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 29, 2021
To: "Aileen M. Gariepy" [redacted]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-21-1737

RE: Manuscript Number ONG-21-1737

Patient-centered safety outcomes after hysteroscopic compared to laparoscopic sterilization

Dear Dr. Gariepy:

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 Oct 20, 2021, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1:

Comments to the author:

The authors present a retrospective cohort study comparing laparoscopic to hysteroscopic sterilization in a large Medicaid population in California from 2008 to 2014. The outcomes of interest were procedural complications, additional surgical procedures (e.g. hysterectomy), repeat sterilization procedures, pelvic pain, pelvic inflammatory disease (PID), abdominal pain, non-abdominal pain, abnormal uterine bleeding. The findings were consistent with other studies showing an increased rate of repeat surgery for sterilization in the hysteroscopic group. Rates of PID and pelvic/abdominal pain however were less common.

Abstract:

Line 18 Specify what other procedures were done in the laparoscopic cohort other than hysterectomy. This is confusing. Were other procedures planned or were they the result of a complication? It makes sense if for example, the patient had an ovarian cyst and decided to have a laparoscopic tubal instead of hysteroscopic sterilization so the cyst could be removed. To what extent was the increased transfusion risk for laparoscopic tubal ligation due to salpingectomy vs other procedures? In general transfusion risk for laparoscopic tubal one would think should be extremely low unless there was a complication with great vessel injury during trocar insertion.

Introduction:

Overall this is a good review. I would suggest also including the other FDA cleared device Adiana. It looks like this was approved from 2009-2012 before it was removed. I am not sure if there is overlapping CPT codes for both. Was there any Adiana procedures included in your cohort?

Methods:

Line 59 What type of partnership was formed in the study design between patients, physicians and stakeholders? Were they included in the study design, data collection or analysis? Please clarify.

Line 87 Why was 30 days used to define the complications listed? Most would occur prior to 30 days but not all.

Line 95 Describe what type of tubal ligations were performed over the study time period. Fulguration, fallope ring, clips and or opportunistic salpingectomy. Each of these procedures has some unique complications that may impact the outcomes of interest. Using claims data how do you distinguish patients who had subsequent salpingectomy for incomplete occlusion vs. Elective removal for pain and or other complaints? As case reports and litigation started to appear this may bias both the rate and indications for repeat surgery in the hysteroscopic cohort.

Line 96 Were outcomes of pelvic pain and endometriosis considered together or separately? Since the gold standard diagnosis is by laparoscopy there are bound to be more patients with confirmed diagnosis of endometriosis in the laparoscopic cohort which may bias further reporting of pain etc by the patient.

Line 100-105 This explains a little more about the partnership and decisions about choice of outcomes. The topic of autoimmune symptoms and allergies is important.

Line 110-126 This is a thorough description of your propensity scoring and included confounders.

Results:

Table 1

Usually, the columns for demographics will have total number for each characteristic with % in ( ).

What was the rate of HSG performance post Essure placement? This is an important marker for success yet historically a high non-compliance rate. I think there would be a way to query CPT codes.

Table 2

The transfusion rate seems high .37% for BTL. What were the reasons? Is there more information on types of complications? How are you defining infection on the day of surgery? Usually, it is an outpatient procedure and SSI would show up later. This was reported in 101 patients or .44%.

Table 3

The high number of concurrent hysterectomy and oophorectomy suggest these were the primary surgery and the bilateral salpingectomy was more risk reduction. The comparative cohort should be those who were going into surgery solely for the intent of sterlization. It's hard to believe that 3.91% of patients going in for a tubal ligation ended up with a hysterectomy for a complication.

Table 4

What were the indications for repeat sterilizations for the laparoscopic cohort? 2.25% over 5 yrs seems very high.

Discussion:

Line 271-273 The claim about additional procedures including hysterectomy do not make sense. This may be an issue with coding and claims review without the ability to delve into indications. See previous comments.

Line 275-276 The need for any repeat procedure with hysteroscopy is consistent with prior reports. More information is needed on whether this was due to non-occluded tube, incomplete original procedure, or elective removal due to pain and or selection bias over time with FDA warning.

Line 281-282 The findings of increased reported pain with laparoscopy may be subject to reporting bias given the possibility of newly diagnosed endometriosis at the time of sterilization and disclosure to patients

Line 288-290 It is not surprising there would be higher rates of future surgery in younger patients compared to those over 45. Being closer to menopause patients may have opted out of any future procedure.

Reviewer #2:

This is a well-written, much-needed comparison of two sterilization approaches commonly employed in the past decade.

Numerous anecdotes involving negative experiences after hysteroscopic sterilization have appeared in the lay press, and protestors against this form of sterilization have even carried signs outside ACOG's Annual Clinical Meeting. Actual data comparing it to the laparoscopic procedures more commonly performed could be extremely valuable to both patients and clinicians.

Abstract: The Abstract is clear and inclusive of all major aspects of this multi-faceted study. However, based on the Results, it would seem important that the Conclusion read "fewer procedural complications and fewer claims for pelvic or abdominal pain."

Methods: Although there are limitations to using a single database, this retrospective review of MediCal claims offers considerable advantages - a significant number of patients who underwent each procedure, racial/ethnic diversity, relatively long-term follow up, and a population on which hysteroscopic sterilization has not previously been studied. All significant outcomes of both types of sterilization procedure were analyzed, including procedural complications, additional surgical and repeat sterilization procedures, pelvic inflammatory disease (PID), subsequent gynecologic and non-gynecologic symptoms, and additional outcomes of concern to stakeholders. Confounding variables were appropriately considered with propensity weighting and balancing tests, and multivariable models were used to assess the effect of sociodemographic and pre-sterilization clinical variables

Results: The results are presented as succinctly as possible given the complexity of the investigation. Individually labeled sections for each aspect studied direct readers to the areas of most interest to them. In my opinion, the discussion of behavioral outcomes (lines 236-40) and the lists of statistics regarding age differences in Sociodemographic and Pre-sterilization Clinical Variables (lines 246-251) might be best relegated to an accompanying chart such as S3 in the Appendix. Finally, although pregnancies after sterilization are referred to in lines 398-352 if the Discussion, I cannot find results of that critical outcome listed or described in the tables or text.

Discussion: The discussion includes a concise presentation of the most important conclusions of the study, as well as thoughtful attention to both its contributions and its limitations. A clearer discussion of the findings regarding pregnancies, and a brief expansion of the reference to racial/ethnic variations in access to care (lines 289-290) might further enhance the article. The conclusions expressed in the final paragraph concerning the importance of premarketing research and post-marketing surveillance of new devices and the value of using such to help women make informed decisions on contraception provide a fitting ending to an important article.

Reviewer #3:

I feel this manuscript significantly adds to the existing research on hysteroscopic vs. laparoscopic permanent contraception. I appreciate the focus on Medicaid claims data, as people with Medicaid have been excluded from much of the prior data on this topic. I do think it would be helpful in the discussion to include a little more information after presenting the current findings (line 278) on how these findings compare with the prior data on hysteroscopic vs. laparoscopic permanent contraception (e.g. specific complications for each procedure in prior studies) .

I feel the authors adequately identify and describe limitations of claims data based studies, and do feel that their research has clinical implications for how we counsel patients who underwent hysteroscopic permanent contraception.

I do want to note, our family planning field has shifted language to replace the term "sterilization" with "permanent contraception" and I would ask the authors to consider possible use of this language.

STATISTICS EDITOR COMMENTS:

Table 1: Need units for age, BMI. Should round months to nearest 0.1, not cite to 0.01 months precision. Need to enumerate all missing data.

Table 2: Given the number of comparisons, should use stricter inference threshold than $p < .05$ to account for multiple hypothesis testing. The $p = 0.03$ will then become NS.

Table 3: Same issue as in Table 2 with multiple hypothesis testing and need for stricter inference threshold.

Tables in General and lines 11-14: There are 8 outcomes being assessed and each of them are evaluated at multiple times. That is, there are many hypotheses being tested, but without appropriate adjustment for multiple hypothesis testing. By using 95% CIs and $p < 0.05$ as the threshold, no doubt many of the inferences are potentially spurious. Need to address this issue.

EDITORIAL OFFCIE 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. If your study is based on data obtained from the National Center for Health Statistics, please review the Data Use Agreement (DUA) for Vital Statistics Data Files that you or one of your coauthors signed. If your manuscript is accepted for publication and it is subsequently found to have violated any of the terms of the DUA, the journal will retract your article. The National Center for Health Statistics may also terminate your access to any future vital statistics data.

5. 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). 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.

6. If you have an administrative database study: to be considered for publication in Obstetrics & Gynecology, the database used must be shown to be reliable and validated. In your response, please tell us who entered the data and how the accuracy of the database was validated. This same information should be included in the Materials and Methods section of the manuscript.

7. 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.

8. 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.

9. 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]."

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 (NNTb) or harm (NNTh). When comparing two procedures, please express the outcome of the comparison in U.S. dollar amounts.

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

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

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

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

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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 Oct 20, 2021, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

John O. Schorge, MD
Associate Editor, Gynecology

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

Yale University School of Medicine
Department of Obstetrics, Gynecology & Reproductive Sciences

Aileen M. Gariepy, MD, MPH, MHS
Associate Professor
Section of Family Planning
Director, Yale Fellowship in Family Planning
[redacted]

October 18, 2021

Dwight J. Rouse, MD, MSPH
Editor-in Chief
Obstetrics & Gynecology
409 12th Street SW
Washington, DC 20024

Dear Dr. Rouse,

It is our pleasure to submit the revision of our manuscript, "Patient-centered safety outcomes after hysteroscopic compared to laparoscopic sterilization" for consideration for publication in *Obstetrics & Gynecology*. We have attached our point-by-point responses to Reviewers and the Editor at the end of this letter.

As noted previously, this manuscript constitutes original work not published previously (except in the form of an abstract) and is not under consideration for publication elsewhere. We will not submit this manuscript elsewhere until a final negative decision is made by the Editors of *Obstetrics & Gynecology*. Preliminary findings were presented as a poster abstract at the virtual 2020 Society of Family Planning Annual Meeting.

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 and registered.

I, Aileen Gariepy MD, have reviewed and edited the submission to omit any identifying information. I hereby submit this self-blinded manuscript for consideration in *Obstetrics & Gynecology*.

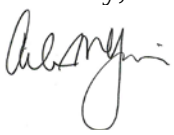
All authors have contributed to the development and conceptualization of the manuscript, reviewed the drafts and final version, and approve the submission. All persons named in the acknowledgements have given permission to be named in the manuscript. Institutional Review Board approval for this

study was obtained from the Committee for the Protection of Human Subjects at the University of California Davis. This trial and its protocol are registered at ClinicalTrials.gov (NCT03438682). Research reported in this article was funded through a Patient-Centered Outcomes Research Institute® (PCORI®) Award (1609-36359).

Female sterilization is the most commonly used contraceptive method worldwide; 219 million women and their partners rely on sterilization to prevent pregnancy. As this manuscript provides new findings regarding real-world patient-centered safety outcomes after hysteroscopic compared to laparoscopic sterilization, we expect it will be of great interest to *Obstetrics & Gynecology* readers. We found that among women who had Medicaid-funded hysteroscopic (n=5,906) or laparoscopic (n=23,965) sterilization, **hysteroscopic sterilization was followed by more claims for repeat sterilization procedures and abnormal uterine bleeding, but fewer claims for pelvic or abdominal pain compared to laparoscopic sterilization**. This information will likely be reassuring to the 750,000 women worldwide that have undergone Essure hysteroscopic sterilization procedures and the doctors that performed these procedures, given Essure hysteroscopic sterilization was removed from the US market in 2019 amid concerns about its safety. These findings also highlight the importance of adequate pre- and post-marketing research when new clinical devices are brought to market.

Thank you for your consideration of this manuscript.

Sincerely,



Aileen M. Gariepy, MD

RE: Manuscript Number ONG-21-1737

Patient-centered safety outcomes after hysteroscopic compared to laparoscopic sterilization

REVIEWER COMMENTS:

Reviewer #1:

The authors present a retrospective cohort study comparing laparoscopic to hysteroscopic sterilization in a large Medicaid population in California from 2008 to 2014. The outcomes of interest were procedural complications, additional surgical procedures (e.g. hysterectomy), repeat sterilization procedures, pelvic pain, pelvic inflammatory disease (PID), abdominal pain, non-abdominal pain, abnormal uterine bleeding. The findings were consistent with other studies showing an increased rate of repeat surgery for sterilization in the hysteroscopic group. Rates of PID and pelvic/abdominal pain however were less common.

Response: Thank you.

Abstract:

Line 18 Specify what other procedures were done in the laparoscopic cohort other than hysterectomy. This is confusing. Were other procedures planned or were they the result of a complication? It makes sense if for example, the patient had an ovarian cyst and decided to have a laparoscopic tubal instead of hysteroscopic sterilization so the cyst could be removed. To what extent was the increased transfusion risk for laparoscopic tubal ligation due to salpingectomy vs other procedures? In general transfusion risk for laparoscopic tubal one would think should be extremely low unless there was a complication with great vessel injury during trocar insertion.

Response: Additional surgical procedures are defined with further detail in the Methods (Lines 92-93) and Table 3. Because this analysis is based on claims data, we cannot evaluate whether the additional surgical procedures were planned or the result of a complication. Similarly, we cannot discern from claims data *why* a blood transfusion was given, just that it was given.

Introduction:

Overall this is a good review. I would suggest also including the other FDA cleared device Adiana. It looks like this was approved from 2009-2012 before it was removed. I am not sure if there is overlapping CPT codes for both. Was there any Adiana procedures included in your cohort?

Response: Both Adiana and Essure use the same CPT code**.** However, Adiana was not approved by California Medicaid and therefore Adiana procedures are not part of our cohort.

Methods:

Line 59 What type of partnership was formed in the study design between patients, physicians and stakeholders? Were they included in the study design, data collection or analysis? Please clarify.

Response: Patient and physician stakeholders were included in study design, data collection and analysis. This retrospective observational study was proposed following discussions the PI and co-investigators had with patient and physician stakeholders who were concerned about the lack of data comparing safety and effectiveness of hysteroscopic and laparoscopic sterilization. Stakeholders felt that a prospective clinical trial would potentially subject women to unnecessary harms, while analyses of existing data might provide the needed information without subjecting any additional women to potential harms. Patient and physician stakeholders also provided valuable input that guided the secondary outcomes we examined. As noted below by this Reviewer, more details are provided in Lines 101-106.

Line 87 Why was 30 days used to define the complications listed? Most would occur prior to 30 days but not all.

Response: Although most complications would occur prior to 30 days, in some health systems delays may occur in submitting claims for payment. We therefore used 30 days to define short-term complications, as previously done by Mao et al in 2015.

Line 95 Describe what type of tubal ligations were performed over the study time period. Fulguration, fallope ring, clips and or opportunistic salpingectomy. Each of these procedures has some unique complications that may impact the outcomes of interest. Using claims data how do you distinguish patients who had subsequent salpingectomy for incomplete occlusion vs. Elective removal for pain and or other complaints? As case reports and litigation started to appear this may bias both the rate and indications for repeat surgery in the hysteroscopic cohort.

Response: Unfortunately, with the available claims data, we are not able to differentiate between electrocoagulation, falope rings, clips, and opportunistic salpingectomies as the CPT codes for laparoscopic sterilization are heterogeneous and overlap. Similarly, because claims data do not include the indication for surgery, we cannot elucidate why a subsequent salpingectomy was performed. This is noted in our study limitations (Lines 313-316).

Line 96 Were outcomes of pelvic pain and endometriosis considered together or separately? Since the gold standard diagnosis is by laparoscopy there are bound to be more patients with confirmed diagnosis of endometriosis in the laparoscopic cohort which may bias further reporting of pain etc by the patient.

Response: The codes for pelvic pain and endometriosis were considered together.

Line 100-105 This explains a little more about the partnership and decisions about choice of outcomes. The topic of autoimmune symptoms and allergies is important.

Response: Thank you.

Line 110-126 This is a thorough description of your propensity scoring and included confounders.

Response: Thank you.

Results:

Table 1

Usually, the columns for demographics will have total number for each characteristic with % in ( ).

Response: As depicted in the top row of Table 1, we have listed the column % for each characteristic.

What was the rate of HSG performance post Essure placement? This is an important marker for success yet historically a high non-compliance rate. I think there would be a way to query CPT codes.

Response: Thank you for this question. We agree this is an important question but beyond the scope of the current manuscript. We agree that HSG performance is an important outcome and have included this outcome in a separate manuscript on pregnancies after sterilization that is in process.

Table 2

The transfusion rate seems high .37% for BTL. What were the reasons? Is there more information on types of complications? How are you defining infection on the day of surgery? Usually, it is an outpatient procedure and SSI would show up later. This was reported in 101 patients or .44%.

Response: We cannot discern the indication for interventions such as blood transfusion using the available claims data. Infection was defined using multiple ICD-9 and CPT codes detailed in Appendix 1, that included codes for surgical site infection, fever, and septicemia (Line 91-92 and Table S1 in Appendix 2).

Table 3

The high number of concurrent hysterectomy and oophorectomy suggest these were the primary surgery and the bilateral salpingectomy was more risk reduction. The comparative cohort should be those who were going into surgery solely for the intent of sterilization. It's hard to believe that 3.91% of patients going in for a tubal ligation ended up with a hysterectomy for a complication.

Response: We agree. Unfortunately, claims data do not allow us to discern the indication for surgery. This is specified in the manuscript (Lines 174-175).

Table 4
What were the indications for repeat sterilizations for the laparoscopic cohort? 2.25% over 5 yrs seems very high.

Response: Unfortunately, available claims data are not detailed enough to discern indication for surgery.

Discussion:
Line 271-273 The claim about additional procedures including hysterectomy do not make sense. This may be an issue with coding and claims review without the ability to delve into indications. See previous comments.

Response: As noted above, claims data are not detailed enough to discern indication for surgery or planned surgeries. We identify this issue in the manuscript (Lines 174-175).

Line 275-276 The need for any repeat procedure with hysteroscopy is consistent with prior reports. More information is needed on whether this was due to non-occluded tube, incomplete original procedure, or elective removal due to pain and or selection bias over time with FDA warning.

Response: This analysis reflects hysteroscopic and laparoscopic sterilization procedures performed from 2008 to 2014. As an FDA warning wasn't issued until 2016, we feel it is unlikely to bias this study's findings. As noted above, claims data are not detailed enough to discern indication for surgery.

Line 281-282 The findings of increased reported pain with laparoscopy may be subject to reporting bias given the possibility of newly diagnosed endometriosis at the time of sterilization and disclosure to patients

Response: Thank you for this insight. We have added to our discussion of limitations that patients found to have endometriosis at the time of laparoscopy may have been more likely to have subsequent claims for endometriosis that this study would have considered indicative of pelvic pain (Line 316-317).

Line 288-290 It is not surprising there would be higher rates of future surgery in younger patients compared to those over 45. Being closer to menopause patients may have opted out of any future procedure.

Response: Agree. Thank you.

Reviewer #2:

This is a well-written, much-needed comparison of two sterilization approaches commonly employed in the past decade. Numerous anecdotes involving negative experiences after hysteroscopic sterilization have appeared in the lay press, and protestors against this form of sterilization have even carried signs outside ACOG's Annual Clinical Meeting. Actual data comparing it to the laparoscopic procedures more commonly performed could be extremely valuable to both patients and clinicians.

Response: Thank you.

Abstract: The Abstract is clear and inclusive of all major aspects of this multi-faceted study. However, based on the Results, it would seem important that the Conclusion read "fewer procedural complications and fewer claims for pelvic or abdominal pain."

Response: Thank you. We have added this suggested language to the Abstract.

Methods: Although there are limitations to using a single database, this retrospective review of MediCal claims offers considerable advantages - a significant number of patients who underwent each procedure, racial/ethnic diversity, relatively long-term follow up, and a population on which hysteroscopic sterilization has not previously been studied. All significant outcomes of both types of sterilization procedure were analyzed, including procedural complications, additional surgical and repeat sterilization procedures, pelvic inflammatory disease (PID), subsequent gynecologic and non-gynecologic symptoms, and additional outcomes of concern to stakeholders. Confounding variables were appropriately considered with propensity weighting and balancing tests, and multivariable models were used to assess the effect of sociodemographic and pre-sterilization clinical variables

Response: Thank you.

Results: The results are presented as succinctly as possible given the complexity of the investigation. Individually labeled sections for each aspect studied direct readers to the areas of most interest to them. In my opinion, the discussion of behavioral outcomes (lines 236-40) and the lists of statistics regarding age differences in Sociodemographic and Pre-sterilization Clinical Variables (lines 246-251) might be best relegated to an accompanying chart such as S3 in the Appendix. Finally, although pregnancies after sterilization are referred to in lines 398-352 if the Discussion, I cannot find results of that critical outcome listed or described in the tables or text.

Response: Thank you for this suggestion. Given that patient stakeholders identified these "additional patient-centered outcomes) (e.g. autoimmune disorders) and "Sociodemographic and pre-clinical variables associated with post-sterilization claims" as very important outcomes, we prefer to include this discussion in the main text. We agree that pregnancies after sterilization are an important outcome and have a separate manuscript in process on this topic.

Discussion: The discussion includes a concise presentation of the most important conclusions of the study, as well as thoughtful attention to both its contributions and its limitations. A clearer discussion of the findings regarding pregnancies, and a brief expansion of the reference to racial/ethnic variations in access to care (lines 289-290) might further enhance the article. The conclusions expressed in the final paragraph concerning the importance of premarketing research and post-marketing surveillance of new devices and the value of using such to help women make informed decisions on contraception provide a fitting ending to an important article.

Response: Thank you. We have briefly expanded the reference to racial/ethnic variations in access to care and removed the discussion of pregnancies after sterilization, which while important, are beyond the scope of this manuscript. We have a separate manuscript on pregnancies after sterilization that is in process.

Reviewer #3:

I feel this manuscript significantly adds to the existing research on hysteroscopic vs. laparoscopic permanent contraception. I appreciate the focus on Medicaid claims data, as people with Medicaid have been excluded from much of the prior data on this topic. I do think it would be helpful in the discussion to include a little more information after presenting the current findings (line 278) on how these findings compare with the prior data on hysteroscopic vs. laparoscopic permanent contraception (e.g. specific complications for each procedure in prior studies).

Response: Thank you for this suggestion. On Lines 301-310, we provide a brief discussion of how these findings compare with prior studies of complications following permanent contraception for women.

I feel the authors adequately identify and describe limitations of claims data based studies, and do feel that their research has clinical implications for how we counsel patients who underwent hysteroscopic permanent contraception.

Response: Thank you.

I do want to note, our family planning field has shifted language to replace the term "sterilization" with "permanent contraception" and I would ask the authors to consider possible use of this language.

Response: Philosophically, we understand this shift in language, but at this point prefer to keep the language that was used by our funder and stakeholders for this particular study.

STATISTICS EDITOR COMMENTS:

Table 1: Need units for age, BMI. Should round months to nearest 0.1, not cite to 0.01 months precision. Need to enumerate all missing data.

Response: We have added units for age and BMI and rounded months to nearest 0.1 decimial point. Given the data source, there aren't missing data to enumerate except for Race category "other" which includes "unknown" as noted in the footnote.

Table 2: Given the number of comparisons, should use stricter inference threshold than $p < .05$ to account for multiple hypothesis testing. The $p = 0.03$ will then become NS.

Response: We have opted to provide p-values to 3 decimal place for p-values between 0.01 and 0.05 so that readers can draw conclusions as they feel appropriate, as it is not necessarily the case that a p-value of 0.03 would yield an adjusted value above 0.05, as that depends on the procedure being used and where the p-value ranks among the other p-values in the "family". For example, if a p=0.03 is the lowest p-value, it likely wouldn't be strong enough to remain significant, but *if* there are plenty of other p-values that were below it, as was largely the case in this study, then the false discovery rate procedures astutely take this into account, in the same way that positive predictive values go up when disease prevalence goes up.

Table 3: Same issue as in Table 2 with multiple hypothesis testing and need for stricter inference threshold.

Response: Please see above response.

Tables in General and lines 11-14: There are 8 outcomes being assessed and each of them are evaluated at multiple times. That is, there are many hypotheses being tested, but without appropriate adjustment for multiple hypothesis testing. By using 95% CIs and $p< 0.05$ as the threshold, no doubt many of the inferences are potentially spurious. Need to address this issue.

Response: Whether and which approaches should be used for adjusting for multiplicity, particularly in a study evaluating complications as outcomes is debatable, because there is an inherent tension between sensitivity and specificity. If one uses a stricter definition for counting something as a "finding" then one risks missing what may in fact be a true harm. In keeping with the goals of our patient stakeholders, we prioritized sensitivity over specificity. As such, the approach that we've taken is to report on all of the outcomes without adjustment. We recognize that there are different strategies for adjusting for multiplicity. Some pertain to hypothesis testing and controlling what is called the familywise type-1 error rate. Some pertain to another approach, one that has become very popular in recent decades, due to the explosion of high-dimensional datasets (omics), which is to control for "false discoveries". The difference between them is analogous to the difference in how false positives affect (1 -specificity) versus how they affect (1 - positive predictive value positive):

1-Sp = FP/ (TN + FP), so the denominator are all the cases where truly the condition was not present, whereas

1-PPV = FP / (TP + FP), so the denominator are all the cases where the testing decision

Controlling type-1 error pertains to 1 – Sp, because the denominator is all the cases when the null hypothesis is true, while controlling false discoveries pertains to controlling 1 – PPV, because the denominator is all the times when a result was flagged as significant.

Because we are reporting unadjusted p-values and all of the outcomes that we looked at, that allows a reader to implement their own strategies for controlling for either type-1 error or for false discoveries, as those strategies can be applied to "families" of p-values to yield either multiplicity adjusted p-values (for controlling type-1 error) or q-values (for controlling false discoveries).

EDITORIAL OFFICE COMMENTS:

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

Response: OPT-IN: Yes, please 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.*

Response: Responsiveness to the above instructions has been verified.

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.

Response: Verified.

4. If your study is based on data obtained from the National Center for Health Statistics, please review the Data Use Agreement (DUA) for Vital Statistics Data Files that you or one of your coauthors signed. If your manuscript is accepted for publication and it is subsequently found to have violated any of the terms of the DUA, the journal will retract your article. The National Center for Health Statistics may also terminate your access to any future vital statistics data.

Response: Our study is not based on data obtained from the National Center for Health Statistics. Our study is based on data obtained from the Centers for Medicare and Medicaid

Services (CMS) Research Data Assistance Center (ResDAC). Per Centers for Medicare and Medicaid Services Data Use Agreement, cells with a value of 1-10 may not be specified. This footnote is included for all relevant tables.

5. 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). 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.

Response: The race/ethnicity field used for our analyses comes from the Medicaid data files used by ResDac to create the research files and data extracts. It reflects the information reported by the state of California to the federal government at the time of data file preparation. California's Medicaid program collects race and ethnicity as separate self-reported responses from applicants themselves as part of its eligibility screening process. However, the number of racial groups available for selection on the Medicaid application and the algorithm used by California for combining groups into the required federal reporting format may have varied over the time-period included in this research.

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.

Response: Black and White have been capitalized when used to refer to racial categories and all use of an "Other" category is further described in the manuscript.

6. If you have an administrative database study: to be considered for publication in Obstetrics & Gynecology, the database used must be shown to be reliable and validated. In your response, please tell us who entered the data and how the accuracy of the database was validated. This same information should be included in the Materials and Methods section of the manuscript.

Response: Not applicable.

7. 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://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.acog.org%2Fpractice-management%2Fhealth-it-and-clinical-informatics%2Frevitalize-obstetrics-data-definitions&data=04%7C01%7Caileen.gariepy%40yale.edu%7Cd038eee488e8475e988908d983591f83%7Cdd8cbebb21394df8b4114e3e87abeb5c%7C0%7C0%7C637685242996045215%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000&sdata=7ROfKPKxtCPNoanXvz1Ctxwq%2BZ0kjFxEOdY0o%2FO%2FInU%3D&reserved=0* *and the gynecology data definitions at* *https://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.acog.org%2Fpractice-management%2Fhealth-it-and-clinical-informatics%2Frevitalize-gynecology-data-definitions&data=04%7C01%7Caileen.gariepy%40yale.edu%7Cd038eee488e8475e988908d983591f83%7Cdd8cbebb21394df8b4114e3e87abeb5c%7C0%7C0%7C637685242996045215%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000&sdata=UwDReP9ABGiOh4MPjxRG6mM90%2BvvBxp8TfEjO9%2Bxgt8%3D*

&reserved=0. If use of the reVITALize definitions is problematic, please discuss this in your point-by-point response to this letter.

Response: We use reVITALize definitions in the manuscript.

8. 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.

Response: We have ensured that the revised manuscript adheres to the length restrictions by manuscript type. Of note, we moved 2 tables (previously numbered Tables 2 and 3) to the Appendix to ensure adherence.

9. 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]."*

Response: Responsiveness to the above instructions has been verified.

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.

Response: We have verified consistency.

In addition, the abstract length should follow journal guidelines. The word limit for Original Research articles is 300 words. Please provide a word count.

Response: The Abstract is 267 words.

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11. Only standard abbreviations and acronyms are allowed. A selected list is available online at https://nam12.safelinks.protection.outlook.com/?url=http%3A%2F%2Fedmgr.ovid.com%2Fong%2Faccounts%2Fabbreviations.pdf&data=04%7C01%7Caileen.gariepy%40yale.edu%7Cd038eee488e8475e988908d983591f83%7Cdd8cbebb21394df8b4114e3e87abeb5c%7C0%7C0%7C637685242996045215%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000&sdata=IlTtleLMO8I6ulx9ZtsF%2BIUnqTTbTW5DTJx2xCL1swE%3D&reserved=0. 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.

Response: Only standard abbreviations and acronyms are used.

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.

Response: We have revised the manuscript to remove use of the virgule symbol (/) except when used for “race/ethnicity” as is used in Editorial Office Comments #5 above.

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.

Response: Major findings are presented using Incident Rate Ratios and 95% Confidence Intervals. Some findings, with small cell sizes (e.g. Table 2 and Table 3) report bivariate analyses and p-values only.

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

Response: Not applicable.

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%").

Response: We have standardized all data presentation in the manuscript and have ensured that P values do not exceed three decimal places and we have corrected all percentages so that they do not exceed one decimal place.

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:
https://nam12.safelinks.protection.outlook.com/?url=http%3A%2F%2Fedmgr.ovid.com%2Fong%2Faccounts%2Ftable_checklist.pdf&data=04%7C01%7Caileen.gariepy%40yale.edu%7Cd038eee488e8475e988908d983591f83%7Cdd8cbebb21394df8b4114e3e87abeb5c%7C0%7C0%7C637685242996045215%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000&sdata=4pyq3maCjMXzMN4tv4SRF9lbdTpe3waaNJcn2Y%2FzE4Y%3D&reserved=0.

Response: All tables conform to the journal’s style.

15. Please review examples of our current reference style at
https://nam12.safelinks.protection.outlook.com/?url=http%3A%2F%2Fong.editorialmanager.com%2F&data=04%7C01%7Caileen.gariepy%40yale.edu%7Cd038eee488e8475e988908d983591f83%7Cdd8cbebb21394df8b4114e3e87abeb5c%7C0%7C0%7C637685242996045215%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000&sdata=RUzNApWfsrUd8EjqWGspDphb4GR8%2F3k62iVTPUnyypU%3D&reserved=0 (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.

Response: Verified.

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://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.acog.org%2Fclinical&data=04%7C01%7Caileen.gariepy%40yale.edu%7Cd038eee488e8475e988908d983591f83%7Cdd8cbebb21394df8b4114e3e87abeb5c%7C0%7C0%7C637685242996045215%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000&sdata=PEgQf4%2F957y3jioxMa9QE9y2YPcDeHp%2FYmkUbFZmyik%3D&reserved=0 (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.

Response: Verified.

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

Response: Verified.

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 https://nam12.safelinks.protection.outlook.com/?url=http%3A%2F%2Flinks.lww.com%2FLWW-ES%2FA48&data=04%7C01%7Caileen.gariepy%40yale.edu%7Cd038eee488e8475e988908d983591f83%7Cdd8cbebb21394df8b4114e3e87abeb5c%7C0%7C0%7C637685242996045215%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000&sdata=qlYkLwJjoLpcVv1CbII0gQu86beFE4EadK2sN5x5UHA%3D&reserved=0. The cost for publishing an article as open access can be found at https://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwkauthorservices.editage.com%2Fopen-access%2Fhybrid.html&data=04%7C01%7Caileen.gariepy%40yale.edu%7Cd038eee488e8475e988908d983591f83%7Cdd8cbebb21394df8b4114e3e87abeb5c%7C0%7C0%7C637685242996045215%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000&sdata=2f7HalG0bHzeek5AWN00VQC%2FghkRHUUcJniGBpITQTA%3D&reserved=0.

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.

Response: Thank you.

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

Response: Thank you.