughout the paper to "risk for major depression" as to not mislead readers about a definitive diagnosis. We acknowledge that other psychopathology could be contributing to increased CES-D scores. Our conclusion intends to focus mainly on the existence of the

disparity in depressive symptoms between racial groups.

Methods:

5. In describing the methods, it would be helpful to include more information about where patients were recruited from: clinic vs hospital, suburban vs urban, in order to give the reader a better idea of what population was recruited in order to better interpret the findings (line 77). Was this based on previous literature?

Upper tertile or quartile?

We appreciate this suggestion. We have included a sentence in the methods that states which hospitals participants were recruited from in the primary clinical trial. Per the study protocol (available at nejm.org) of the primary study (Schreiber CA, Creinin MD, Atrio J, Sonalkar S, Ratcliffe SJ, Barnhart KT. Mifepristone Pretreatment for the Medical Management of Early Pregnancy Loss. *N Engl J Med.* 2018;378(23):2161-2170), "Participants will be recruited by referral from the clinical practices and Emergency Departments at the Penn Medicine and UC Davis, as well as referring practices."

6. It would be helpful to know more about the make up of the non-Black participants- do they include Latinx women, for example who may have similar rates of ACEs or baseline depression or stressors as black women? (line 124)

We have included a statement in the results section outlining the racial and ethnicity make-up of all participants.

7. Regarding the CES-D cutoff scores, it is unclear how the cutoff of, greater than 21 was reached to defined as "likely MDD" (line 101).

We appreciate this question. Based on a literature review, there is currently no agreed upon cutoff score that defines "likely major depression." We chose a cutoff score of 21 based on an optimal balance between sensitivity and specificity. One study reports of a sensitivity of 73% and specificity of 96% with this cutoff score. [Siddaway, AP. The Center for Epidemiologic Studies- Depression The Center for Epidemiologic Studies-Depression (CES-D) scale measures a continuum from well-being to depression: Testing two key predictions of positive clinical psychology. *J Affect Disord.* 2017 Apr 15; 213:180-186]; We have included this reference in our manuscript.

8. Line 129 addresses the multivariable logistic analysis where ACE is used as a dichotomized variable. It is unclear why ACE is used as a categorical variable instead of as a continuous variable in the analysis to allow for the full variance in the data.

We appreciate this concern. ACE scores are interpreted as ordinal and not continuous. Similar to prior research, we included ACE in our model as a categorical variable.

9. Similarly, it would be helpful to know the overall mean scores for the ACE, CES-D, PSS variables instead of within each of the categories (and are there differences between Black and non-Black groups on these scales when not categorized?).

We appreciate this suggestion. The percentage of all participants who were at risk for baseline major depression is included in the results section. The percentage of all participants who reported high ACE scores is reported in the result section. We added a sentence in the results section for the percentage of all participants who met criteria for baseline high perceived stress scores. We hope that displaying the percentages for all participants in each of these specific categories will help make comparisons to the percentages we describe for each racial group.

10. Results: Table 1- Both education and medical insurance are significantly different between the groups and should be considered as a covariate in the logistic regression analyses. They may serve as a proxy for SES, which is not accounted for in this analysis, and may play an important moderating or mediating effect.

We appreciate this comment. For our multivariable models we considered covariates if their p value was <0.2 . Therefore, both education and medical insurance were considered for our final model and dropped during the performance of backwards selection.

STATISTICAL EDITOR COMMENTS:

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

1. General, lines 30-32: Since the primary outcome was major depressive disorder, with primary exposure as race and secondary exposure as high ACE, should separate more clearly those two results. That is, the primary exposure and outcome should be cited with more emphasis. The others, including associations with high perceived stress vs baseline stress are secondary.

We appreciate this suggestion. We have removed the statement describing the association between Black race and ACE score from the abstract in order to focus only on the primary results.

2. lines 37-38: Should expand this section to include proportions of women of each race cohort who met criteria for major depressive disorder at 30 days

We have made this edit, as described.

3. Table 1: The cohorts differ in many baseline characteristics, particularly completed education level, medical insurance etc which confounds comparisons.
We appreciate this concern. We have considered all covariates with $P < 0.2$ for our model.

4. Table 2: The strongest association was with baseline major depression. Should perform a sensitivity analysis by excluding all women with prior history of major depression to evaluate whether the association with race still holds.

We appreciate this suggestion. We included risk for baseline depression in our multivariable model as it was related to the outcome (risk for post-treatment depression) based on biologic plausibility.

5. Tabe 3: Given the numbers of women with high perceived stress, adjustment for two covariates may have resulted in over fitted models on the one hand and under powered analyses on the other.

We appreciate this comment. We looked at parameters of model fit when building our final perceived stress model. We found ACE and baseline perceived stress to be strong confounders of the relationship between race and perceived stress. Therefore, we looked to keep them both in the model. When assessing model fit using Akaike Information Criteria, the model with both covariates (ACE and baseline stress) had a lower AIC than either model using only ACE or baseline stress alone. We understand that while the model fit is improved, we are underpowered.

EDITOR'S COMMENTS

We no longer require that authors adhere to the Green Journal format with the first submission of their papers. However, any revisions must do so. I strongly encourage you to read the instructions for authors (the general bits as well as those specific to the feature-type you are submitting). The instructions provide guidance regarding formatting, word and reference limits, authorship issues and other relevant topics. Adherence to these requirements with your revision will avoid delays during the revision process by avoiding re-revisions on your part in order to comply with formatting.

Numbers below refer to line numbers.

1. 56. The comparison group is women not pregnant within the preceding year and the patients included women with loss up to 28 weeks. The EGA alone makes this a less than perfect comparison to your population, which you

describe as women with early pregnancy loss. Also, this reference is 23 years old. Are there more current data?

We appreciate this concern. We recognize that this study does not provide a perfect comparison to our early pregnancy population. We did not find any studies that examine the risk of major depression in women with only early pregnancy loss. Due to this concern as well as word limitations, we have removed line with this reference.

2. ACE should be spelled out throughout the manuscript. Similarly, EPL and PSS should be spelled out.

We have made these edits so that ACE, EPL and PSS are spelled out throughout the manuscript.

3. 92. As noted by one of the reviewers your study has not included steps for making a diagnosis of major depression. The CED-D scale is “The CES-D scale is a brief self-report scale designed to measure self-reported symptoms associated with depression experienced in the past week”, according to the Measurement Instrument Database for the Social Sciences. As such, throughout your paper you cannot say the participants were diagnosed with a major depression—you can only say that they had elevated depression symptom score. This is a very important distinction, that needs to be clear in the abstract, precis and manuscript. Similar to the PSS, the CES-D is “not a diagnostic instrument” (line 107.)

We have made edits throughout the manuscript that make it clear that participants are “at risk” for major depression and do not meet diagnostic criteria.

4. You state on line 125 that your primary outcome was “MDD 30 days after medical management”. As noted, you have not made a diagnosis of MDD. So was it a score of 21 or more that was your primary outcome? Please clarify.

We have changed the sentence to read, “The primary outcome was the risk for major depression 30 days after medical management of miscarriage.”

5. 119. Should be “sexually transmitted infections”.

We have made the edit as described.

6. P Values vs Effect Size and Confidence Intervals

While P values are a central part of inference testing in statistics, when cited alone, often the strength of the conclusion can be misunderstood. Whenever possible, 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.

This is true for the abstract as well as the manuscript, tables and figures.
We have made these edits throughout the abstract, manuscript, and figures whenever possible.

7. Please provide absolute values for variables, in addition to assessment of statistical significance.

We have included absolute values for variables, in addition to assessment of statistical significance.

8. We ask that you provide crude OR's followed by adjusted OR's for all relevant variables. (For instance, see line 164)

We have made these edits for all relevant variables.

9. 162. Given there is only a one month difference in baseline to 30 day follow up, it should not be a surprise that there is such a high aOR here, do you think?

We appreciate this comment. We have removed the word "however" at beginning of the sentence in order to not imply that these results are surprising.

10. 167. Here is an example of a place that requires editing re: "Baseline depression". You could say something like "elevated baseline CES-D score" here. Another example is line 189. I'm not being exhaustive pointing these out, but instead pointing out some examples of different ways you've phrased this to alert you to look for this throughout your paper.

We have added "risk for" prior to baseline depression. We have made similar edits throughout the manuscript.

11. 220. As noted by one reviewer, you need to tell us in the methods about the racial and geographic diversity in the methods section.

We have included the geographic diversity of the primary study participants in the methods section, and racial diversity of the participants included in our data analysis in the results sections.

12. 214, 221 and perhaps later in the paper you recommend "future research". We consider that as a bit of a "throw away" phrase as every author could include such a statement given the non-definitive nature of research. Please remove such statements. If you wish to include a paragraph

suggesting a particular study design with relevant questions that you think might further this research, that would perhaps be acceptable.

We have removed all statements that refer to future research.

13. Line 251 seems to be referencing research to decrease ACE's in society in general and seems somewhat out of place here in which you are addressing a very specific question.

We have removed this sentence, as suggested by another reviewer.

14. Table 1: Since the results are dichotomous for ACE scores (ie, they either had high or low scores) , you only need to report either the high or the low ace scores—I'd recommend keeping the high ACE scores.

We have made this edit, as described in Table 1.

15. Please describe the CES-D scores as “likely not depressed”, “likely mild/moderate depression”. Etc. here and in other places in the tables and manuscript.

We have made the suggested edits in manuscript and the tables.

16. Table 4 could be moved to online material

We appreciate this suggestion. We would like to keep Table 4 as part of the manuscript as it helps to display the specific components of the ACE survey that are contributing to the differences we saw between the two racial groups.

17. you have 2 copies of figure 1 included in the manuscript. Is this an oversight or was there supposed to be a figure 2?

We have removed the second copy of figure 1 as there is only supposed to be one figure in the manuscript.

EDITORIAL OFFICE COMMENTS:

1. The Editors of Obstetrics & Gynecology are seeking to increase 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.

We select choice A

2. Obstetrics & Gynecology uses an "electronic Copyright Transfer Agreement" (eCTA). When you are ready to revise your manuscript, you will be prompted in Editorial Manager (EM) to click on "Revise Submission." Doing so will launch the resubmission process, and you will be walked through the various questions that comprise the eCTA. Each of your coauthors will receive an email from the system requesting that they review and electronically sign the eCTA. Please check with your coauthors to confirm that the disclosures listed in their eCTA forms are correctly disclosed on the manuscript's title page.

The disclosures are correctly disclosed on the manuscript's title page.

3. For studies that report on the topic of race, 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).

We indicate in the manuscript that participants "self-identified" their race and ethnicity. In our manuscript race was analyzed in order to explore racial disparities within an early pregnancy loss population. We describe prior literature in the introduction section that supports our hypothesis that participants may differ in mental health outcomes based on race.

Use "Black" and "White" (capitalized) when used to refer to racial categories.

We have capitalized all racial categories.

The category of "Other" is a 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.

We do not use the category of "other" in our manuscript.

4. Clinical trials submitted to the journal as of July 1, 2018, must include a data sharing statement. The statement should indicate 1) whether individual deidentified participant data (including data dictionaries) will be shared; 2) what data in particular will be shared; 3) whether additional, related documents will be available (eg, study protocol, statistical analysis plan, etc.); 4) when the data will

become available and for how long; and 5) by what access criteria data will be shared (including with whom, for what types of analyses, and by what mechanism). Responses to the five bullet points should be provided in a box at the end of the article (after the References section).

Our manuscript is a planned secondary analysis of an already published clinical trial, which contains information about the original data. The reference to the primary study is: Schreiber CA, Creinin MD, Atrio J, Sonalkar S, Ratcliffe SJ, Barnhart KT. Mifepristone Pretreatment for the Medical Management of Early Pregnancy Loss. *N Engl J Med*. 2018;378(23):2161-2170.

5. Please submit a completed STROBE checklist.

Responsible reporting of research studies, which includes a complete, transparent, accurate and timely account of what was done and what was found during a research study, is an integral part of good research and publication practice and not an optional extra. *Obstetrics & Gynecology* supports initiatives aimed at improving the reporting of health research, and we ask authors to follow specific guidelines for reporting randomized controlled trials (ie, CONSORT), observational studies (ie, STROBE), observational studies using ICD-10 data (ie, RECORD), meta-analyses and systematic reviews of randomized controlled trials (ie, PRISMA), harms in systematic reviews (ie, PRISMA for harms), studies of diagnostic accuracy (ie, STARD), meta-analyses and systematic reviews of observational studies (ie, MOOSE), economic evaluations of health interventions (ie, CHEERS), quality improvement in health care studies (ie, SQUIRE 2.0), and studies reporting results of Internet e-surveys (CHERRIES). Include the appropriate checklist for your manuscript type upon submission. Please write or insert the page numbers where each item appears in the margin of the checklist. Further information and links to the checklists are available at <http://onq.editorialmanager.com>. In your cover letter, be sure to indicate that you have followed the CONSORT, MOOSE, PRISMA, PRISMA for harms, STARD, STROBE, RECORD, CHEERS, SQUIRE 2.0, or CHERRIES guidelines, as appropriate.

We have included the STROBE checklist at the end of our manuscript. We have indicated in our cover letter that we have followed the STROBE guidelines, as appropriate.

6. 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>

[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.

We have no problems with the revitalize definitions.

7. 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 22 typed, double-spaced pages (5,500 words). Stated page limits include all numbered pages in a manuscript (i.e., title page, précis, abstract, text, references, tables, boxes, figure legends, and print appendixes) but exclude references.

Our manuscript adheres to these length requirements with less than 5,500 words of the text in the body of the manuscript, and 21 pages of material, excluding references.

8. Specific rules govern the use of acknowledgments in the journal. Please note the following guidelines:

*** All financial support of the study must be acknowledged.**

We acknowledged the financial support we received from the Society of Family Planning Research Fund.

*** 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.**

We received no assistance with manuscript preparation.

*** 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.**

We acknowledge the support of C. Neill Epperson, MD, who received no funding for her participation and gave written permission to be named.

*** 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).**

Our manuscript and the contained data have not been presented at any meetings.

9. Precis: The Editors would like you to replace "Black participants" with "Black women."

We have made this suggested edit to the Precis.

10. 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.

The abstract for our manuscript has a word count of 299 words, excluding section headers. We have used the journal's recommended headers for Original Research articles.

11. Only standard abbreviations and acronyms are allowed. A selected list is available online at <http://edmgr.ovid.com/ong/accounts/abbreviations.pdf>.

Abbreviations and acronyms cannot be used in the title or précis. Abbreviations and acronyms must be spelled out the first time they are used in the abstract and again in the body of the manuscript.

We have utilized standard abbreviations and acronyms.

12. 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.

All such constructs have been edited out of the manuscript.

13. In your Abstract, manuscript Results sections, and tables, the preferred citation should be in terms of an effect size, such as odds ratio or relative risk or the mean difference of a variable between two groups, expressed with appropriate confidence intervals. When such syntax is used, the P value has only secondary importance and often can be omitted or noted as footnotes in a Table format. Putting the results in the form of an effect size makes the result of the statistical test more clinically relevant and gives better context than citing P values alone. If appropriate, please include number needed to treat for benefits (NNT_b) or harm (NNTh). When comparing two procedures, please express the

outcome of the comparison in U.S. dollar amounts. Please standardize the presentation of your data throughout the manuscript submission. For P values, do not exceed three decimal places (for example, "P = .001"). For percentages, do not exceed one decimal place (for example, 11.1%).

We have attempted to follow these guidelines in our reporting.

14. 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://edmqr.ovid.com/ong/accounts/table_checklist.pdf.

We have attempted to follow the table guidelines as stated.

15. 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 reference you are citing is still current and available. If the reference you are citing has been updated (ie, 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 (exceptions could include manuscripts that address items of historical interest). All ACOG documents (eg, Committee Opinions and Practice Bulletins) may be found at the Clinical Guidance page at <https://www.acog.org/clinical> (click on "Clinical Guidance" at the top).

In our manuscript, we reference ACOG Committee Opinion, Number 649. We have confirmed that the reference is still current and available. There is no newer version of this document and it supports the statement me make in the manuscript.

16. Figure 1 may be resubmitted with the revision as-is.

We have resubmitted Figure 1 as-is.

17. 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>. Please note that 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.
We will consider this if accepted.