

# 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)\*

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**Date:** Dec 11, 2020  
**To:** "Daniel Grossman" [REDACTED]  
**From:** "The Green Journal" em@greenjournal.org  
**Subject:** Your Submission ONG-20-2759

RE: Manuscript Number ONG-20-2759

Medication abortion with pharmacist dispensing of mifepristone

Dear Dr. Grossman:

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 paper will be maintained in active status for 21 days from the date of this letter. If we have not heard from you by Jan 01, 2021, we will assume you wish to withdraw the manuscript from further consideration.

#### REVIEWER COMMENTS:

Reviewer #1:

This is a timely and much-needed study of patient experience of pharmacist dispensing of mifepristone. The authors present data from a multicenter prospective cohort study that examines the effectiveness of medication abortion with mifepristone prescribed by clinicians and dispensed by pharmacists and patients' satisfaction with that method of treatment. The analysis is sound and the results clearly show the safety of pharmacist dispensing of mifepristone and that women like it. These findings support the American College of Obstetrician and Gynecologists in their position statement recommending the removal of the REMS and ETASU for mifepristone.

Materials and Methods:

By allowing each clinical site to follow their own medical abortion follow-up protocol, these results are generalizable to many settings. By using multiple choice and open-response fields in the survey, the authors captured participant's experiences to the fullest.

Specific questions:

Line 119-121: For clarification, was the entire cost of the medical abortion covered by the study?

Reviewer #2:

The presented manuscript reports the results of a prospective study evaluating the effectiveness and acceptability of medication abortion with mifepristone dispensed by pharmacists. The study was conducted at 8 different sites in CA and WA states over 2 years. Patients were evaluated, counseled, and consented by physicians within the clinic, but then picked up their medications (mifepristone and misoprostol) at a pharmacy. The authors performed the study under an IND and with IRB approval.

If the primary outcome is efficacy, it would have been stronger data to have randomized patients instead of using a prospective cohort without controls.

1. Line 23 - To fully disclose, I would recommend adding that Danco, Inc. is the manufacturer of Mifeprix.
2. Abstract: The primary outcome should be more clearly stated.
3. Introduction: Line 72 - please give some indication as to why the Mifepristone REMS was established. I would also

recommend adding a reference that demonstrates that the addition of mifepristone to misoprostol increases the efficacy of medication abortion.

4. Methods: Line 104 - prior to the study, did patients pick-up mifepristone at the clinic and then go to the pharmacy for other medications (i.e. misoprostol, etc.) or was everything picked up at the clinic? Lines 114-115 - did the pharmacies that refused to participate indicate why? Line 139 - please indicate why this dose regimen was chosen. Line 234 - Did you evaluate if there was a difference in satisfaction based upon those pharmacies that were farther away vs. onsite?

5. Results: Line 264 - Did those patients who declined to participate indicate why? Line 279 - Add to the end of this sentence "with medication alone". Line 281-282 - move this sentence to immediately after line 279.

6. Discussion: Lines 371-372 - The statement that a majority of patients expressed a preference for pharmacist dispensing is incorrect based upon the way the survey questions were asked (Prefer to have medication abortion available through primary care and pick up at pharmacy vs. prefer to have medication abortion available only in select clinics where pill is given directly in clinic). The use of the word "only" means that patients are aware that their options are limited if they chose #2, not necessarily that they "prefer" pharmacist dispensing. They might simply prefer easier access.

7. Figure 1: only shows the title; there is no figure.

8. Recommend moving table 2 to the appendix.

Reviewer #3:

Given the reality that the current rules concerning drug dispensing for medication abortion are not based on evidence that supports that the dispensing of these medications is best done at a medical facility, the concept of this study is somewhat of a "straw man" given that our considerable experience with medication abortion shows clearly that these medications do not need to be dispensed only at a health care facility. Nonetheless, the authors are to be commended for developing a robust clinical trial that provides strong support for pharmacists to be able to dispense mifepristone. The paper describing this study is well written and easy-to-follow. Accordingly, this paper presents important and interesting information to our readers and to clinicians and researchers worldwide.

STATISTICS EDITOR COMMENTS:

Table 2: In the subset with n = 25, should round all %s to nearest integer %, not report to nearest 0.1% precision.

Table 3: Same issue with the subset of n = 48

lines 234-247, Tables 1 & 5: The multivariable models included many covariates and some of the subsets (by age, race or educational level) had relatively low counts. Thus, there are two general issues with the aOR analyses: (1) they may be underpowered and (2) they are likely over fitted. In any event, all were NS, so they should not be generalized from these data.

It might be preferable to simply report the satisfaction %s with CIs, as the Authors did in text, in Table format. That is, simply to include CIs to the relevant sections of Tables 2 and 3.

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.

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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 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 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.

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. Obstetrics & Gynecology follows the Good Publication Practice (GPP3)\* guideline for manuscripts that report results that are supported or sponsored by pharmaceutical, medical device, diagnostics and biotechnology companies. The GPP3 is designed to help individuals and organization maintain ethical and transparent publication practices.

(1) Adherence to the GPP3 guideline should be noted in the cover letter.

(2) For publication purposes, the portions of particular importance to industry-sponsored research are below. In your cover letter, please indicate whether the following statements are true or false, and provide an explanation if necessary:

(2a) All authors had access to relevant aggregated study data and other information (for example, the study protocol) required to understand and report research findings.

(2b) All authors take responsibility for the way in which research findings are presented and published, were fully involved at all stages of publication and presentation development and are willing to take public responsibility for all aspects of the work.

(2c) The author list accurately reflects all substantial intellectual contributions to the research, data analyses, and publication or presentation development. Relevant contributions from persons who did not qualify as authors are disclosed in the acknowledgments.

(2d) The role of the sponsor in the design, execution, analysis, reporting, and funding (if applicable) of the research has been fully disclosed in all publications and presentations of the findings. Any involvement by persons or organizations with an interest (financial or nonfinancial) in the findings has also been disclosed.

(2e) All authors have disclosed any relationships or potential competing interests relating to the research and its publication or presentation.

(3) The abstract should contain an additional heading, "Funding Source," and should provide an abbreviated listing of the funder(s).

(4) In the manuscript, a new heading—"Role of the Funding Source"—should be inserted before the Methods and contain a detailed description of the sponsor's role as well as the following language:

"The authors had access to relevant aggregated study data and other information (such as study protocol, analytic plan and report, validated data table, and clinical study report) required to understand and report research findings. The authors take responsibility for the presentation and publication of the research findings, have been fully involved at all stages of publication and presentation development, and are willing to take public responsibility for all aspects of the work. All individuals included as authors and contributors who made substantial intellectual contributions to the research, data

analysis, and publication or presentation development are listed appropriately. The role of the sponsor in the design, execution, analysis, reporting, and funding is fully disclosed. The authors' personal interests, financial or non-financial, relating to this research and its publication have been disclosed." Authors should only include the above statement if all of it is true, and they should attest to this in the cover letter (see #2, above).

\*From Battisti WP, Wager E, Baltzer L, Bridges D, Cairns A, Carswell CI, et al. Good publication practice for communicating company-sponsored medical research: GPP3. *Ann Intern Med* 2015;163:461-4.

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. 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; Reviews is 300 words; Case Reports is 125 words; Current Commentary articles is 250 words; Executive Summaries, Consensus Statements, and Guidelines are 250 words; Clinical Practice and Quality is 300 words; Procedures and Instruments is 200 words. Please provide a word count.

10. Abstracts for all randomized, controlled trials should be structured according to the journal's standard format. The Methods section should include the primary outcome and sample size justification. The Results section should begin with the dates of enrollment to the study, a description of demographics, and the primary outcome analysis. Please review the sample abstract that is located online here: [http://edmgr.ovid.com/ong/accounts/sampleabstract\\_RCT.pdf](http://edmgr.ovid.com/ong/accounts/sampleabstract_RCT.pdf). Please edit your abstract as needed.

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

14. 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%).

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

16. Please review the journal's Table Checklist to make sure that your tables conform to journal style. The Table Checklist is available online here: [http://edmgr.ovid.com/ong/accounts/table\\_checklist.pdf](http://edmgr.ovid.com/ong/accounts/table_checklist.pdf).

17. 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 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](mailto: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).

18. When you submit your revision, art saved in a digital format should accompany it. If your figure was created in

Microsoft Word, Microsoft Excel, or Microsoft PowerPoint formats, please submit your original source file. Image files should not be copied and pasted into Microsoft Word or Microsoft PowerPoint.

When you submit your revision, art saved in a digital format should accompany it. Please upload each figure as a separate file to Editorial Manager (do not embed the figure in your manuscript file).

If the figures were created using a statistical program (eg, STATA, SPSS, SAS), please submit PDF or EPS files generated directly from the statistical program.

Figures should be saved as high-resolution TIFF files. The minimum requirements for resolution are 300 dpi for color or black and white photographs, and 600 dpi for images containing a photograph with text labeling or thin lines.

Art that is low resolution, digitized, adapted from slides, or downloaded from the Internet may not reproduce.

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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.

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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 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. Do not omit your responses to the Editorial Office or Editors' comments.

If you submit a revision, we will assume that it has been developed in consultation with your co-authors and that each author has given approval to the final form of the revision.

Again, your paper will be maintained in active status for 21 days from the date of this letter. If we have not heard from you by Jan 01, 2021, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

John O. Schorge, MD  
Associate Editor, Gynecology

2019 IMPACT FACTOR: 5.524  
2019 IMPACT FACTOR RANKING: 6th out of 82 ob/gyn journals

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Dear Editors,

Thank you very much for the opportunity to revise our manuscript. We appreciate the helpful feedback from the reviewers, and we have responded to each of their points below in bullets. I have read the journal's Instructions for Authors.

We look forward to hearing from you soon.

Sincerely,

Daniel Grossman, MD

#### REVIEWER COMMENTS:

##### Reviewer #1:

This is a timely and much-needed study of patient experience of pharmacist dispensing of mifepristone. The authors present data from a multicenter prospective cohort study that examines the effectiveness of medication abortion with mifepristone prescribed by clinicians and dispensed by pharmacists and patients' satisfaction with that method of treatment. The analysis is sound and the results clearly show the safety of pharmacist dispensing of mifepristone and that women like it. These findings support the American College of Obstetrician and Gynecologists in their position statement recommending the removal of the REMS and ETASU for mifepristone.

##### Materials and Methods:

By allowing each clinical site to follow their own medical abortion follow-up protocol, these results are generalizable to many settings. By using multiple choice and open-response fields in the survey, the authors captured participant's experiences to the fullest.

##### Specific questions:

Line 119-121: For clarification, was the entire cost of the medical abortion covered by the study?

- At the Washington and Kaiser sites, the study only paid for the mifepristone, misoprostol, and pharmacy dispensing fees; clinical services were billed in the standard fashion, so patient costs were no different in the study compared to the standard of care. At the University of California sites, it was not possible to bill Medi-Cal (the state Medicaid program) for any part of the clinical services because the service was not provided in a manner consistent with the mifepristone REMS. In order to not increase costs for patients, the study covered the clinical costs at these sites, in addition to the mifepristone, misoprostol, and pharmacy dispensing fees.
- We would prefer not to include these details, which would single out the Medi-Cal program. If the editors do not feel the text at L201-4 is sufficient, we can certainly edit.

##### Reviewer #2:

The presented manuscript reports the results of a prospective study evaluating the effectiveness and acceptability of medication abortion with mifepristone dispensed by pharmacists. The study was conducted at 8 different sites in CA and WA states over 2 years. Patients were evaluated, counseled, and consented by physicians within the clinic, but then picked up their medications (mifepristone and misoprostol) at a pharmacy. The authors performed the study under an IND and with IRB approval.

If the primary outcome is efficacy, it would have been stronger data to have randomized patients instead of using a prospective cohort without controls.

1. Line 23 - To fully disclose, I would recommend adding that Danco, Inc. is the manufacturer of Mifeprix.

- We added this in L23-4. We also clarified that GenBioPro is the manufacturer of a generic mifepristone product.

2. Abstract: The primary outcome should be more clearly stated.

- We clarified in L55 that effectiveness or complete abortion proportion was the primary outcome.

3. Introduction: Line 72 - please give some indication as to why the Mifepristone REMS was established. I would also recommend adding a reference that demonstrates that the addition of mifepristone to misoprostol increases the efficacy of medication abortion.

- We added in L73-4 a hypothesis that the FDA instituted these restrictions due to the limited experience with medication abortion at the time of approval.
- Reference 1 (the ACOG Practice Bulletin on medication abortion) includes information about the increased efficacy of the mifepristone-misoprostol regimen.

4. Methods: Line 104 - prior to the study, did patients pick-up mifepristone at the clinic and then go to the pharmacy for other medications (i.e. misoprostol, etc.) or was everything picked up at the clinic?

- We clarified in L104-5 that prior to study, patients obtained at least some other medications at the pharmacy. Some of the sites dispensed misoprostol in the clinic, but all gave prescriptions for at least some medications, such as antiemetics and analgesics, to be picked up at a pharmacy.

Lines 114-115 - did the pharmacies that refused to participate indicate why?

- No, they did not indicate why.

Line 139 - please indicate why this dose regimen was chosen.

- We clarified in L138-9 that this is the regimen described in the FDA-approved labeling for mifepristone.

Line 234 - Did you evaluate if there was a difference in satisfaction based upon those pharmacies that were farther away vs. onsite?

- We explored whether satisfaction with the pharmacy experience differed between those who traveled 1.5 miles to the pharmacy (n=49) compared to those for whom the pharmacy was adjacent to the clinic (n=203). Satisfaction was similar in the two groups. Among those traveling 1.5 miles, 65.3% were very satisfied, while 69.5% were very satisfied among those with an adjacent pharmacy (p=0.574). We have not added this information to the text but can certainly do so if the editors prefer.

5. Results: Line 264 - Did those patients who declined to participate indicate why?

- The reasons for nonparticipation are included in Figure 1 (it seems that this reviewer was unable to download this figure).

Line 279 - Add to the end of this sentence "with medication alone".

- This was added to L271.

Line 281-282 - move this sentence to immediately after line 279.

- We moved this sentence as requested (now L271-2).

6. Discussion: Lines 371-372 - The statement that a majority of patients expressed a preference for pharmacist dispensing is incorrect based upon the way the survey questions were asked (Prefer to have medication abortion available through primary care and pick up at pharmacy vs. prefer to have medication abortion available only in select clinics where pill is given directly in clinic). The use of the

word "only" means that patients are aware that their options are limited if they chose #2, not necessarily that they "prefer" pharmacist dispensing. They might simply prefer easier access.

- We appreciate this comment from the reviewer. Given that 62.0% expressed a preference for pharmacy dispensing and 28.7% reported that either way was fine, we changed this sentence at L357 to say "over 90% indicated their support for pharmacist dispensing of mifepristone in the future."

7. Figure 1: only shows the title; there is no figure.

- We are unsure why the reviewer was unable to see the figure.

8. Recommend moving table 2 to the appendix.

- Table 2 has been moved to online Appendix 1.

Reviewer #3:

Given the reality that the current rules concerning drug dispensing for medication abortion are not based on evidence that supports that the dispensing of these medications is best done at a medical facility, the concept of this study is somewhat of a "straw man" given that our considerable experience with medication abortion shows clearly that these medications do not need to be dispensed only at a health care facility. Nonetheless, the authors are to be commended for developing a robust clinical trial that provides strong support for pharmacists to be able to dispense mifepristone. The paper describing this study is well written and easy-to-follow. Accordingly, this paper presents important and interesting information to our readers and to clinicians and researchers worldwide.

- We appreciate the reviewer's comments.

STATISTICS EDITOR COMMENTS:

Table 2: In the subset with  $n = 25$ , should round all %s to nearest integer %, not report to nearest 0.1% precision.

- This table is now online Appendix 1. We realize it was confusing, but in fact all of the proportions have a denominator of 260. We have tried to clarify this in the updated table.

Table 3: Same issue with the subset of  $n = 48$

- We made this change in the current Table 2.

lines 234-247, Tables 1 & 5: The multivariable models included many covariates and some of the subsets (by age, race or educational level) had relatively low counts. Thus, there are two general issues with the aOR analyses: (1) they may be underpowered and (2) they are likely over fitted. In any event, all were NS, so they should not be generalized from these data.

It might be preferable to simply report the satisfaction %s with CIs, as the Authors did in text, in Table format. That is, simply to include CIs to the relevant sections of Tables 2 and 3.

- We removed the presentation of covariates from Table 4 (previously Table 5) and added a footnote explaining the covariates included in the models. We also made some edits in the methods to clarify how the multivariable analysis was done, and we shortened the description in the text of the results shown in Table 4 (L329-338).
- To reduce concerns that our regression models were over specified, we applied the conservative general rule of thumb of 10 observations per variable (Vittinghoff et al. 2007). To detect any multicollinearity concerns, we calculated variance inflation factors (VIF). Average VIFs of 1.55 for pharmacy satisfaction (range 1.1-3.0) and 1.5 for satisfaction with medication abortion (range

1.1-3.1) were small, suggesting low correlation between predictors.

Reference: Eric Vittinghoff, Charles E. McCulloch, Relaxing the Rule of Ten Events per Variable in Logistic and Cox Regression, *American Journal of Epidemiology*, Volume 165, Issue 6, 15 March 2007, Pages 710–718,

#### 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.

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 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.

- It is wonderful to see the journal include this requirement. We added information in L144-7 to explain that race and ethnicity were self-described, and we explain why we thought it was important to collect and control for in our analysis. We also added a footnote to Table 1 explaining that there were 4 participants who selected their race as "other" and did not give additional information in the open-response field.

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).

- This is included in L404-10.

5. Obstetrics & Gynecology follows the Good Publication Practice (GPP3)\* guideline for manuscripts that report results that are supported or sponsored by pharmaceutical, medical device, diagnostics and biotechnology companies. The GPP3 is designed to help individuals and organization maintain ethical and transparent publication practices.

- This study was not supported or sponsored by pharmaceutical, medical device, diagnostics or biotechnology companies.

(1) Adherence to the GPP3 guideline should be noted in the cover letter.

(2) For publication purposes, the portions of particular importance to industry-sponsored research are below. In your cover letter, please indicate whether the following statements are true or false, and provide an explanation if necessary:

(2a) All authors had access to relevant aggregated study data and other information (for example, the study protocol) required to understand and report research findings.

(2b) All authors take responsibility for the way in which research findings are presented and published, were fully involved at all stages of publication and presentation development and are willing to take public responsibility for all aspects of the work.

(2c) The author list accurately reflects all substantial intellectual contributions to the research, data analyses, and publication or presentation development. Relevant contributions from persons who did not qualify as authors are disclosed in the acknowledgments.

(2d) The role of the sponsor in the design, execution, analysis, reporting, and funding (if applicable) of the research has been fully disclosed in all publications and presentations of the findings. Any involvement by persons or organizations with an interest (financial or nonfinancial) in the findings has also been disclosed.

(2e) All authors have disclosed any relationships or potential competing interests relating to the research and its publication or presentation.

(3) The abstract should contain an additional heading, "Funding Source," and should provide an abbreviated listing of the funder(s).

(4) In the manuscript, a new heading—"Role of the Funding Source"—should be inserted before the Methods and contain a detailed description of the sponsor's role as well as the following language:

"The authors had access to relevant aggregated study data and other information (such as study protocol, analytic plan and report, validated data table, and clinical study report) required to understand and report research findings. The authors take responsibility for the presentation and publication of the research findings, have been fully involved at all stages of publication and presentation development, and are willing to take public responsibility for all aspects of the work. All individuals included as authors and contributors who made substantial intellectual contributions to the research, data analysis, and publication or presentation development are listed appropriately. The role of the sponsor in the design, execution, analysis, reporting, and funding is fully disclosed. The authors' personal interests, financial or non-financial, relating to this research and its publication have been disclosed." Authors should only include the above statement if all of it is true, and they should attest to this in the cover letter (see #2, above).

\*From Battisti WP, Wager E, Baltzer L, Bridges D, Cairns A, Carswell CI, et al. Good publication practice for communicating company-sponsored medical research: GPP3. *Ann Intern Med* 2015;163:461-4.

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://urldefense.proofpoint.com/v2/url?u=https-3A\\_www.acog.org\\_practice-2Dmanagement\\_health-2Dit-2Dand-2Dclinical-2Dinformatics\\_revitalize-2Dobstetrics-2Ddata-2Ddefinitions&d=DwIGaQ&c=iORugZls2LIYyCAZRB3XLg&r=KLDHp7paDHvA4H-JcR-aj4COUzss5fD8dRaH3j\\_IP48&m=ykKm0mzbRptBz6dsU1YT-7tPIKNxId6bsTfkC4Bhvo&s=Z9kyZXQDcgi1pZojSRr2kfuE14Q8SnEVer0hVYvB69M&e=](https://urldefense.proofpoint.com/v2/url?u=https-3A_www.acog.org_practice-2Dmanagement_health-2Dit-2Dand-2Dclinical-2Dinformatics_revitalize-2Dobstetrics-2Ddata-2Ddefinitions&d=DwIGaQ&c=iORugZls2LIYyCAZRB3XLg&r=KLDHp7paDHvA4H-JcR-aj4COUzss5fD8dRaH3j_IP48&m=ykKm0mzbRptBz6dsU1YT-7tPIKNxId6bsTfkC4Bhvo&s=Z9kyZXQDcgi1pZojSRr2kfuE14Q8SnEVer0hVYvB69M&e=) and the gynecology data definitions at [https://urldefense.proofpoint.com/v2/url?u=https-3A\\_www.acog.org\\_practice-2Dmanagement\\_health-2Dit-2Dand-2Dclinical-2Dinformatics\\_revitalize-2Dgynecology-2Ddata-2Ddefinitions&d=DwIGaQ&c=iORugZls2LIYyCAZRB3XLg&r=KLDHp7paDHvA4H-JcR-aj4COUzss5fD8dRaH3j\\_IP48&m=ykKm0mzbRptBz6dsU1YT-7tPIKNxId6bsTfkC4Bhvo&s=IRLmyxc0Ka3hOwD7FJOlfYbcMV7VGFEEkMd2V6M44m8&e=](https://urldefense.proofpoint.com/v2/url?u=https-3A_www.acog.org_practice-2Dmanagement_health-2Dit-2Dand-2Dclinical-2Dinformatics_revitalize-2Dgynecology-2Ddata-2Ddefinitions&d=DwIGaQ&c=iORugZls2LIYyCAZRB3XLg&r=KLDHp7paDHvA4H-JcR-aj4COUzss5fD8dRaH3j_IP48&m=ykKm0mzbRptBz6dsU1YT-7tPIKNxId6bsTfkC4Bhvo&s=IRLmyxc0Ka3hOwD7FJOlfYbcMV7VGFEEkMd2V6M44m8&e=) . If use of the reVITALize definitions is problematic, please discuss this in your point-by-point response to this letter.

- We believe we are using the reVITALize data 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.

- The current word count is 4846 for the text and tables.

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. 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; Reviews is 300 words; Case Reports is 125 words; Current Commentary articles is 250 words; Executive Summaries, Consensus Statements, and Guidelines are 250 words; Clinical Practice and Quality is 300 words; Procedures and Instruments is 200 words. Please provide a word count.

- The word count for the abstract (not counting the section headers) is 300 words.

10. Abstracts for all randomized, controlled trials should be structured according to the journal's standard format. The Methods section should include the primary outcome and sample size justification. The Results section should begin with the dates of enrollment to the study, a description of demographics, and the primary outcome analysis. Please review the sample abstract that is located online here: [https://urldefense.proofpoint.com/v2/url?u=http-3A\\_edmgr.ovid.com\\_ong\\_accounts\\_sampleabstract-5FRCT.pdf&d=DwlGaQ&c=iORugZls2LIYyCAZRB3XLg&r=KLDHp7paDHvA4H-JcR-aJ4COUzss5fD8dRaH3j\\_IP48&m=ykKm0mzbRptBz6dsU1YT-7tPIKNxId6bsTfkC4Bhvo&s=8lrKky2xDR1-FaQcWhKoA5LHioDYDFGpBqQawG7RwgU&e=](https://urldefense.proofpoint.com/v2/url?u=http-3A_edmgr.ovid.com_ong_accounts_sampleabstract-5FRCT.pdf&d=DwlGaQ&c=iORugZls2LIYyCAZRB3XLg&r=KLDHp7paDHvA4H-JcR-aJ4COUzss5fD8dRaH3j_IP48&m=ykKm0mzbRptBz6dsU1YT-7tPIKNxId6bsTfkC4Bhvo&s=8lrKky2xDR1-FaQcWhKoA5LHioDYDFGpBqQawG7RwgU&e=) . Please edit your abstract as needed.

11. Only standard abbreviations and acronyms are allowed. A selected list is available online at [https://urldefense.proofpoint.com/v2/url?u=http-3A\\_edmgr.ovid.com\\_ong\\_accounts\\_abbreviations.pdf&d=DwlGaQ&c=iORugZls2LIYyCAZRB3XLg&r=KLDHp7paDHvA4H-JcR-aJ4COUzss5fD8dRaH3j\\_IP48&m=ykKm0mzbRptBz6dsU1YT-7tPIKNxId6bsTfkC4Bhvo&s=tYsaHvchYxwS\\_sqwEiF6-pVi3mT6QeYDYxXKomalrcres&e=](https://urldefense.proofpoint.com/v2/url?u=http-3A_edmgr.ovid.com_ong_accounts_abbreviations.pdf&d=DwlGaQ&c=iORugZls2LIYyCAZRB3XLg&r=KLDHp7paDHvA4H-JcR-aJ4COUzss5fD8dRaH3j_IP48&m=ykKm0mzbRptBz6dsU1YT-7tPIKNxId6bsTfkC4Bhvo&s=tYsaHvchYxwS_sqwEiF6-pVi3mT6QeYDYxXKomalrcres&e=) . 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.

- We have removed all usages of the virgule.

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

- Our only usage of "provider" is a direct quote from our survey instrument.

14. 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 (NNT<sub>h</sub>). When comparing two procedures, please express the outcome of the comparison in U.S. dollar amounts.

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The Table Checklist is available online here: [https://urldefense.proofpoint.com/v2/url?u=http-3A\\_edmgr.ovid.com\\_ong\\_accounts\\_table-5Fchecklist.pdf&d=DwIGaQ&c=iORugZIs2LIYyCAZRB3XLg&r=KLDHp7paDHvA4H-JcR-aj4COUzss5fD8dRaH3j\\_IP48&m=ykKm0mzbRptBz6dsU1YT-7tPIKNxld6bsTfkC4Bhvo&s=yx4JRbeTUoMwqlbcJMZMF7Beo53HOzw3kb9Ndk2mjjw&e=](https://urldefense.proofpoint.com/v2/url?u=http-3A_edmgr.ovid.com_ong_accounts_table-5Fchecklist.pdf&d=DwIGaQ&c=iORugZIs2LIYyCAZRB3XLg&r=KLDHp7paDHvA4H-JcR-aj4COUzss5fD8dRaH3j_IP48&m=ykKm0mzbRptBz6dsU1YT-7tPIKNxld6bsTfkC4Bhvo&s=yx4JRbeTUoMwqlbcJMZMF7Beo53HOzw3kb9Ndk2mjjw&e=) .

- We have reviewed the table checklist and made some small changes to the tables.

17. Please review examples of our current reference style at

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- We made some edits to the references and added DOIs.

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 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](mailto: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

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[aJ4COUz5fD8dRaH3j\\_IP48&m=ykKm0mzbRptBz6dsU1YT-7tPIKNxld6bsTfkC4Bhvo&s=rH35p8M6Bh\\_1WicRiZkgK\\_YKAeirj82pMe4Z2Xwe1gk&e=](https://urldefense.proofpoint.com/v2/url?u=http-3A_links.lww.com_LWW-2DES_A48&d=DwIGaQ&c=iORugZls2LIYyCAZRB3XLg&r=KLDHp7paDHvA4H-JcR-aJ4COUz5fD8dRaH3j_IP48&m=ykKm0mzbRptBz6dsU1YT-7tPIKNxld6bsTfkC4Bhvo&s=rH35p8M6Bh_1WicRiZkgK_YKAeirj82pMe4Z2Xwe1gk&e=) (click on "Clinical Guidance" at the top).

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