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: Mar 08, 2021
To: "David K. Turok" [redacted]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-21-293

RE: Manuscript Number ONG-21-293

Pregnancy risk by frequency and timing of unprotected intercourse prior to intrauterine device insertion

Dear Dr. Turok:

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 Mar 29, 2021, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1: This is a secondary analysis of data from a randomized controlled trial evaluating the efficacy of LNG-IUS vs. Copper IUD for emergency contraception efficacy. The author's goal was to evaluate the impact of unprotected sexual intercourse events prior to the 5-day recommended window. Though it is interesting to consider the possibility of using EC up to 14 days after UPI, it seems that the timing of UPI in relation to ovulation and placement of EC is also vitally important. It would be nice to see this discussed. Specific comments follow.

1. Title: Does not clearly represent the manuscript. Consider adding "for Emergency Contraception" to the end.
2. Precis: Lines 62-63: would also recommend adding Emergency Contraception ("Following intrauterine device placement for emergency contraception,…").
3. Abstract: Recommend re-writing the results section for clarity. Consider changing line 113 to "one pregnancy occurred among the 655 participants in a subject with one sexual event 48hrs prior to EC".
4. Introduction: Line 168: Add a brief sentence describing the reasoning behind the CDC/WHO recommendations for 5 days. Line 174: luteal phase pregnancy is not a well-accepted term; please define. Lines 180-183: it's not clear to me that this sentence is helpful in the current manuscript; consider deleting. Line 190: recommend adding the number of patients and pregnancies in the referenced study. Line 192: remove "who selected their IUD type". What did the data from this trial show?
5. Role of the Funding Source: recommend merging this paragraph to the earlier section which already discusses funding sources (lines 30-47).
6. Methods: Line 239: recommending adding that the electronic data capture method was added later as a protocol amendment due to missing outcome data. Recommend removing lines 267-270 as they are unclear and unnecessary here.
7. Discussion: Line 354: Consider how the addition of a sensitivity analysis excluding those 48 subjects without urine testing might impact the study results.

Reviewer #2: This is a clearly written secondary analysis of a randomized, prospective study comparing the efficacy of a hormonal IUD to a copper IUD as emergency contraceptives. All women were required to have had one episode of unprotected intercourse within 5 days of the IUD placement and negative urine pregnancy tests, but subjects were still allowed into the study if they had also had other episodes of unprotected intercourse up to 14 days prior. This allowed the authors to study the impact of multiple actions of unprotected intercourse as well as more remote exposure. In practice these extra episodes are considered exclusionary at least for use of IUDs as EC. Studies of oral agents have and are allowing women with multiple prior episodes to participate, but often the timing of those episodes is not recorded or not analyzed. The authors cited one study of 134 women who had IUDs placed 6-14 days after unprotected intercourse, and a second study of 76 subjects reported multiple unprotected episodes of intercourse in the prior 14 days., including 40 in the

6-14-day range. This study adds the experience of another 94 women (50% increase) in the 6-14-day range as well as an additional 182 who had multiple acts of unprotected intercourse within 5 days of IUD placement. By contributing explicitly to 2 deviations from the CDC guidelines, this paper would make a significant contribution to the literature and could help change restrictive practice guidelines.

My colleague, Dr. Brian Nguyen, who was kind enough to provide insightful comments to this review and I offer the following more specific comments:

Methods: While it may be in the previously published article, this manuscript should specify whether participants were made aware that EC would not be expected to protect against unprotected intercourse that occurred >5 days previous

Definition of unprotected intercourse: we appreciate that the researchers used a clear and inclusive definition of UPI that incorporates risks associated with broken condoms or withdrawal: "How many times in the last two weeks have you had sex when a method of birth control was not used or you were worried that the method you used did not work?" However, one might suggest analyzing UPI based on two definitions - (1) the more stringent where no method is used at all versus (2) the more inclusive where no method is used and where the user has a concern. We appreciate the author's use of the second definition, but if the proportion of individuals using a method w/ some worry was particularly high, then the population might skew towards less pregnancy risk given that some methods may have partial effect with use the day prior. While examining those two different scenarios, perhaps the authors could collapse all categories that resulted in no method being used and all categories in which attempt was made to use method. The readers do not need to know why a method was not used.

Line 263: Unclear why UPI at 7, 10, and 14 d prior to IUD insertion is examined. Should also be clearer about whether this represents three episodes or one episode across one of those three days.

Information about luteal phase pregnancy and CDC guidelines from 266-270 would be better placed in the background b/c they better inform why this study was conducted in the first place. Also, the endpoint of continuing pregnancies at one month following IUD placement is very important, but it may not completely address the concerns of patients and clinicians. They may worry that the IUD may work more as an interceptive if it is placed at a time when fertilization may have already taken place. General readers of this journal may not recognize that this "luteal phase pregnancy" as readily as specialty journal readers. Could that be more thoroughly defined?

Results
We would like to see Table 1 also have columns for those with UPIs restricted to 0-5 and within 14d. This is the question that is perhaps most interesting. Showing this distinction may not ultimately impact the results but it would provide some clarity.

Results notable for 43.7% with multiple UPI in the 14d prior, the proportion with at least one UPI in the 6-14d though is much smaller at 14.5%, which is another reason why I would want to see that in Table 1. Only nine women had any episodes between 11-14 days. That should be mentioned in the discussion lines 350-351. Even if the IUD were not effective as an EC, there is a good chance of finding zero pregnancies in those 4 days in women with negative pregnancy tests.

Tables 2 & 3: Not sure why we are looking at difference between copper vs LNG when there was only 1 pregnancy. This substudy was not aimed at looking for differences especially after the authors explicitly said they combined the data. Having the IUD type data there makes it harder for the reader to focus on the differences between EC groups by UPI timing. We understand your interest in highlighting in efficacy of the LNG IUS< but it is really distracting.

Overall, we think this is a meaningful manuscript that, with these minor revisions, should be accepted. We would be happy to review any revisions that the authors are willing to submit.

Reviewer #3: SUMMARY
Secondary analysis of data from an RCT randomizing people presenting for emergency contraception to copper or levonorgestrel (52 mg) intrauterine devices. This secondary analysis has two parts, comparing pregnancy risk (pooled device cohorts) for those reporting a single versus multiple episodes of unprotected sex and making a similar comparison of those reporting unprotected sex
This analysis this study presents is greatly needed, for as stated in the manuscript, clinicians following national guidance often turn away patients requesting IUD placement when they also report unprotected sex greater than 6-14 days prior to placement. Thank you for contributing data to help guide clinical care in these scenarios.

TITLE
You use IUD "placement" throughout the abstract and manuscript and yet used "insertion" in the title. Was this difference intentional? Seems best to keep consistent.

PRECIS
1. Clear as written.

ABSTRACT

2. Over word count (remove from text).
3. UPI is not a frequent abbreviation used by the majority of the readership of the journal. While I personally don't mind it, perhaps simply writing "unprotected sex" would be better suited for this journal.
4. Line 117: consider adding "single" after "or with a…." to improve clarity.
5. Lines 118-121: consider removing the colon for grammar and replacing with a dash and then repeating similar sentence structure with the point estimate after "prior" in line 120.

INTRODUCTION

6. Line 166: remove capital letters from "Emergency Contraception".
7. Line 168: really these folks are beyond CDC and WHO guidelines for eligibility for EC.
8. Lines 172-173: Remove the sentence that starts with "If researchers can…" and remove "However" from the sentence that follows.
9. Line 175: …delay initiation of contraception for patients....
10. Line 184: "quickstart", while family planning researchers certainly understand the definition of quickstart contraception, perhaps the general readership of the journal may not?

METHODS

11. Line 223: "presenting" really means enrollment, no? If so, replace.
12. Lines 228-229: Last sentence, remove. Not pertinent to the methods of this study.
13. The paragraph beginning with on Line 247 is too wordy and I would argue, not relevant to this subanalysis other than to keep the the portion stating [we] "showed the LNG IUS to be noninferior…" and then going on to describe why the IUD device type groups were combined for this planned subanalysis. No one really needs to know what the trial was called/abbreviation.
14. Line 259: replace both with "either" and then change "types" to "type".
15. Lines 266-70: Sentences that starts with "UPi reported "and "Data from" are redundant to the Introduction and don't belong in the Methods section.
16. Otherwise, sound statistical methods.
17. Were participants in the parent RCT offered oral EC concomitant to IUD placement?

RESULTS

18. Line 279: 655 (of planned 706 of parent study) met inclusion for the parent study or for this subanalysis (had outcome data). Please clarify.
19. Table 3 seems very wordy and redundant, again, really to the text starting with line 302. Suggest removing table 3 entirely, especially because overall numbers are small and information is contained within the text.

DISCUSSION

20. Overall, this section is quite wordy and needs refinement for clarity and succinctness.
21. Line 334: consider change to "do not seem to increase…."
22. Lines 348-354: Suggest removing the sentences starting with "For example through … to 14 days."
23. Line 356: EHR needs to be spelled out.
24. Lines 363-368: Suggest removing from "Narrowly…. to "expected menses". While these sentences are true, the second, in particular, is confusing (a pregnancy declares itself??). Suggest, "This secondary analysis informs specific clinical situations that can limit contraceptive access, especially for people requesting IUD placement and reporting UPI 6-14 dyas prior to placement" followed by the sentence starting with "No pregnancies…".
25. Line 373-376: again, this section needs refinement. Replace with something like, "These estimates of pregnancy risk from this study can help guide patients and providers when considering IUD placement in the setting of unprotected sex greater than 6-14 days ago".
26. Line 383: replace "quickstart may significantly…". The data presented here are reassuring about pregnancy risk but no data presented here supports the claim that this actually increases access.

TABLES

27. Table 1

a. Spell out IUD in title.
b. Why was age not presented and analyzed as a continuous variable?
c. Why did the authors include race and ethnicity? Are the two subanalyses presented here reasonably expected to differ by race and ethnicity?
d. Income level: $ presented is per person per year?
e. "EC" needs to be spelled out in the Legend as all tables should stand alone/independent of the manuscript. Same for "LNG" in the legend.

28. Table 2

a. No Legend included (at least in the pdf downloaded from the Editorial Manager).
b. IUD needs to be spelled out in the title.
c. Multiple abbreviations used that need to be spelled out in the Legend (IUD, LNG IUS, UPI).

29. Table 3. Suggest removing entirely as numbers are small (beyond 0-5 days) and data is presented in the text of the manuscript.

FIGURE
30. No Legend.
31. IUD needs to be spelled out in the title.

STATISTICAL EDITOR COMMENTS:

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

Lines 119, 121: The 95% CIs for the risk difference should be formatted as -0.3%, 0.8% and as -0.2%, 0.5%.

Table 1: Need to include units for age. For the EC reason, the p-value should be changed to some non-zero value, e.g., < 0.001, since statistical probabilities cannot equal zero.

Table 2: Although a minor point, the upper bounds for CI for the entries 0/95, 0/94 and 0/90 are equal. By my calculation they should differ slightly. Please verify your calculations.

General: The overall rate of pregnancy is low, as of course, are all subsets. There is little power to generalize that there is a difference, however slight, in terms of number of unprotected intercourse events nor their timing. Those comparisons should be tempered and the overall low rate, with its CIs, should be emphasized.

EDITOR 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.

The following authors need to complete the eCTA, and a link was sent to them by email on March 8th:

Jessica Sanders (Jessica.Sanders@hsc.utah.edu)
Rebecca Simmons (Rebecca.Simmons@hsc.utah.edu)

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.

4. The "Role of the Funding Source" should be included only if your study was directly funded by industry. Since it was not, this section may be removed.

"The contraceptive products for the project were purchased from the distributors" may be added to the acknowledgment on the title page.

5. Responsible reporting of research studies, which includes a complete, transparent, accurate and timely account of what was done and what was found during a research study, is an integral part of good research and publication practice and

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

6. Standard obstetric and gynecology data definitions have been developed through the reVITALize initiative, which was convened by the American College of Obstetricians and Gynecologists and the members of the Women's Health Registry Alliance. Obstetrics & Gynecology has adopted the use of the reVITALize definitions. Please access the obstetric data definitions at https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-obstetrics-data-definitions and the gynecology data definitions at https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-gynecology-data-definitions. If use of the reVITALize definitions is problematic, please discuss this in your point-by-point response to this letter.

7. Because of space limitations, it is important that your revised manuscript adhere to the following length restrictions by manuscript type: Original Research reports should not exceed 22 typed, double-spaced pages (5,500 words). Stated page limits include all numbered pages in a manuscript (i.e., title page, précis, abstract, text, references, tables, boxes, figure legends, and print appendixes) but exclude references.

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

* All financial support of the study must be acknowledged.
* Any and all manuscript preparation assistance, including but not limited to topic development, data collection, analysis, writing, or editorial assistance, must be disclosed in the acknowledgments. Such acknowledgments must identify the entities that provided and paid for this assistance, whether directly or indirectly.
* All persons who contributed to the work reported in the manuscript, but not sufficiently to be authors, must be acknowledged. Written permission must be obtained from all individuals named in the acknowledgments, as readers may infer their endorsement of the data and conclusions. Please note that your response in the journal's electronic author form verifies that permission has been obtained from all named persons.
* If all or part of the paper was presented at the Annual Clinical and Scientific Meeting of the American College of Obstetricians and Gynecologists or at any other organizational meeting, that presentation should be noted (include the exact dates and location of the meeting).

Please spell out any names in the acknowledgment instead of using initials.

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. Please provide a word count.

10. 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.

11. 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.

12. 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%").

13. 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.

14. 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).

15. 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.

Figure 1: Please upload as a figure file on Editorial Manager.

16. Authors whose manuscripts have been accepted for publication have the option to pay an article processing charge and publish open access. With this choice, articles are made freely available online immediately upon publication. An information sheet is available at http://links.lww.com/LWW-ES/A48. The cost for publishing an article as open access can be found at https://wkauthorservices.editage.com/open-access/hybrid.html.

Please note that if your article is accepted, you will receive an email from the editorial office asking you to choose a publication route (traditional or open access). Please keep an eye out for that future email and be sure to respond to it promptly.

***

If you choose to revise your manuscript, please submit your revision through Editorial Manager at http://ong.editorialmanager.com. Your manuscript should be uploaded in a word processing format such as Microsoft Word. Your revision's cover letter should include the following:

* A confirmation that you have read the Instructions for Authors (http://edmgr.ovid.com/ong/accounts/authors.pdf), and
* A point-by-point response to each of the received comments in this letter. 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 Mar 29, 2021, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

The Editors of Obstetrics & Gynecology

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

Response to Green Journal comments on Manuscript Number ONG-21-293

Pregnancy risk by frequency and timing of unprotected intercourse prior to intrauterine device insertion

We have responded to each comment and demonstrate revisions to the text with *italics.*

REVIEWER COMMENTS:

Reviewer #1

This is a secondary analysis of data from a randomized controlled trial evaluating the efficacy of LNG-IUS vs. Copper IUD for emergency contraception efficacy. The author's goal was to evaluate the impact of unprotected sexual intercourse events prior to the 5-day recommended window. Though it is interesting to consider the possibility of using EC up to 14 days after UPI, it seems that the timing of UPI in relation to ovulation and placement of EC is also vitally important. It would be nice to see this discussed. Specific comments follow.

Response: This is an important point. As such, we have identified the proportion of participants who had any act of intercourse in the menstrual cycle of EC use occurring prior to IUD placement occurring in the "fertile window." This analysis divides participants into those reporting intercourse in the fertile window in the 5 days prior to IUD placement vs. those having intercourse in the fertile window 6-14 days prior to IUD placement.

Revision: We added a description of our methodology to identify the "fertile window" to the **methods section** as follows-

Based on menstrual cycle information participants provided at enrollment we calculated the fertile window for the menstrual cycle of study IUD placement. We identified the likely day of next expected menses by adding the usual menstrual cycle length in days to the date of the reported first day of the last menstrual period. From this date we subtracted 14 to estimate the day of ovulation. The fertile window was identified as the period from 5 days before the day of ovulation to one day after. We then identified all the episodes of UPI that occurred in this window and report them by whether any occurred in the 0-5 days or 6-14 days prior to IUD placement.

In addition, we described these findings in the **results section** as follows-

Among the 642 women with one-month outcome data, 187 (29.1%) were in their fertile window at the time of at least one their reported UPI events. Among those allocated to the copper IUD, 65 (67.7%) reported that all fertile window UPI events occurred in the five days preceding IUD placement, while 31 (32.3%) reported that at least one UPI episode occurred 6-14 days prior to enrollment. The corresponding numbers for those allocated to the LNG IUS, were 67 (73.6%) in the previous 5 days, and 24 (26.4%) 6-14 days prior to enrollment.

1. Title: Does not clearly represent the manuscript. Consider adding "for Emergency Contraception" to the end.

Response: We appreciate this comment and while we feel this information applies to all quick-start IUD users we see the need to include "emergency contraception." Thus, we have changed the title.

Revised Title: Pregnancy risk by frequency and timing of unprotected intercourse prior to intrauterine device insertion for *emergency contraception*

2. Precis: Lines 62-63: would also recommend adding Emergency Contraception ("Following intrauterine device placement for emergency contraception,…").

Response: agree and same as above.

Revised Precis: Following intrauterine device placement for emergency contraception, pregnancy risk remains low regardless of timing and frequency of unprotected intercourse episodes in the prior 14 days.

3. Abstract: Recommend re-writing the results section for clarity. Consider changing line 113 to "one pregnancy occurred among the 655 participants in a subject with one sexual event 48hrs prior to EC".

Response: This has been changed as suggested.

Revision: One pregnancy occurred among the 655 participants *in a subject reporting intercourse once 48hrs prior to IUD placement*. *Of these,* 43.7% (n=286) reported multiple UPI episodes in the 14 days prior to IUD placement; 14.4% (n=95) reported at least one UPI episode during the 6-14 day window.

4. Introduction: Line 168: Add a brief sentence describing the reasoning behind the CDC/WHO recommendations for 5 days.
Response: Neither the CDC's Medical Eligibility Criteria nor the Selective Practice Recommendations (SPR), 2016 provide reasoning for their timing recommendations. The issue of emergency contraception timing is most thoroughly addressed in the 2016 SPR on pages 34-36. Since we are not able to find an explanation for this reasoning we are not able to report one. Thus, we have not changed the text in regards to this comment. However, later in that paragraph we address this issue as we suppose "the lack of data and the theoretical risk of luteal phase pregnancy, causes some medical providers to delay contraception for patients who report having UPI more than 5 days beforehand."
No revision made

5. Line 174: luteal phase pregnancy is not a well-accepted term; please define.
Response: Thank you for raising this point. We have added the following sentence to follow the one quoted immediately above.
Revision: *A luteal phase pregnancy refers to the time in a menstrual cycle after ovulation when a future pregnancy may develop from intercourse that has already occurred and resulted in fertilization but the pregnancy defining event of implantation has not occurred.*

6. Lines 180-183: it's not clear to me that this sentence is helpful in the current manuscript; consider deleting.
Response: While we appreciate the reviewers view of this sentence we see this as a limiter to patient centered care and would prefer to acknowledge it. It identifies the gap in available data and supports the need to execute this analysis. We do not wish to delete this sentence and paste it here to ease editorial review.
"This practice causes a delay in provision of desired contraception resulting in an increased risk of unintended pregnancy and may disincentivize contraceptive clients from sharing a complete sexual history if doing so limits access to the service they seek."
No revision made

7. Line 190: recommend adding the number of patients and pregnancies in the referenced study.
Response: We have added the number of participants in the cited study to the text.
Revision: "A retrospective study of *353* levonorgestrel (LNG) intrauterine system (IUS) patients who met CDC criteria to reasonably exclude pregnancy compared to *239* who did not at time of IUS placement *found no pregnancies in the former group and* one in the latter group (0.4%).[7]"

8. Line 192: remove "who selected their IUD type". What did the data from this trial show?
Response: We wish to leave this phrase in place because it juxtaposes that observational study with a smaller sample size to the RCT with a larger sample that provided data for this analysis. However, we added information on pregnancy outcomes for the group reporting multiple episodes of unprotected intercourse.
Revision: "We previously presented data on 176 IUD EC users who selected their IUD type; *we identified one pregnancy among* the 76 (43%) *who* reported multiple episodes of UPI.[1]"

9. Role of the Funding Source: recommend merging this paragraph to the earlier section which already discusses funding sources (lines 30-47).
Response: We have removed this paragraph as directed by the Editor.

10. Methods: Line 239: recommending adding that the electronic data capture method was added later as a protocol amendment due to missing outcome data.
Response: We have modified this description to acknowledge the protocol change.

Revision: "*As detailed in the manuscript detailing the primary outcome of the parent study, we modified the protocol to add electronic health record review for* participants who did not report pregnancy results by any of these methods. *In those cases* we conducted an in-depth medical chart review and reviewed participant follow-up surveys from 1,3, and 6 months post IUD placement to assess evidence of a possible pregnancy occurring in the first month of use."

11. Recommend removing lines 267-270 as they are unclear and unnecessary here.
Response: This comment suggests to remove the last sentence (**bolded)** in the section pasted here:
"We split the time ranges of UPI episodes into two categories, 0-5 days and 6-14 days, because current CDC clinical guidelines limit IUD placement for EC to within 5 days from of UPI. UPI reported 6-14 days prior raises possible concern of a luteal phase pregnancy and prompts some providers to delay IUD placement. **Data from this latter time period inform the conservative CDC guideline on initiating an IUD when you can be "reasonably certain that a woman is not pregnant" as none of the participants in this study met those criteria.**[10]"

We feel that the greatest potential use of these data presented in this manuscript could be to change the CDC guidelines. So, we have modified the sentence to improve clarity.

Revision: Data from this latter time period provide evidence to challenge the conservative CDC guideline on initiating an IUD when you can be "reasonably certain that a woman is not pregnant." *All of the participants in this study would fail the checklist and could be denied IUD placement according to the guidelines*.[10]"

12. Discussion: Line 354: Consider how the addition of a sensitivity analysis excluding those 48 subjects without urine testing might impact the study results.
Response: Thank you for raising this interesting point. We conducted such a sensitivity analysis in the main paper to assess the difference in pregnancy risk between the copper and levonorgestrel assignment groups. The pregnancy risk difference did not change. In this situation we do not feel this is necessary because the secondary method of data collection is rigorous and we are not addressing the study's primary outcome. In addition, this study does not address a pre-specified analysis plan that was changed over the course of the study (this was what prompted the sensitivity analysis in the main paper).

Reviewer #2:

1. Methods: While it may be in the previously published article, this manuscript should specify whether participants were made aware that EC would not be expected to protect against unprotected intercourse that occurred >5 days previous
Response: This is an excellent point that we now address by adding the following sentence to this section of the methods.
Revision: *"Participants provided this information as a component of their study enrollment data. This information was not provided to clinicians and participants were not informed emergency contraception would not protect against pregnancy from intercourse occurring greater than 5 days prior to IUD placement."*

2. Definition of unprotected intercourse: we appreciate that the researchers used a clear and inclusive definition of UPI that incorporates risks associated with broken condoms or withdrawal: "How many times in the last two weeks have you had sex when a method of birth control was not used or you were worried that the method you used did not work?" However, one might suggest analyzing UPI based on two definitions - (1) the more stringent where no method is used at all versus (2) the more inclusive where no method is used and where the user has a concern. We appreciate the author's use of the second definition, but if the proportion of individuals using a method w/ some worry was particularly high, then the population might skew towards less pregnancy risk given that some methods may have partial effect with use the day prior. While examining those two different scenarios, perhaps the authors could collapse all categories that resulted in no method being used and all categories in which attempt was made to use method. The readers do not need to know why a method was not used.
Response: Thank you for introducing this issue. The reviewer makes an excellent point. We used this same approach with two categories to obtain all the possible information on exposure to unprotected intercourse in a

prior study (Sanders AJOG 2016 (citation #1 in this paper). No gold standard measure exists to assess this exposure, but all participants in both groups expressed concern about pregnancy. In this particular situation parsing the data as suggested would make for increasingly smaller analysis groups and further compromise power. That said, we did analyze the data as such and found that a strong majority of UPI events involved no contraceptive method (76.8% of all UPI events). This is an excellent consideration for future work assessing larger populations. As such, we have elected not to change the text.

3. Line 263: Unclear why UPI at 7, 10, and 14 d prior to IUD insertion is examined. Should also be clearer about whether this represents three episodes or one episode across one of those three days.
Response: Thank you for identifying the lack of clarity in this sentence. We have changed the text and added a comment explaining the reason behind this analysis.
Revision: "We then compared pregnancy risk by those with UPI only within the first five days prior to IUD placement versus those with UPI 6-14 days prior to IUD placement, as well as pregnancy risk by those with at least one episode *at 6-7, 6-10, and 6-14 days* prior to IUD placement. *These data are presented to identify the frequency of these occurrences among IUD EC users and to potentially inform an expansion of the IUD EC efficacy window*."

4. Information about luteal phase pregnancy and CDC guidelines from 266-270 would be better placed in the background b/c they better inform why this study was conducted in the first place. Also, the endpoint of continuing pregnancies at one month following IUD placement is very important, but it may not completely address the concerns of patients and clinicians. They may worry that the IUD may work more as an interceptive if it is placed at a time when fertilization may have already taken place. General readers of this journal may not recognize that this "luteal phase pregnancy" as readily as specialty journal readers. Could that be more thoroughly defined?
Response: This issue was addressed in response to Reviewer #1, comment #5. We have added a sentence explaining luteal phase pregnancy to the introduction. Thank you for this suggestion.
Revision: *A luteal phase pregnancy refers to the time in a menstrual cycle after ovulation when a future pregnancy may develop from intercourse that has already occurred and resulted in fertilization but the pregnancy defining event of implantation has not occurred.*

Results
5. We would like to see Table 1 also have columns for those with UPIs restricted to 0-5 and within 14d. This is the question that is perhaps most interesting. Showing this distinction may not ultimately impact the results but it would provide some clarity.
Response: We agree that this could be an interesting comparison and this information is in the study flowchart (Figure 1). For copper users 144 people reported multiple UPI episodes, for 97 participants all episodes of UPI occurred in 0-5 days and for 47 at least one additional UPI episode occurred in 6-14 days prior to IUD placement. To make this clearer for readers, rather than repeat the presentation of all demographic variables by UPI timing, we have added the following rows to Table 1: 1) all unprotected intercourse occurred 0-5 days prior to IUD placement, 2) at least one episode 6-14 days. A more complete analysis of demographics comparing those with UPI restricted to 0-5 days vs. those reporting any UPI episodes 6-14 days would be better suited to larger sample sizes that may occur in future studies as this could provide adequate power for this type of comparison.

6. Results notable for 43.7% with multiple UPI in the 14d prior, the proportion with at least one UPI in the 6-14d though is much smaller at 14.5%, which is another reason why I would want to see that in Table 1. Only nine women had any episodes between 11-14 days. That should be mentioned in the discussion lines 350-351. Even if the IUD were not effective as an EC, there is a good chance of finding zero pregnancies in those 4 days in women with negative pregnancy tests.
Response: Again, an excellent point. We have added more detailed information to the place in the discussion where this is addressed.
Revision: "In the current study considering 14 days prior to IUD placement, greater time between UPI and IUD placement does not appear to impact pregnancy risk though we have a small proportion of participants reporting UPI beyond 5 days prior to IUD placement *including only eight participants reporting UPI 11-14 days prior*."

7. Tables 2 & 3: Not sure why we are looking at difference between copper vs LNG when there was only 1 pregnancy. This substudy was not aimed at looking for differences especially after the authors explicitly said they combined the data. Having the IUD type data there makes it harder for the reader to focus on the differences between EC groups by UPI timing. We understand your interest in highlighting in efficacy of the LNG IUS< but it is really distracting.
Response: We have removed Table 3 as we present the data in the text of the results section (as suggested by Reviewer #3). While we understand the desire to make Table 2 as concise as possible we feel that it is worth presenting the risk of pregnancy by all users and then dividing that into the two IUD groups. This approach is preferred by our team to preserve the potential for future work to systematically review these pregnancy risks by IUD type.

Reviewer #3: SUMMARY

TITLE

You use IUD "placement" throughout the abstract and manuscript and yet used "insertion" in the title. Was this difference intentional? Seems best to keep consistent.
Response: Thank you for pointing this out. We have changed the title as suggested.
Revised title: Pregnancy risk by frequency and timing of unprotected intercourse prior to intrauterine device placement for emergency contraception

ABSTRACT

2. Over word count (remove from text).
Response: The word count for the abstract is 300 and the abstract now meets the work count.
Revisions are made throughout the abstract to meet reviwer comments elsewhere.

3. UPI is not a frequent abbreviation used by the majority of the readership of the journal. While I personally don't mind it, perhaps simply writing "unprotected sex" would be better suited for this journal.
Response: We appreciate this suggestion. However, the term “UPI” is defined with first use and used 84 times in the manuscript. Because of the frequency of use and the somewhat cumbersome language we prefer to leave the abbreviation. If the editorial staff prefers, we can eliminate this abbreviation.

4. Line 117: consider adding "single" after "or with a…." to improve clarity.
Response: Of those reporting episodes of unprotected intercourse 6-14 days prior to IUD insertion some participants had reports of multiple episodes in that range. Thus, we clarified this statement by changing the text to “or with *any* UPI episode 6-14 days prior to IUD placement…”
Revision: “No pregnancies occurred among those with multiple UPI episodes (0%, 97.5% CI (0%, 1.3%)) or with *any* UPI episode 6-14 days prior to IUD placement (0.0%, 97.5% CI (0.0%, 3.8%)).”

5. Lines 118-121: consider removing the colon for grammar and replacing with a dash and then repeating similar sentence structure with the point estimate after "prior" in line 120.
Response: Thank you for pointing out this inconsistency. We have preceded the statistical summary with a comma in both places in that sentence.
Revision: “Pregnancy risk difference did not significantly differ by single versus multiple UPI episodes, 0.3%, 95% CI (-0.3, 0.8), nor by UPI only within the last five days prior to IUD placement versus those reporting UPI 6-14 days prior, 0.2%, 95% CI (-0.2, 0.5)).”

INTRODUCTION

6. Line 166: remove capital letters from "Emergency Contraception".
Response: This change to lower case was made.
Revision: “Many people engage in multiple episodes of unprotected intercourse (UPI) before presenting for *emergency contraception* (EC).”

7. Line 168: really these folks are beyond CDC and WHO guidelines for eligibility for EC.

Response: We agree with the reviewer that our point is that some of these episodes of unprotected intercourse occur beyond the current guidelines. We have pasted the sentence here to highlight this communication without making any changes.

No revision made: "Many people engage in multiple episodes of unprotected intercourse (UPI) before presenting for emergency contraception (EC),[1] including episodes that occur beyond the current Centers for Disease Control and Prevention (CDC) and World Health Organization (WHO) guidelines of 5 days.[2,3]"

8. Lines 172-173: Remove the sentence that starts with "If researchers can…" and remove "However" from the sentence that follows.

Response: We feel that it is essential to highlight this information as it is the reason to present the data. So, we have not altered the text.

No revision made

9. Line 175: …delay initiation of contraception for patients....

Response: we agree that adding the words "initiation of" provides greater clarity.

Revision: "However, the lack of data and the theoretical risk of luteal phase pregnancy causes some *health care professionals* to delay *initiation of* contraception for patients who report having UPI more than 5 days beforehand."

10. Line 184: "quickstart", while family planning researchers certainly understand the definition of quickstart contraception, perhaps the general readership of the journal may not?

Response: Thank you for pointing this out. We have added a definition of "quickstart" at the first mention of the term in the introduction.

Revision: However, recent IUD data address the safety of quickstart intrauterine device (IUD) placement, including specifically the risk of pregnancy when IUD placement occurs 6-14 days after UPI.[7-9] *"Quickstart" refers to providing the desired method of contraception on the day people present for care regardless of menstrual cycle timing.*

METHODS

11. Line 223: "presenting" really means enrollment, no? If so, replace.

Response: We have changed "presenting" to "enrollment."

Revision: "The original study included people aged 18-35 years who had at least one UPI episode 5 days prior to *enrollment*, normal menstrual cycle lengths (21-35 days), and knew their last menstrual period (LMP, +/- 3 days)."

12. Lines 228-229: Last sentence, remove. Not pertinent to the methods of this study.

Response: The following sentence was removed: "Neither of these IUDs is FDA approved for emergency contraception."

13. The paragraph beginning with on Line 247 is too wordy and I would argue, not relevant to this subanalysis other than to keep the portion stating [we] "showed the LNG IUS to be noninferior…" and then going on to describe why the IUD device type groups were combined for this planned subanalysis. No one really needs to know what the trial was called/abbreviation.

Response: We disagree with the opinion of this reviewer in this case. This concise, three-sentence paragraph provides essential information on the parent study including a brief explanation of the sample size and the primary outcome of one-month pregnancies. This paragraph frames further descriptions of the trial and introduces this low rate of pregnancy to the reader. We elected not to change this paragraph.

No revisions made

14. Line 259: replace both with "either" and then change "types" to "type".

Response: Thank you for pointing this out. We have made the change. The sentence now reads as follows.

Revision: "For the full complement of participants who received an IUD *(either type),* we compared pregnancy risk between those reporting single versus multiple episodes of UPI.

15. Lines 266-70: Sentences that starts with "UPi reported "and "Data from" are redundant to the Introduction and don't belong in the Methods section.
Response: We appreciate this comment and acknowledge that it was not appropriate for the methods setion and the material has been addressed in the introduction. Thus, we have removed the following text. "UPI reported 6-14 days prior raises possible concern of a luteal phase pregnancy and prompts some health care professionals to delay IUD placement. Data from this latter time period inform the conservative CDC guideline on initiating an IUD when you can be "reasonably certain that a woman is not pregnant." All of the participants in this study would fail the checklist and could be denied IUD placement according to the guidelines.[10]"

16. Otherwise, sound statistical methods.
Response: No response required.
17. Were participants in the parent RCT offered oral EC concomitant to IUD placement?
Response: No, participants in the parent RCT received only an IUD for EC. No oral EC was provided to any participant and use of oral EC in the menstrual cycle of enrollment excluded study participation. We feel this is clearly stated in the text and does not require additional explanation.
No revision made

RESULTS
18. Line 279: 655 (of planned 706 of parent study) met inclusion for the parent study or for this subanalysis (had outcome data). Please clarify.
Response: We have clarified as follows.
Revision: "Six hundred and fifty-five participants from the parent study met the inclusion criteria, received an IUD for EC, and provided one-month pregnancy outcome data for this analysis."

19. Table 3 seems very wordy and redundant, again, really to the text starting with line 302. Suggest removing table 3 entirely, especially because overall numbers are small and information is contained within the text.
Response: We agree that the content of table 3 is repeated in the text and have removed it.

DISCUSSION
20. Overall, this section is quite wordy and needs refinement for clarity and succinctness.
Response: We have edited this section and cut down the word count.
Revisions: please see the revised text throughout the discussion section.

21. Line 334: consider change to "do not seem to increase…."
Response: This change is made. The sentence now reads as follows.
Revised text: "While we lack definitive data assessing a decrease in efficacy with oral EC following multiple episodes of UPI, with IUDs we can affirm multiple exposures *do not seem* to increase pregnancy risk."

22. Lines 348-354: Suggest removing the sentences starting with "For example through … to 14 days."
Response: These sentences have been removed. Here we paste the removed section:
"For example, only 59 participants reported outcomes following UPI 6-7 days prior to IUD placement and the numbers drop further when assessing each IUD type. If you were specifically interested in providing an IUD for EC 6 or 7 days after the last UPI this could inform your decision. Basing this decision solely on that summary statistic is not sufficient. However, in reviewing the aggregate of the UPI data the sample size increases and the confidence interval around the low pregnancy rate tightens as you include data from UPI out to 14 days."

23. Line 356: EHR needs to be spelled out.
Response: This has been done.

24. Lines 363-368: Suggest removing from "Narrowly"…. to "expected menses". While these sentences are true,

the second, in particular, is confusing (a pregnancy declares itself??). Suggest, "This secondary analysis informs specific clinical situations that can limit contraceptive access, especially for people requesting IUD placement and reporting UPI 6-14 days prior to placement" followed by the sentence starting with "No pregnancies…".
Response: Thank you for this suggestion. We have revised this section by deleting the bulk of what you suggest. We have left in the material addressing the Canadian EC guidelines going out to 7 days from UPI for copper IUDs. We feel this is an important point that is not known among U.S. clinicians. The beginning of the paragraph now reads as follows.
Revision: "This secondary analysis informs specific clinical situations that can limit contraceptive access *especially for people requesting IUD placement and reporting UPI 6-14 days prior to placement. It is worth noting that the Canadian EC guidelines already support use of the copper IUD out to 7 days from UPI*.[13] No pregnancies occurring in the 94 participants reporting UPI 6-14 days prior to IUD placement provide a point estimate and confidence interval for this risk (0%, 97.5% CI 0%, 3.8%)."

25. Line 373-376: again, this section needs refinement. Replace with something like, "These estimates of pregnancy risk from this study can help guide patients and providers when considering IUD placement in the setting of unprotected sex greater than 6-14 days ago".
Response: While we appreciate this suggestion toward brevity we carefully chose the original language to present a patient-centered focus for the implications. As such, we prefer to leave the original language and paste it here. "Sharing this information with clients allows them to make the decision that is right for them. These data help health care professionals and IUD users move toward a place where an IUD could be placed anytime regardless of recent UPI exposure when a pregnancy test is negative, a simplified version of IUD quickstart."
No revision made

26. Line 383: replace "quickstart may significantly…". The data presented here are reassuring about pregnancy risk but no data presented here supports the claim that this actually increases access.
Response: We have changed this as suggested.
Revision: "Applying these data to clinical care for people seeking an IUD for EC or quickstart *may* significantly improve contraceptive access."

TABLES
27. Table 1
a. Spell out IUD in title.
Response: This is done.

b. Why was age not presented and analyzed as a continuous variable?
Response: Presenting age in these categories is more informative as the mean and statement of the range would not adequately describe the number of participants in the 18-19 year old group and would not demonstrate the largest group was 20-24 years old. This is a standard approach in contraceptive studies.
No revision made

c. Why did the authors include race and ethnicity? Are the two sub-analyses presented here reasonably expected to differ by race and ethnicity?
Response: A common expectation when data are presented from Utah is that participants will lack racial and ethnic diversity and this could limit external validity. Thus, we present these data to demonstrate that a little more than half of our population was white and that this variable may not be a limitation to external validity. However, we fully agree with the reviewer that race and ethnicity should not alter the analysis. Thus we have removed these variables from Table 1.
Revision: Deletion of race/ethnicity data from table 1.

d. Income level: $ presented is per person per year?
Response: We changed this label to "Participant annual mean income."
e. "EC" needs to be spelled out in the Legend as all tables should stand alone/independent of the manuscript. Same for "LNG" in the legend.

Response: These changes are made

28. Table 2
    a. No Legend included (at least in the pdf downloaded from the Editorial Manager).
    b. IUD needs to be spelled out in the title.
    c. Multiple abbreviations used that need to be spelled out in the Legend (IUD, LNG IUS, UPI).

Response: These issues have been addressed.

29. Table 3. Suggest removing entirely as numbers are small (beyond 0-5 days) and data is presented in the text of the manuscript.
Response: We have removed Table 3

FIGURE
30. No Legend.
Response: Thank you for pointing this out. The legend has been added and spells out use of the abbreviations IUD and IUS.

31. IUD needs to be spelled out in the title.
Response: This has been done.

STATISTICAL EDITOR COMMENTS:

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

Lines 119, 121: The 95% CIs for the risk difference should be formatted as -0.3%, 0.8% and as -0.2%, 0.5%.
Response: These changes are made in the abstract.
Revised text: "Pregnancy risk difference did not significantly differ by single versus multiple UPI episodes, 0.3*%*, 95% CI *(-0.3%, 0.8%),* nor by UPI only within the last five days prior to IUD placement versus those reporting UPI 6-14 days prior, 0.2%, 95% CI *(-0.2%, 0.5%)).*"

Table 1: Need to include units for age. For the EC reason, the p-value should be changed to some non-zero value, e.g., < 0.001, since statistical probabilities cannot equal zero.
Response: These changes are made to Table 1.

Table 2: Although a minor point, the upper bounds for CI for the entries 0/95, 0/94 and 0/90 are equal. By my calculation they should differ slightly. Please verify your calculations.
Response: We repeated these calculations and report the results with rounding presented in the paper.
0/95 0-3.808 rounded to 0-3.8
0/90 0-4.015 rounded to 0-4.0 (this is changed in the table)
0/94 0-3.848 rounded to 0-3.8

General: The overall rate of pregnancy is low, as of course, are all subsets. There is little power to generalize that there is a difference, however slight, in terms of number of unprotected intercourse events nor their timing. Those comparisons should be tempered and the overall low rate, with its CIs, should be emphasized.
Response: We fully understand the limitations of this analysis based on the low number of trial pregnancies occurring in the first month of IUD use. In the Discussion Section we added a comment to address this in the section addressing study weaknesses.
Revision: Study weaknesses include report of outcomes for which we did not specifically power the trial. Certain assessment categories lack power for rigorous analysis. *Since only one pregnancy was reported in the first month of IUD use there is little power to compare differences in pregnancy rate by timing or frequency of UPI.*

EDITOR 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.

Response: We will OPT-IN for publishing our response.

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

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

The following authors need to complete the eCTA, and a link was sent to them by email on March 8th:

Jessica Sanders (Jessica.Sanders@hsc.utah.edu)
Rebecca Simmons (Rebecca.Simmons@hsc.utah.edu)

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.

Response: We have deleted race as a category in Table 1 as exposures and outcomes are not expected to vary by this factor.

4. The "Role of the Funding Source" should be included only if your study was directly funded by industry. Since it was not, this section may be removed.

Response: This was removed.

"The contraceptive products for the project were purchased from the distributors" may be added to the acknowledgment on the title page.

Response: As instructed, this was added to the acknowledgment on the title page.

5. Responsible reporting of research studies, which includes a complete, transparent, accurate and timely account of what was done and what was found during a research study, is an integral part of good research and publication practice and not an optional extra. Obstetrics & Gynecology supports initiatives aimed at improving the reporting of health research, and we ask authors to follow specific guidelines for reporting randomized controlled

trials (ie, CONSORT), observational studies (ie, STROBE), observational studies using ICD-10 data (ie, RECORD), meta-analyses and systematic reviews of randomized controlled trials (ie, PRISMA), harms in systematic reviews (ie, PRISMA for harms), studies of diagnostic accuracy (ie, STARD), meta-analyses and systematic reviews of observational studies (ie, MOOSE), economic evaluations of health interventions (ie, CHEERS), quality improvement in health care studies (ie, SQUIRE 2.0), and studies reporting results of Internet e-surveys (CHERRIES). Include the appropriate checklist for your manuscript type upon submission. Please write or insert the page numbers where each item appears in the margin of the checklist. Further information and links to the checklists are available at http://ong.editorialmanager.com. In your cover letter, be sure to indicate that you have followed the CONSORT, MOOSE, PRISMA, PRISMA for harms, STARD, STROBE, RECORD, CHEERS, SQUIRE 2.0, or CHERRIES guidelines, as appropriate.

Response: The parent study, a randomized controlled trial was submitted with a CONSORT checklist and complied with the CONSORT guidelines. The exposures and outcomes included in this analysis are not dependent on the randomization sequence. As such, we did not include the CONSORT checklist. Figure 1 is a flowchart explaining the allocation of participants and the total number with given exposures.

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.

Response: We have reviewed the reVITALize definitions. The only item that applies in our paper is Emergency (postcoital) Contraceptives. We feel our use of this term is consistent with the guidance.

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.

Response: Our revision meets these guidelines.

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).

Please spell out any names in the acknowledgment instead of using initials.
Response: Our acknowledgements meet these instructions.

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. Please provide a word count.
Response: The abstract word count is 257 words. We reviewed the abstract which is consistent with the text of the body of the manuscript. The conclusion statement is based on the results presented and does not extend beyond data presented.

10. The journal does not use the virgule symbol (/) in sentences with words. Please rephrase your text to avoid using "and/or," or similar constructions throughout the text. You may retain this symbol if you are using it to express data or a measurement.
Response: We only use the virgule symbol with data. For example, "…(LMP, +/- 3 days). All had a negative urine pregnancy test (human chorionic gonadotropin ≤ 20IU/L).

11. 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.
Revision: We have replaced "provider" with "health care professional" throughout the manuscript.

12. In your Abstract, manuscript Results sections, and tables, the preferred citation should be in terms of an effect size, such as odds ratio or relative risk or the mean difference of a variable between two groups, expressed with appropriate confidence intervals. When such syntax is used, the P value has only secondary importance and often can be omitted or noted as footnotes in a Table format. Putting the results in the form of an effect size makes the result of the statistical test more clinically relevant and gives better context than citing P values alone.
Response: The only effect sizes presented in the paper have to do with the pregnancy risk difference. For example, in the abstract: "Pregnancy risk was similar between those reporting UPI only within the last five days prior to IUD placement versus those reporting UPI 6-14 days prior (RD: 0.2%, 95% CI (-0.2, 0.5))."

If appropriate, please include number needed to treat for benefits (NNTb) or harm (NNTh). When comparing two procedures, please express the outcome of the comparison in U.S. dollar amounts.
Response: This does not apply to the data we present.

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

13. 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.
Response: This has been done and our tables now comply with journal instructions.

14. 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.
Response: We have added the DOI to all the citations.

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).
Response: We have not cited any ACOG documents.

15. 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.

Figure 1: Please upload as a figure file on Editorial Manager.
Response: We created Figure 1 as a separate document and loaded it as such in Editorial Manager.

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Response: We do not wish to publish this as open access.