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: Dec 23, 2020
To: "Kate Coleman-Minahan" [redacted]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-20-3047

RE: Manuscript Number ONG-20-3047

Contraindications to hormonal contraception among postpartum women in Texas

Dear Dr. Coleman-Minahan:

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 15, 2021, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1:

In this study, researchers examined the prevalence of contraindications to CHCs and progestin only methods to examine factors associated w/ contraindications and the proportion of women using a contraindicated method at 6 months postpartum.

Abstract: Clear and concise. The conclusion should mention the most important finding, 19.2% of the sample had a cat 3 or 4 contraindications to CHCs.

Introduction, lines 99-102:
The sentence beginning: "Limited prior research..." is confusing. The first set of references (2-4) reports a "relatively low prevalence of contraindications" to CHCs among women in the general population, but then references 2,5,&6 report a lower range for those "using or interested" in CHCs. While I think I understand what you are reporting, I had to re-read the sentence multiple times and I am still uncertain. Please revise for clarity.

Methods: No edits.

Result: Line 183: I think this is the most relevant information from the study: 19.2% of the sample had a cat 3 or 4 contraindications to CHCs. This is appropriately in the first lines of the discussion, but it should also be in the conclusion of the abstract.

In the discussion, I would like more of a discussion as to why you believe you saw certain patterns, including:
- Why does being insured make you more likely to have a contraindications?
- Why are those who attended a postpartum visit less likely to have a contraindication

Your limitations paragraph succinctly captured all of the limitations I was compiling while reading through your methods. Nicely done.

Line 262-2: I think 19% of this cohort is not "relatively low". I would highlight that providers who care for similar populations should be aware that 1 in 5 postpartum patients they see may have a contraindication, and therefore providers should not be assuming that all methods are safe, which is likely a prevailing attitude given the overall safety of contraception.

Reviewer #2:

This article reports on a prospective cohort of 1700 women recruited after delivery in 8 Texas hospitals. Baseline interviews were done in hospital and telephone follow ups were done at various intervals. You have a good rate of follow up - 85% at 6 months. In your method section you report including data from baseline and six month visits, however I don't see much reported from baseline. For example if a woman reported hypertension at 6 months, which you include as a contraindicaiton, why not compare to objective data from the hospital record? Granted it would change over time but I do not see much of the baseline included in this paper.
Line 69: One of your conclusions is that almost 20% rate of contraindications is "low." Do you use a standard for calling this rate "low"? If so, please cite by whose definition this is considered low.
Line 130 it states that the baseline asked whether they attended a postpartum visit. How could they answer this while still in the hospital after delivery?
Line 137" "we were unable to differentiate between combined hormonal and progestin-only pills so we categorized all pills as combined." This is a serious limitation since its possible many postpartum women were on POPs. Related to this you did not ask about breastfeeding which would be a clue about which type of pill they might have been prescribed. COCs are contraindicated to breastfeeding women in the first month postpartum and many of the women were without insurance and might have continued with this method.
Line 147-50: I do not understand the rationale presented here for using DMPA contraindications. It is an assumption that makes your data slippery.
156: you admit that classifications of contraindicaitions depends on severity which you did not ask about. You also state that you use 3 month data on hypertension for some of the six month data reported.
You report useful results for understanding the populations most at risk of contraindicaiotns e.g., over 30 and Black.
You conclude that antepartum counseling and clinician screening for contraindications is important. Agreed! But how do you know they didn't do that?
Line 233: On the one hand you recommend screening for contraindications, on the other you condemn the use of "less effective" methods which might have been chosen due to identified contraindications.
Many women in this cohort were uninsured at 6 months. Were they using the less effective methods such as condoms because that is what they had access to?
You mention some other limitations to your data and interpretations in the conclusion that I agree with. I have a hard time with your concluding sentence because we don't know whether these subjects received prenatal counseling and more about how their insured status may have influenced the method they were using. Most striking is that 75% women with contraindications had no insurance at 6 months. Were they refilling prescriptions they got at discharge? Were they obtaining pills from Mexico? These issues are not addressed.

Reviewer #3:

This paper describes a prospective cohort study in which low-income post-partum women self-reported contraindications to hormonal contraceptive methods. Most data was collected 6 months after delivery. The CDC's 2016 Medical Eligibility Criteria (MEC) were used to categorize the risk of hormonal contraceptive use relative to the reported medical condition.

Abstract:
1. The abstract is specific to the manuscript.

Introduction:,
2. Brief, well described background.

Methods:
3. Methods seem suitable to the design.
4. Lines 152- 153: Consider adding 1 or 2 lines that define what MEC categories 3 and 4 are.
5. Lines 139-140: Just to clarify, these 19 medical conditions were selected because they were classified as category 3 or 4 in regards to hormone use?

Results:
6. Line 180: Does the 1452 exclude the 28 women who were pregnant at the 6 month interview and the six who were missing data on contraceptive use?

7. Can data be provided on demographics and socioeconomic factors either in the text or compiled in a table?

Discussion:

8. The data support the conclusions.

References:

9. Consider adding the following reference:

ACOG Practice Bulletin No. 206: Use of Hormonal Contraception in Women With Coexisting Medical Conditions. American College of Obstetricians and Gynecologists' Committee on Practice Bulletins—Gynecology. Obstet Gynecol. 2019 Feb;133(2):e128-e150. doi: 10.1097/AOG.0000000000003072.

Tables/Figures:

10. Consider adding a table that summarizes patient demographics.

STATISTICS EDITOR COMMENTS:

Lines 177-178, Table 3: While the overall rate of missing data may be < 1%, for BMI, the rate of missing data was 21.6%, which complicates analysis of adjustment by BMI class.

General: This study used data from a study of 1700 women. Need to address issue of whether that cohort and those who consented and were eligible (1452) were representative of all women. Also, was there any verification from medical records of the reasons for contraindication?

Table 2: For the proportions with contraindications, should include CIs as well as the point estimates.

Table 3: Need units for BMI and BMI classes. The column of %s should format as n(%) to identify both the n and % of women with contraindication within that covariate subset.

Table 4: Should include in footnote the variables used as adjustors in the final model.

EDITORIAL OFFICE COMMENTS:

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

A. OPT-IN: Yes, please publish my point-by-point response letter.
B. OPT-OUT: No, please do not publish my point-by-point response letter.

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

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

3. Our journal requires that all evidence-based research submissions be accompanied by a transparency declaration statement from the manuscript's lead author. The statement is as follows: "The lead author* affirms 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 (and, if relevant, registered) have been explained." *The manuscript's guarantor.

If you are the lead author, please include this statement in your cover letter. If the lead author is a different person, please ask him/her to submit the signed transparency declaration to you. This document may be uploaded with your submission in Editorial Manager.

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. All submissions that are considered for potential publication are run through CrossCheck for originality. The following lines of text match too closely to previously published works.

If applicable, please make sure the Abstract is either cited or disclosed as it is similar to the Abstract in P60 Contraindications to hormonal contraception among postpartum women in Texas.

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 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.

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).

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. 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.

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). 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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***

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 15, 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

College of Nursing
UNIVERSITY OF COLORADO
ANSCHUTZ MEDICAL CAMPUS

[redacted]

February 4, 2021

Nancy C. Chescheir, MD
Editor
Obstetrics & Gynecology
University of North Carolina
Chapel Hill, NC

Dear Dr. Chescheir,

Thank you for the opportunity to revise our paper "Contraindications to hormonal contraception among postpartum women in Texas" (ONG-20-3047). Our responses to each reviewer and editor are included below.

The material contained in the manuscript has not been submitted for publication elsewhere. All authors meet the guidelines for authorship. We did not obtain outside assistance for the analysis and writing of this manuscript and have no conflicts of interest to disclose. 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.

This study was approved by the Institutional Review Boards at the University of Texas at Austin and of the eight hospitals in which participants were recruited. In the case of university affiliated hospitals, it was reviewed by the corresponding IRB (Texas Tech University at El Paso, Texas Tech University at Odessa/Lubbock, University of Texas Southwestern, and University of Texas Health Science Center at Houston).

We verify that permission has been obtained from all persons named in the acknowledgments. The paper was presented as a poster at the virtual Society of Family Planning Annual Meeting, October 9-10, 2020.

Thank you for your consideration.

Sincerely,

Kate Coleman-Minahan PhD, RN, FNP-BC
Assistant Professor
University of Colorado College of Nursing
Anschutz Medical Campus

Response to Reviewers
We appreciate the opportunity to revise the manuscript. The reviewers' comments are reproduced in bold text, and our responses to the reviewers' comments are inserted beneath in normal text.

REVIEWER COMMENTS:

Reviewer #1:

In this study, researchers examined the prevalence of contraindications to CHCs and progestin only methods to examine factors associated w/ contraindications and the proportion of women using a contraindicated method at 6 months postpartum.

Abstract: Clear and concise. The conclusion should mention the most important finding, 19.2% of the sample had a cat 3 or 4 contraindications to CHCs.
We added this finding to the abstract conclusion.

Introduction, lines 99-102:
The sentence beginning: "Limited prior research..." is confusing. The first set of references (2-4) reports a "relatively low prevalence of contraindications" to CHCs among women in the general population, but then references 2,5,&6 report a lower range for those "using or interested" in CHCs. While I think I understand what you are reporting, I had to re-read the sentence multiple times and I am still uncertain. Please revise for clarity.
We edited this sentence for clarity. Lines 103-109 now read, "*Limited prior research has reported the prevalence of contraindications to combined hormonal contraception is between 2% and 16%*[4–7] *among combined hormonal contraceptive users and among the general population; the prevalence of contraindications was higher (39%) in a study of reproductive-aged Latinas in Texas.*[8]"

Methods: No edits.

Result: Line 183: I think this is the most relevant information from the study: 19.2% of the sample had a cat 3 or 4 contraindications to CHCs. This is appropriately in the first lines of the discussion, but it should also be in the conclusion of the abstract.
As noted above, we added this finding to the abstract conclusion.

In the discussion, I would like more of a discussion as to why you believe you saw certain patterns, including:
- Why does being insured make you more likely to have a contraindications?
- Why are those who attended a postpartum visit less likely to have a contraindication
We added additional discussion of these findings, including possible reasons for these patterns on lines 245-255.

Your limitations paragraph succinctly captured all of the limitations I was compiling while reading through your methods. Nicely done.
Thank you for the positive feedback.

Line 262-2: I think 19% of this cohort is not "relatively low". I would highlight that providers who care for similar populations should be aware that 1 in 5 postpartum patients they see may have a contraindication, and therefore providers should not be assuming that all methods are safe, which is likely a prevailing attitude given the overall safety of contraception.
This is a good point. In lines 286-291, we removed the clause "relatively low" from this sentence and replaced it with the suggested, "*Clinicians caring for similar populations should be aware that one in five postpartum patients may have a contraindication …*"

Reviewer #2:

This article reports on a prospective cohort of 1700 women recruited after delivery in 8 Texas hospitals. Baseline interviews were done in hospital and telephone follow ups were done at various intervals. You have a good rate of follow up - 85% at 6 months. In your method section you report including data from baseline and six month visits, however I don't see much reported from baseline. For example if a woman reported hypertension at 6 months, which you include as a contraindicaiton, why not compare to objective data from the hospital record? Granted it would change over time but I do not see much of the baseline included in this paper.
On lines 136-137, we describe the five variables taken from the baseline interview. These demographic characteristics were unlikely to change over the 6-month period that was the focus of the study. Although health conditions associated with contraindications could change over time, we assessed most contraindications at one time point- six months after delivery. Breast cancer (of which there were few participants with this diagnosis), migraines with aura (which would not likely change over time), and hypertension were assessed at 3 months following delivery; hypertension was also assessed at 6 months. Unfortunately, we did not collect data from hospital records for this study.

Line 69: One of your conclusions is that almost 20% rate of contraindications is "low." Do you use a standard for calling this rate "low"? If so, please cite by whose definition this is considered low.
This is a good point and was brought up by another reviewer. We removed the qualification of 20% as "low" from the sentence on lines 286-291 and from the abstract conclusion.

Line 130 it states that the baseline asked whether they attended a postpartum visit. How could they answer this while still in the hospital after delivery?
Thank you for catching this error. Participants were not asked about attendance at a postpartum visit until the six-month interview. We now include the question about attending a postpartum visit with the six-month interview questions on line 138.

Line 137" "we were unable to differentiate between combined hormonal and progestin-only pills so we categorized all pills as combined." This is a serious limitation since its possible many postpartum women were on POPs. Related to this you did not ask about breastfeeding which would be a clue about which type of pill they might have been prescribed. COCs are contraindicated to breastfeeding women in the first month postpartum and many of the women were without insurance and might have continued with this method.
We acknowledge that being unable to differentiate combined hormonal from progestin-only pills is a limitation. We assessed contraindications at six-months postpartum. Breastfeeding was not assessed because breastfeeding six months after delivery is not a category 3 or 4 contraindication to combined

hormonal contraception. Breastfeeding is also not an effective form of contraception after six-months postpartum.

Line 147-50: I do not understand the rationale presented here for using DMPA contraindications. It is an assumption that makes your data slippery.
We report contraindications to DMPA, progestin-only pills, and the implant in Tables 1 & 2 so this qualification on assessing contraindications to DMPA only was removed.

156: you admit that classifications of contraindicaitions depends on severity which you did not ask about. You also state that you use 3 month data on hypertension for some of the six month data reported.
You report useful results for understanding the populations most at risk of contraindicaiotns e.g., over 30 and Black.You conclude that antepartum counseling and clinician screening for contraindications is important. Agreed! But how do you know they didn't do that?
In this paper, we do not report the proportion of participants who received prenatal contraceptive counseling. However, because many patients may lose coverage shortly after delivery or do not attend their postpartum visit, we believe it is important to offer recommendations about counseling/screening during prenatal care and prior to delivery.

Line 233: On the one hand you recommend screening for contraindications, on the other you condemn the use of "less effective" methods which might have been chosen due to identified contraindications.
Many women in this cohort were uninsured at 6 months. Were they using the less effective methods such as condoms because that is what they had access to?
We do not have data on the reasons participants were using a particular method. However, on lines 257-262, we report that data from prior papers that suggest many of the women using less effective methods would prefer to be using more effective contraception and many experienced barriers to obtaining their preferred method postpartum. For clarification, we added, “In addition to cost barriers, some women report that clinicians…” to clarify that women may use less-effective methods when they prefer a more effective method because of cost or other provider-related barriers.

You mention some other limitations to your data and interpretations in the conclusion that I agree with. I have a hard time with your concluding sentence because we don't know whether these subjects received prenatal counseling and more about how their insured status may have influenced the method they were using. Most striking is that 75% women with contraindications had no insurance at 6 months. Were they refilling prescriptions they got at discharge? Were they obtaining pills from Mexico? These issues are not addressed.
Unfortunately, assessing how participants accessed contraception is beyond the scope of this paper. Although we do not assess whether participants received prenatal contraceptive counseling as described above, we did edit the concluding paragraph to better flow from our results. After describing the prevalence of contraindications, lines 286-291 now read, “*Clinicians should be aware that one in five postpartum patients may have a contraindication and that patients already at higher risk for adverse birth outcomes are more likely to have contraindications. Thus, clinicians should screen for contraindications during prenatal and postpartum contraceptive counseling*.”

Reviewer #3:

This paper describes a prospective cohort study in which low-income post-partum women self-reported contraindications to hormonal contraceptive methods. Most data was collected 6 months after delivery. The CDC's 2016 Medical Eligibility Criteria (MEC) were used to categorize the risk of hormonal contraceptive use relative to the reported medical condition.

Abstract:

1. The abstract is specific to the manuscript.

Thank you for the positive feedback.

Introduction:,

2. Brief, well described background.

Thank you for the positive feedback.

Methods:

3. Methods seem suitable to the design.

Thank you for the positive feedback.

4. Lines 152- 153: Consider adding 1 or 2 lines that define what MEC categories 3 and 4 are.

This is a great suggestion. We added the CDC definitions of MEC categories 3 and 4 on lines 163-166.

5. Lines 139-140: Just to clarify, these 19 medical conditions were selected because they were classified as category 3 or 4 in regards to hormone use?

This interpretation is correct. For clarity, on line 148, we added, "19 medical conditions associated with *category 3 or 4 contraindications*…"

Results:

6. Line 180: Does the 1452 exclude the 28 women who were pregnant at the 6 month interview and the six who were missing data on contraceptive use?

This is an important question. The 1452 includes all participants who completed a six-month interview. The 28 women who were pregnant were not asked about contraceptive use so they and the six who were missing on contraceptive use have missing data and are not included in the contraceptive use analysis (Table 4). They were not purposively excluded. To avoid confusion and because this is still <1% missing data as we state on line 196, we removed the reference to a different sample size for this particular analysis. All n's are provided in each table. For further clarity, on line 146 we clarify that participants who were pregnant at the 6-month interview were not asked about current contraceptive use. On line 168 we added an explanation of how we handled pregnancy as a contraindication. For participants who were pregnant at the 6-month interview, we did not consider pregnancy as a contraindication and instead we assessed whether they had any contraindication other than pregnancy. Hopefully this clears up confusion around sample size and the analytic sample of 1,452 is clear.

7. Can data be provided on demographics and socioeconomic factors either in the text or compiled in a table?

Demographics and socioeconomic characteristics for the entire sample have been reported in articles published previously (as cited on line 134). For the sample used specifically in this analysis, we provide the counts for demographic and socioeconomic factors for the full sample in Table 3, column 2.

Discussion:

8. The data support the conclusions.

Thank you for the positive feedback.

References:

9. Consider adding the following reference:

ACOG Practice Bulletin No. 206: Use of Hormonal Contraception in Women With Coexisting Medical Conditions. American College of Obstetricians and Gynecologists' Committee on Practice Bulletins—Gynecology. Obstet Gynecol. 2019 Feb;133(2):e128-e150. doi: 10.1097/AOG.0000000000003072.

As suggested, we added this reference and cite it on line 103.

Tables/Figures:

10. Consider adding a table that summarizes patient demographics.

As described above, demographic data is reported in Table 3, column 2.

STATISTICS EDITOR COMMENTS:

Lines 177-178, Table 3: While the overall rate of missing data may be < 1%, for BMI, the rate of missing data was 21.6%, which complicates analysis of adjustment by BMI class.

For the full sample included in the multivariable analysis (N=1,444), 7.6% of participants are missing data on BMI. Among participants with any contraindication to hormonal contraception, 21.6% have missing data on BMI. Because we do not believe data are missing at random on BMI, as described on Lines 182-184, we included a category for missing data on BMI. Although including a category for missing data makes interpretation more complex, there is less distortion in the model than using list-wise deletion and excluding 7.6% of participants from the entire multivariable analysis. Moreover, inclusion or exclusion of BMI missing data does not affect the direction of findings on any other covariates.

General: This study used data from a study of 1700 women. Need to address issue of whether that cohort and those who consented and were eligible (1452) were representative of all women. Also, was there any verification from medical records of the reasons for contraindication?

All 1700 women were eligible for and consented to participate in the study and completed the baseline interview; 1452 women completed the six-month interview and are included in the analysis for this paper. As cited on line 134, full study procedures and recruitment are described in a prior publication. In the limitations, we describe that the sample is not generalizable to all postpartum women (line 284) and that we assessed contraindications by self-report (line 277). We do not have medical record data.

Table 2: For the proportions with contraindications, should include CIs as well as the point estimates.

We have added 95% confidence intervals to Table 2.

Table 3: Need units for BMI and BMI classes. The column of %s should format as n(%) to identify both the n and % of women with contraindication within that covariate subset.
We added the BMI units and formatted this column as n(%) to indicate the frequency and percentage of women with a contraindication within each level of each covariate.

Table 4: Should include in footnote the variables used as adjustors in the final model.
The results presented in this table are descriptive and not from a multivariable adjusted model. As such, we have not included a footnote variables that were adjusted for in the table.

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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.
Data were not obtained from the National Center for Health Statistics.

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.
We describe that race and ethnicity were self-reported by participants on line 136. We added the reasons race and ethnicity were assessed on line 178 along with how race and ethnicity were categorized, including the “other” category. There were no missing data on race and ethnicity.

6. All submissions that are considered for potential publication are run through CrossCheck for originality. The following lines of text match too closely to previously published works.

If applicable, please make sure the Abstract is either cited or disclosed as it is similar to the Abstract in P60 Contraindications to hormonal contraception among postpartum women in Texas.
This poster presentation abstract is disclosed in the cover letter and on the title page.

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.
We removed the term "parity" from Table 3 and replaced it with "living biological children." No other definitions deviate from reVITALize definitions.

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 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.
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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.
All abbreviations, with the exception of the Centers for Disease Control and Prevention (CDC)'s 2016 Medical Eligibility Criteria (MEC) for Contraceptive Use, which if written out in the entirety each time would detract from the readability of the paper, are approved.

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All virgules not used to express a proportion were removed.

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We use the term clinicians because physicians, nurse practitioners, nurse-midwives, and physician assistants can provide and prescribe contraception.

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.
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