Date: Mar 08, 2019
To: "Kate M Guthrie" [redacted]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-19-205

RE: Manuscript Number ONG-19-205

Beyond hormonal impact: A qualitative study of the contraceptive effect on women's sexual experiences

Dear Dr. Guthrie:

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, 2019, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1: This is a study that qualitatively analyzes womens' experiences using 3 different contraceptive options. They were asked about these options specifically affecting their sexual experiences and participants were allowed to answer questions using their own words. Qualitative themes were created.

1. On line 24, the presis States physical products can impact sexual experiences. Although physical products are component of this study, I do not feel that this is an accurate summary of the study.

2. On line 55, 16 women that completed interviews with 33 transcripts are mentioned. These are very low numbers to consider. This is addressed within the main described.

3. In reading the abstract, the reader is led to wonder why these 3 specific contraceptive options were selected. Why did the researcher not include arm implant, intrauterine device, or other contraceptive options. This could be mentioned in either in areas of future study, or could be clarified as to why these 3 were selected for this study.

4. On line 93, it is discussed that this current study adds depth to the literature. While the results of the study are interesting and could be helpful to providers, I am not sure if 16 participants adds significant amount of depth to the literature.

5. On line 102, this specific OCP utilized in the study was mentioned. The reader wonders why a triphasic pill was selected. These are not used often in our practice.

6. On line at 113, the specific study designs are described. I do wonder about not allowing some of these contraceptive options more time for side effects to minimize. It is very common that we recommend patients wait 3 months after starting a new contraceptive option before trying something new. They are only trying these for 3 months, could any side effects that they are having be minimized during this time or could they become even more comfortable with routine? Another study design to consider would be allowing moving to select the own contraceptive method and then report their experiences. I wonder if this could have impact on study size and patient's opinions of their own contraceptive option.

7. I like that to the breakdown is relatively even as described in line 143-144 of the different contraceptive options.

8. I really found the patient commentary in the results section is helpful. This really helped understand qualitative themes that were suggested.

9. In line 369, the discussion section discusses overall findings. I would like to know of the participants that tried all 3

options, which did they prefer and why. I feel that there is no section that really describes women comparing the different options and why certain ones would be their favorite to use.

10. I also think that should be mentioned somewhere in the study that condoms are helpful in prevention of sexually transmitted infections while the intravaginal ring and birth control pill or not. It is not mentioned whether users the intra vaginal ring and oral contraceptive are using condoms in addition for STI prevention and I feel that this topic should be addressed.

Reviewer #2: This was a qualitative study of interviews with sexually active women on the affect of three different contraceptive methods; vaginal rings, oral contraceptive pills and condoms and spermicide, on their sexual experience.

Abstract:

1. Line 48-50. The objectives are not clear. What is meant by sexual experience? I would recommend relating this to domains of arousal, desire, pain, orgasm or concerns about compliance. Also explain what is meant by use of contraceptive methods as physical products.

2. Line 64 The study design did not explore efficacy of contraceptive use as implied in the conclusion. The general understanding of physical barriers such as condoms, diaphragm and to a lesser extent other barriers such as rings is well established.

3. Line 59-60. In what direction were alterations in use and opinions between methods?

Introduction:

4. This is a good overview of the problem. The references American Journal of Public Health, 2008. 98(10): p. 1803-1813 specifically look at some of the contraceptive methods and gender/social class and seems to overlap with many of the objectives of this study.

Materials and methods:

5. Line 99 Specify what types of experiences you are referring to. This is vague.

6. Line 103-105 The recruitment methods and sources are quite variable with potential reporting bias. Were patients contacted in the phone list arm? These patients may be different from other forms of self recruitment. Explain in more detail.

7. Line 114 How were participants counseled on the serial use of hormonal options without condom use and potentially STD risks? How did this get approved through the IRB?

8. Line 115 The randomized order of use I think is an important aspect of the study to minimize recall bias.

9. Line 117 Why were women allowed to continue the first method for an additional 3 months vs. being rerandomized? This may bias the final reporting and original randomization.

10. Line 122. How much were participants compensated? This is important to know for the reader to ascertain risk of coercion.

11. Line 130-132. Explain more about the thematic approach. What happened when the 2 independent reviewers could not reach consensus on a theme? Was the topic discarded or was there an arbitrator?
How was power determined and or the number of participants for recruitment?

Results:

12. Figure 1. Of the recruited patients how many were recruited by which method? Telephone lists vs. social media etc.

13. Line 140-141 The inclusion of the 5 participants who did not use all three methods may bias the thematic analysis. If the intent to randomize the order of method from the start as mentioned to minimize recall or ascertainment bias in the IDI perhaps a per protocol analysis of the 11 participants may minimize this.

14. Table 1 The demographics show a relatively diverse group with some generalizable findings. Given that 13% were cutting back and not paying the bills it is important to know there was not coercion to participate.

Discussion:

15. Line 360-361. This is an important clinical finding regarding disruption in routine.

16. Limitations in general were addressed with some of the exceptions listed above.

Reviewer #3: This is an excellent addition to the literature re: contraceptives. I am disappointed that more common methods were not used and that the authors did not compare quantitatively or group qualitative perceptions on what woman had previously used and that they currently use.

STATISTICAL EDITOR'S COMMENTS:

1. Table 1: Since the total sample size is 16, should round the median age to an integer and round the %s to the nearest whole number.

2. Fig 2: Since 32 declined to enroll and 8 of 24 did not complete the protocol, need to include in Discussion among limitations that there may be bias in the analysis.

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, as well as subsequent author queries. 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:
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2. OPT-OUT: No, please do not publish my response letter and subsequent email correspondence related to author queries.

2. As of December 17, 2018, Obstetrics & Gynecology has implemented an "electronic Copyright Transfer Agreement" (eCTA) and will no longer be collecting author agreement forms. 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.

Any author agreement forms previously submitted will be superseded by the eCTA. During the resubmission process, you are welcome to remove these PDFs from EM. However, if you prefer, we can remove them for you after submission.

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.

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5. 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 and gynecology data definitions at https://www.acog.org/About-ACOG/ACOG-Departments/Patient-Safety-and-Quality-Improvement/reVITALize. If use of the reVITALize definitions is problematic, please discuss this in your point-by-point response to this letter.

6. 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.

7. 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).

8. Provide a précis on the second page, for use in the Table of Contents. The précis is a single sentence of no more than 25 words that states the conclusion(s) of the report (ie, the bottom line). The précis should be similar to the abstract's conclusion. Do not use commercial names, abbreviations, or acronyms in the précis. Please avoid phrases like "This paper presents" or "This case presents."

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12. 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.

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If you choose to revise your manuscript, please submit your revision via Editorial Manager for Obstetrics & Gynecology at http://ong.editorialmanager.com. It is essential that your cover letter list point-by-point the changes made in response to each criticism. Also, please save and submit your manuscript in a word processing format such as Microsoft Word.

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, 2019, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

The Editors of Obstetrics & Gynecology

2017 IMPACT FACTOR: 4.982
2017 IMPACT FACTOR RANKING: 5th out of 82 ob/gyn journals

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Nancy C. Chescheir, MD
Editor-in-Chief, *Obstetrics & Gynecology*
409 12th Street, SW
Washington, DC 20024-2188

January 28, 2019

Dear Dr. Chescheir,

Thank you for the opportunity to revise our manuscript titled "Beyond hormonal impact: A qualitative study of the contraceptive effect on women's sexual experiences," ONG-19-205. We fully appreciate the thoughtful and constructive suggestions offered by the reviewers. We believe that our revised manuscript is significantly improved after revisions enacted upon consideration of the reviewers' comments.

Following this letter are the comments from the reviewers and editors, along with our responses and changes in italics. Changes in the manuscript are marked using track changes. All authors are aware of this revision and have given approval to the final form of this revision.

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. In addition, we have followed the STROBE guidelines, and the appropriate checklist is included with this revision.

Thank you again for your continued consideration of this manuscript.

Sincerely,

Dr. Kate M Guthrie, Corresponding Author
[redacted]

Connie Fei Lu
[redacted]

REVIEWER #1

This is a study that qualitatively analyzes women's experiences using 3 different contraceptive options. They were asked about these options specifically affecting their sexual experiences and participants were allowed to answer questions using their own words. Qualitative themes were created.

1. On line 24, the precis states physical products can impact sexual experiences. Although physical products are component of this study, I do not feel that this is an accurate summary of the study.

We agree that the use of "physical products" in the precis could offer some confusion and, perhaps, redundancy. We believe that the current precis offers a clearer and more accurate summary of the study. It now states, on lines 24-25: "The physical characteristics of contraceptive methods can impact the sexual experiences of women and their partners, shaping their subsequent opinions of each method."

2. On line 55, 16 women that completed interviews with 33 transcripts are mentioned. These are very low numbers to consider. This is addressed within the main described.

The study is a mixed methods study, consisting of both qualitative in-depth interview data and survey data (both daily phone data and survey data). With reference to the qualitative data alone, a sample size of 16 is, by convention, more than reasonable, given the in-depth nature of the interviews. In addition, this study furthers a single cross-sectional qualitative interview design by interviewing each woman more than once (corresponding to each product use period completed). Methodologically speaking, the more important restriction is in the lower end of the sample size, with Creswell (1998) and Morse (1994) suggesting no fewer than 5-6 interviews. Others argue that it is the goal of qualitative work to gather depth of understanding and range of relevant concepts. We believe that both are true, and also continue to consider another longstanding "metric" for determining sample size: data saturation, i.e., the point at which no new information is gained from additional interviews (Mason, 2010). While the former are helpful when planning studies, it is ultimately the data itself that must provide an endpoint. In the current study, we used a combination of saturation, relevant range, and the intersection of contraceptive method coverage in the data to determine our stopping point.

3. In reading the abstract, the reader is led to wonder why these 3 specific contraceptive options were selected. Why did the researcher not include arm implant, intrauterine device, or other contraceptive options. This could be mentioned in either in areas of future study, or could be clarified as to why these 3 were selected for this study.

Thank you for this thoughtful comment. Since the primary goal of the study was to understand how users' interactions with sexual and reproductive health (SRH) products contributed to effective use, we opted to offer methods which patients themselves could have control over. In addition, since users were evaluating methods they could ultimately choose to use in the future, we wanted to have them consider methods they could easily resume after the study. Thus, we chose these three methods because they are commonly and easily used by patients, and their use is under the patient's control. All three methods of use were easy for the research team to review with study participants, and switching from method to method was also easy for participants within the design of 3-month use periods. Methods such as the contraceptive implant and intrauterine device (IUD) would have required insertion and removal at each 3-month interval. In addition, given that the contraceptive implant and IUD are designed to be long-term contraceptive options, we did not want to insert and remove these options after 3 months. Additionally, one of the primary goals of the entire study was to understand user sensory perceptions and experiences of products: the spermicide and IVR provide for local sensory experiences, while the oral contraceptive pill does not (and could serve as a potential comparison). Similarly, the implant or intrauterine device would not have provided for a local user experience <u>and</u> would have been outside the user's control.

4. On line 93, it is discussed that this current study adds depth to the literature. While the results of the study are interesting and could be helpful to providers, I am not sure if 16 participants adds significant amount of depth to the literature.

Though we do believe our 16 participants offered significant amounts of data in both content and depth of discussion, we understand the reviewer's hesitation in our study's ability to significantly change the current depth of contraceptive knowledge. We addressed this by deleting the word "depth" (now on line 97). We continue to believe that the current study adds a substantive focus on the user's (and her partner's) non-hormonally-based experience in a manner not often seen in the contraceptive literature.

5. On line 102, this specific OCP utilized in the study was mentioned. The reader wonders why a triphasic pill was selected. These are not used often in our practice.

We offered this particular triphasic OCP because it is available as a generic at low cost at our local pharmacies. As noted earlier, we wanted to offer options which patients themselves could easily resume after the study should they choose a particular method experienced in the study. If a patient from our study did not have insurance coverage, she would be able to get this particular OCP at low cost after she completed the study.

6. On line at 113, the specific study designs are described. I do wonder about not allowing some of these contraceptive options more time for side effects to minimize. It is very common that we recommend patients wait 3 months after starting a new contraceptive option before trying something new. They are only trying these for 3 months, could any side effects that they are having be minimized during this time or could they become even more comfortable with routine? Another study design to consider would be allowing moving to select the own contraceptive method and then report their experiences. I wonder if this could have impact on study size and patient's opinions of their own contraceptive option.

While we agree that side effects may linger beyond 3 months for some patients, when the study was designed, both the literature and clinical practice suggested that method switching, or patient-initiated discontinuation, tends to occur during the first 3 months of use. As such, it seemed a natural time point at which to systematize product switching in a study designed to provide users with different method experiences (without over-burdening subjects by requiring them to be involved for longer time periods). Also, because it is common in clinical practice to have patients wait 3 months after starting a new contraceptive before trying another method, we set the use period for each method as 3 months at the outset of the study. Notably, we did not find that participants had ongoing side effects and, therefore, maintained our 3-month use period for each method.

7. I like that to the breakdown is relatively even as described in line 143-144 of the different contraceptive options.

Thank you.

8. I really found the patient commentary in the results section is helpful. This really helped understand qualitative themes that were suggested.

Thank you. We found that our participants were the most qualified to speak on their own experiences, and we appreciate your recognition of that.

9. In line 369, the discussion section discusses overall findings. I would like to know of the participants that tried all 3 options, which did they prefer and why. I feel that there is no section that really describes women comparing the different options and why certain ones would be their favorite to use.

Thank you for this thoughtful suggestion. For the women who used all 3 options, their last interview did specifically ask each participant which method they would choose, as well as what their ideal contraceptive method would be. Part of this study's analysis also did include the importance of sexual experience in choosing one's final method, and a few women did note this association. Though the impact of sexual experience was an important factor in method choice, the data also considered other factors such as access, discreet use, user sensory perceptions and experiences other than sexual experience, and dosing, including overall "fit" of the method in the woman's life. Due to this, we felt that it was difficult to discuss method choice solely in the context of sexual experience. As such, users' final contraceptive choice is outside the scope of the current manuscript's focus on characterizing products' impacts on sexual experience.

10. I also think that should be mentioned somewhere in the study that condoms are helpful in prevention of sexually transmitted infections while the intravaginal ring and birth control pill or not. It is not mentioned whether users the intravaginal ring and oral contraceptive are using condoms in addition for STI prevention and I feel that this topic should be addressed.

We agree with the importance of addressing the dual purpose of condom use in pregnancy and STI prevention. We have added to our methods section the following (lines 127-132) in order to portray the work done by the study staff in promoting condom use while respecting our participants' autonomy: "In addition, all participants were provided with condoms and counseled on their use in preventing sexually transmitted infections. Using condoms with the spermicidal gel was required in the study in order to improve contraceptive efficacy; participants employed their own perception of STI risk in their decisions to use or not use study-provided (or their own) condoms with the OCP and IVR."

REVIEWER #2

This was a qualitative study of interviews with sexually active women on the affect of three different contraceptive methods; vaginal rings, oral contraceptive pills and condoms and spermicide, on their sexual experience.

Abstract:
1. Line 48-50. The objectives are not clear. What is meant by sexual experience? I would recommend relating this to domains of arousal, desire, pain, orgasm or concerns about compliance. Also explain what is meant by use of contraceptive methods as physical products.

Thank you for this comment. We have revised the objectives to clarify the purpose of the study: "Objectives: To elucidate the impact of the intravaginal ring (IVR), oral contraceptive pill (OCP), and spermicide and condom (S+C) on women's sexual experiences through an in-depth understanding of the physical characteristics of these contraceptive methods."

With respect to the term "sexual experience," in this qualitative in-depth study, we intentionally did <u>not</u> define the term, so that participants themselves could describe their own understanding of the phenomenon. Interestingly, many participants included the domains the reviewer mentions within their descriptions of their sexual experiences; here, we specifically consider the sexual experience as described by the participants themselves.

2. Line 64 The study design did not explore efficacy of contraceptive use as implied in the conclusion. The general understanding of physical barriers such as condoms, diaphragm and to a lesser extent other barriers such as rings is well established.

We agree that our study did not explore contraceptive efficacy; however, we want to emphasize that our use of the word "effective" encompasses the ways in which women typically use their contraceptive products in order to maintain efficacy. We do believe that our study explores this concept of effective use. Nevertheless, we understand that that word choice may be unclear to some readers. Therefore, we have changed the word "effective" to "successful" on line 67. Lastly, the intention of the final sentence was to present an implication for the study findings, rather than a finding or conclusion itself.

Additionally, your comment mentions that physical barrier methods are well understood. We would like to clarify that the physicality discussed in this study is not limited to physical barrier methods such as condoms. Rather, the physicality represents the physical characteristics of each method, which include biophysical and/or biomechanical properties. A contraceptive method whose mechanism of action is based on a hormonal effect, rather than a physical barrier, can still have physical characteristics; an example of this would be the IVR, including characteristics such as dimensionality or material flexibility.

3. Line 59-60. In what direction were alterations in use and opinions between methods?

The purpose of the in-depth interviews is to explore the <u>range</u> of women's experiences during product use. Results illustrated a range of opinions and experiences for each woman with each contraceptive method, and therefore span directionality. It would be difficult to ascribe direction to both method used and participant opinion, as each woman experienced their contraceptive method differently: i.e., often what is a positive feature for one woman is a negative for another.

Introduction:
4. This is a good overview of the problem. The references American Journal of Public Health, 2008. 98(10): p. 1803-1813 specifically look at some of the contraceptive methods and gender/social class and seems to overlap with many of the objectives of this study.

Thank you.

Materials and methods:

5. Line 99 Specify what types of experiences you are referring to. This is vague.

Thank you for this suggestion. We recognize that the term "experiences" in isolation is vague. We have revised this sentence on lines 100-102 to more accurately and clearly convey what we mean by "experiences": "Project WISH (Women's Input on Sexual Health) was a longitudinal prospective study utilizing a mixed-method integrative design, capturing data on users' sensory experiences of sexual lubricants and contraceptives and the meaning derived from those experiences."

6. Line 103-105 The recruitment methods and sources are quite variable with potential reporting bias. Were patients contacted in the phone list arm? These patients may be different from other forms of self recruitment. Explain in more detail.

We agree that recruitment source could result in biased sampling. We chose to minimize potential reporting bias by implementing a varied set of recruitment strategies that ranged from flyers to clinic outreach to previous participant call lists. Though participants from previous study call lists were

contacted, they did not represent a significant portion of the participant population. We were able to return to our database and found that, out of the participants initially assessed for eligibility, 3 were recruited via previous study call lists compared to 45 participants recruited via internet, intranet and social media and 15 via study flyers. For a full list of the recruitment method breakdown, please refer to our response to your comment #13.

7. Line 114 How were participants counseled on the serial use of hormonal options without condom use and potentially STD risks? How did this get approved through the IRB?

Thank you for your concern. See our response to Reviewer #1, comment #10.

8. Line 115 The randomized order of use I think is an important aspect of the study to minimize recall bias.

Thank you. We want to clarify that while randomized order of use can minimize bias in user's considering prior product experience or opinion, it should not impact recall bias as participants were interviewed after each 3-month product use period before starting the next product.

9. Line 117 Why were women allowed to continue the first method for an additional 3 months vs. being rerandomized? This may bias the final reporting and original randomization.

We acknowledge that the different protocols in our study design may require further explanation. We believed that allowing women the option to continue the first method or choose to be randomized into a second method (protocol v.2) gave the overall study deeper insight into women's contraceptive choices that were absent when the product order was fully randomized (protocol v.1). Note that in protocol v.2, the second method would still be randomly assigned: participants did <u>not</u> get to choose which method they would be switched to.

Though this subject of contraceptive choice was not directly addressed as part of this specific analysis on sexual experience as reported in this manuscript, we believe that protocol v.2 offered important data for the fundamental objectives of the overarching study. We have revised our methods to clarify the intention and utility of protocol v.2 on lines 124-126: "Allowing women this option in protocol v.2 added to the overall study's ability to understand women's contraceptive choices, offering a different perspective from the random assignment in protocol v.1."

10. Line 122. How much were participants compensated? This is important to know for the reader to ascertain risk of coercion.

Thank you for this comment. Reimbursements for study activities (phone surveys, online surveys, IDIs) were carefully determined based on standards being utilized in our other research protocols and were not believed to be coercive, based on time, effort, and study requirements (i.e., $25 for baseline survey; $1/day for phone survey completion; $25/monthly survey; $50/IDI; $25 for final product evaluation survey). Participants were only compensated for activities that were completed. We have added the specific compensation amounts as associated with their task completion on lines 135-136.

11. Line 130-132. Explain more about the thematic approach. What happened when the 2 independent reviewers could not reach consensus on a theme? Was the topic discarded or was there an arbitrator?

Rather than reaching consensus on a theme, the two analysts met to reach consensus on summarized data from the IDIs that were associated with each construct coded. As analysts were trained to a common

coding structure with clear, objective descriptions and examples, any summarized data discarded were data that both analysts agreed did not meet the code description. Rarely, if ever, was consensus not reached. In that case, a third, trained analyst was available to offer insight. We have revised our methods section to elaborate on our thematic approach on lines 147-152: "Prior to data reduction into framework matrices, all analysts were trained to a common coding structure using clear, objective descriptions and examples. Using a summary matrix framework, two researchers independently extracted and summarized the transcripts into matrices representing specific constructs (e.g., sensory experiences). Subsequently, the two researchers met and consensus regarding summarized data was reached. If consensus could not be reached, a third, trained analyst was available to offer insight."

12. How was power determined and or the number of participants for recruitment?

See response to Reviewer #1, comment #2.

Regarding statistical power, the qualitative nature of this study obviates statistical testing. Rather, our goal is to better understand the participants' experiences by exploring the narrative data representing those experiences as shared by the participants. We present those ranges and the depth of their experiences in summative descriptions and via illustrative quotes.

Results:

13. Figure 1. Of the recruited patients how many were recruited by which method? Telephone lists vs. social media etc.

We were able to return to our database, where we determined that 46 participants were recruited via the internet and social media, 15 via study flyer, 7 via word-of mouth, 3 via our call-lists from previous studies, and 2 from outpatient clinics, healthcare provider referral, and community-based organizations. We would like to address that this total number represents the 73 women initially screened for the contraceptive arm of the study, which is reflected in the revised Figure 2. For the 16 participants who enrolled and completed the study, 10 were recruited via the internet and social media, 3 via flyers, 2 via word-of-mouth, and 1 via our call-list from previous studies

14. Line 140-141 The inclusion of the 5 participants who did not use all three methods may bias the thematic analysis. If the intent to randomize the order of method from the start as mentioned to minimize recall or ascertainment bias in the IDI perhaps a per protocol analysis of the 11 participants may minimize this.

To clarify, the intent of randomization was to balance order of products used to minimize any potential order effect within each subject. We do believe that recall bias was controlled for, as each participant completed the method-specific IDI prior to starting the next contraceptive method. Since products previously used in the study were balanced due to randomization, comparisons between products were thus balanced. Regarding potential ascertainment bias, we believe that our decision to include the 5 participants, in fact, further minimized potential ascertainment bias. Rather than only considering data from those who were able to complete the study, we included in our analysis important data from those who exited the study for a variety of reasons. We do understand the potential confusion that may arise from our inclusion of the 5 participants who did not complete the study. We chose to include these 5 participants because this study did not intend to analyze the longitudinal relationship that women had with their three contraceptive methods over 6-9 months. Rather, this study aimed to better understand the impact of each of the 3 contraceptive methods on each woman's sexual experience; in essence, each 3-month use period could be considered as its own distinct data for our study analysis. As all participants discussed the impact of the specific contraceptive method on their sexual experience within the 3-month

use period, we do not believe that the data for those 5 participants who completed a single IDI were significantly different.

One exception is the analysis regarding the effect of OCPs on sexual experience. Many women did describe some effects, such as lack of sexual routine interruption or decreased lubrication, in relation to the previous products that they used (whether IVR or S+C). In this case, those who only completed 1 IDI were unable to compare these experiences. However, we believe that the product-specific data we gained from these participants outweigh this potential difference. We have noted this as a limitation in our discussion section on lines 409-412:"The study aimed to minimize sampling bias through inclusion of IDIs from participants who did not complete all 3 contraceptive methods in the study; while inclusion of these data could impact comparative analyses, the current analysis did not rely on the longitudinal experiences participants had with their contraceptive methods."

15. Table 1 The demographics show a relatively diverse group with some generalizable findings. Given that 13% were cutting back and not paying the bills it is important to know there was not coercion to participate.

Thank you for this thoughtful comment. We hope that our clarification on compensation for your comment #10 addresses the concern of coercion.

Discussion:

16. Line 360-361. This is an important clinical finding regarding disruption in routine.

Thank you.

17. Limitations in general were addressed with some of the exceptions listed above.

Thank you. We hope that our additions to the discussion section more adequately address the limitations of the study.

REVIEWER #3

This is an excellent addition to the literature re: contraceptives. I am disappointed that more common methods were not used and that the authors did not compare quantitatively or group qualitative perceptions on what woman had previously used and that they currently use.

Thank you for this comment. Reviewer #1 had a similar remark in comment #3 regarding the methods chosen for this study. Please see that response.

Regarding your second comment, we agree that those findings would have been interesting to add to the contraceptive literature. However, both quantitative and qualitative perceptions on women's previous and current contraceptive methods were outside the scope of this study. This manuscript specifically analyzes the impact of the contraceptive methods used during this 6- to 9-month study on women's sensory experiences during sexual encounters. Participants' often provided comparisons to their previous contraceptive methods to offer context to the ways they experienced the study's contraceptive methods, but we did not require them to consider experiences with their previous contraceptive methods. Fundamentally, we believe that it was best for our participants to elaborate on their recent experiences soon after using a method in order to formulate a credible understanding of the sensorial experiences they had. In addition, many of the participants had used more than one method prior to study

participation: considering all of them for each participant would have been burdensome, if not fraught with recall bias.

STATISTICAL EDITOR'S COMMENTS

1. Table 1: Since the total sample size is 16, should round the median age to an integer and round the %s to the nearest whole number.

Thank you for this suggestion. We have incorporated the changes in Table 1.

2. Fig 2: Since 32 declined to enroll and 8 of 24 did not complete the protocol, need to include in Discussion among limitations that there may be bias in the analysis.

Thank you. We have revised our discussion section to include on lines 395-398:
"Limitations include potential bias in the participant population due to possible barriers in completing the study, such as the intensive nature of study activities, the study's long duration, and the need to switch contraceptive methods."

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, as well as subsequent author queries. 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:

We would like to opt in.

2. 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), 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, CHEERS, SQUIRE 2.0, or CHERRIES guidelines, as appropriate.

We have uploaded the STROBE checklist with this revision.

Daniel Mosier

From: Denise Shields
Sent: Wednesday, April 17, 2019 9:28 AM
To: Guthrie, Kate
Cc: Daniel Mosier
Subject: RE: Manuscript Revisions: ONG-19-205R1

Thank you, Dr. Guthrie. We sincerely appreciate your helping us to uphold the standards of the journal's (and ACOG's) style.

Regards,
Denise

From: Guthrie, Kate [redacted]
Sent: Tuesday, April 16, 2019 4:28 PM
To: Denise Shields <DShields@greenjournal.org>
Subject: RE: Manuscript Revisions: ONG-19-205R1

Interesting; that would not have been my use at all…

Well, we do not merely mean "associated with" so that will not fix our issue.
If the journal is adamant, we can keep with your change from "impact" to "effect."

The previous version I sent back will, therefore, work.
Thanks.
kg

From: Denise Shields [mailto:DShields@greenjournal.org]
Sent: Tuesday, April 16, 2019 8:39 AM
To: Guthrie, Kate [redacted]
Cc: Daniel Mosier <dmosier@greenjournal.org>; [redacted]
Subject: RE: Manuscript Revisions: ONG-19-205R1

Dear Dr. Guthrie,

Our journal uses "impact" to mean "to strike." It's not used to mean "effect" or "affect." If "association with…" works better for your paper, please use that wording.

Regards,
Denise

Denise Shields
Senior Manuscript Editor
Obstetrics & Gynecology
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LinkedIn (https://www.linkedin.com/groups/4058408)

From: Guthrie, Kate [redacted]
Sent: Monday, April 15, 2019 4:30 PM
To: Daniel Mosier <dmosier@greenjournal.org>; [redacted]
Subject: RE: Manuscript Revisions: ONG-19-205R1
Importance: High

Hi, Daniel,
On further review, I note that you have changed the word "Impact" in the title, short title and precis.
Please explain why.

We chose the word "impact" specifically, as "effect" treads closely to "cause and effect" which we are not purporting. And actually, "impact" carries a wider nuance that we would like to convey.

I would appreciate a return to our wording.
Many thanks!
Dr Kate Guthrie

From: Daniel Mosier [mailto:dmosier@greenjournal.org]
Sent: Friday, April 12, 2019 4:17 PM
To: [redacted]
Subject: Manuscript Revisions: ONG-19-205R1

Dear Dr. Guthrie,

Thank you for submitting your revised manuscript. It has been reviewed by the editor, and there are a few issues that must be addressed before we can consider your manuscript further:

1. Please note the minor edits and deletions throughout. Please let us know if you disagree with any of these changes.
2. LINE 13: The following co-authors will need to complete our electronic Copyright Transfer Agreement, which was sent to them through Editorial Manager: Yaa Frimpong, Melanie Hill

When revising, use the attached version of the manuscript. Leave the track changes on, and do not use the “Accept all Changes”

Please let me know if you have any questions. Your prompt response to these queries will be appreciated; please respond no later than COB on **Tuesday, April 16th**.

Sincerely,
-Daniel Mosier

Daniel Mosier
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Web: http://www.greenjournal.org

From: [redacted]
To: Denise Shields
Subject: RE: figures in your Green Journal manuscript (19-205)
Date: Wednesday, May 1, 2019 4:25:25 PM

Agreed.
Thanks.

From: Denise Shields [mailto:DShields@greenjournal.org]
Sent: Wednesday, May 01, 2019 3:10 PM
To: Guthrie, Kate [redacted]
Cc: Connie Fei Lu (connie_fei_lu@brown.edu) <connie_fei_lu@brown.edu>
Subject: RE: figures in your Green Journal manuscript (19-205)

Here is the figure for your review.

From: Guthrie, Kate [redacted]
Sent: Wednesday, May 1, 2019 2:14 PM
To: Denise Shields <DShields@greenjournal.org>
Subject: RE: figures in your Green Journal manuscript (19-205)

Great! Thanks!
I'm in meetings the rest of the afternoon, so may not get back to you before tomorrow: just fyi.

From: Denise Shields [mailto:DShields@greenjournal.org]
Sent: Wednesday, May 01, 2019 2:12 PM
To: Guthrie, Kate [redacted]
Cc: Connie Fei Lu [redacted]
Subject: RE: figures in your Green Journal manuscript (19-205)

Yes, that looks nice!

Our production editor is making one more edit and I will have the edited figure to you shortly.

From: Guthrie, Kate [redacted]
Sent: Wednesday, May 1, 2019 2:10 PM
To: Denise Shields <DShields@greenjournal.org>
Cc: Connie Fei Lu [redacted]
Subject: RE: figures in your Green Journal manuscript (19-205)

Oh! I was not thinking of it visually like that. That makes better sense now why you would put 'Beyond..' after.
I'm agreeable: like this, correct?

A Qualitative Study of the Contraceptive Effect on Women's Sexual Experiences

Beyond Hormonal Effects

From: Denise Shields [mailto:DShields@greenjournal.org]
Sent: Wednesday, May 01, 2019 1:47 PM
To: Guthrie, Kate [redacted]
Cc: Connie Fei Lu [redacted]
Subject: RE: figures in your Green Journal manuscript (19-205)

Yes, the title edit was proposed to illustrate the point of the science to be presented. It's also for aesthetic reasons. In the proof, the main title would appear as "Beyond Hormonal Effects." Attached is an example from our current issue, so you can get an idea of what it would look like.

From: Guthrie, Kate [redacted]
Sent: Wednesday, May 1, 2019 1:42 PM
To: Denise Shields <DShields@greenjournal.org>
Cc: Connie Fei Lu [redacted]
Subject: RE: figures in your Green Journal manuscript (19-205)

See my responses below.

From: Denise Shields [mailto:DShields@greenjournal.org]
Sent: Wednesday, May 01, 2019 1:17 PM
To: Guthrie, Kate [redacted]
Subject: RE: figures in your Green Journal manuscript (19-205)

We will make the edits and get back to you. The periods in the figure aren't necessary and we will remove them. Thank you!

"OCP" for "oral contraceptive pill" and "y" for years" are both approved abbreviations and still used in the figure. Is it okay to continue to use them in the figure? I'm not sure what I was just looking at… thanks for clarifying.

As far as the title, would you be amenable to using "Beyond Hormonal Effects" as a subtitle? "A Qualitative Study…" states what your paper is about. So, the title would read, "A Qualitative Study of the Contraceptive Effect on Women's Sexual Experiences: Beyond Hormonal Effects."
Frankly, I don't think it makes much sense that way. The 'Beyond Hormonal Impact…' [original] is meant to emphasize exactly what the paper's results are about. Just 'Qualitative…' is not descriptive enough on its own, as *that* potential universe of data is a much greater range... What is the reason for not titling it the way we meant it to be titled, to illustrate the point of the science to be presented?

From: Guthrie, Kate[redacted]
Sent: Wednesday, May 1, 2019 1:09 PM
To: Denise Shields <DShields@greenjournal.org>
Subject: RE: figures in your Green Journal manuscript (19-205)

A few changes … please see comments in the figure attached.

Also, since you spelled out 'OCP' and 'years' in the actual figure, can you delete the explanation of those in the figure caption that we previously edited?

Also, I heard from NIHMS and requested that the full title be used, as per my original feedback to you and Daniel. I'm guessing that got lost in the back-and-forth of emails re use of the word 'impact' (which I still disagree with). But, given the need for me to acquiesce that point, please revise the title to "Beyond Hormonal Effects: A qualitative study of the contraceptive effect on women's sexual experiences."

Thank you!
kg

From: Denise Shields [mailto:DShields@greenjournal.org]
Sent: Wednesday, May 01, 2019 12:44 PM
To: Guthrie, Kate[redacted]

Subject: RE: figures in your Green Journal manuscript (19-205)

Hi Dr. Guthrie,

Does this look okay to you?

-Denise

From: Denise Shields
Sent: Thursday, April 25, 2019 2:08 PM
To: Guthrie, Kate [redacted]
Subject: RE: figures in your Green Journal manuscript (19-205)

In figure 3, we also need to add a period after "(34y, male condom, [B])." I will ask our production editor to make this change.

From: Denise Shields
Sent: Monday, April 22, 2019 3:46 PM
To: Guthrie, Kate [redacted]
Subject: RE: figures in your Green Journal manuscript (19-205)

Here is the edited figure 3.

From: Guthrie, Kate [redacted]
Sent: Wednesday, April 17, 2019 5:43 PM
To: Denise Shields <DShields@greenjournal.org>
Subject: RE: figures in your Green Journal manuscript (19-205)

Hi, Denise,
I will be out of town all next week at a meeting.
Could I ask that you send it to me at my personal email so that I can access it easily?
[redacted]
Many thanks,
kg

From: Denise Shields [mailto:DShields@greenjournal.org]
Sent: Wednesday, April 17, 2019 3:35 PM
To: Guthrie, Kate [redacted]
Cc: Connie Fei Lu [redacted]

Subject: RE: figures in your Green Journal manuscript (19-205)

I will have our production editor make the edit to the figure on Monday and send it to you (she's temporary and here only three days a week). We have the same legends; I'll send that to you as well next week with the edited figure.

From: Guthrie, Kate [redacted]
Sent: Wednesday, April 17, 2019 10:38 AM
To: Denise Shields <DShields@greenjournal.org>
Cc: Connie Fei Lu [redacted]
Subject: RE: figures in your Green Journal manuscript (19-205)

Dear Denise,

Figure 4 looks fine.

Figure 3. That same third box in the top section [Oral contraceptive pill administration "Take it in the morning, forget about it. That's the easiest part"]
This B needs to have square brackets and no comma after 'condom' to be consistent with similar box in the figure and text notations: (34 y, male condom [B])

Figure 3. **Can you confirm that the figure caption now reads?**:
"Figure 3. Representation of overarching themes as organized for each contraceptive method. Illustrative quotes are attributed to each participant by their age and contraceptive method used before the study: [A] and [B] are used to distinguish individuals with the same characteristics and correspond accordingly to their quotes in the text. OCP, oral contraceptive pill, y, years."

Figure 2: **Can you confirm that the figure caption now reads?**:
"Figure 2. Flow diagram of participant selection and study. BMI, body mass index; * Unrelated."

Thank you.
kg

From: Denise Shields [mailto:DShields@greenjournal.org]
Sent: Tuesday, April 16, 2019 1:31 PM
To: Guthrie, Kate [redacted]

Cc: Connie Fei Lu [redacted]
Subject: RE: figures in your Green Journal manuscript (19-205)

Dear Dr. Guthrie,

Here are the edited figures for your review. Please let me know if you have any changes.

Regards,
Denise

From: Denise Shields
Sent: Thursday, April 11, 2019 10:28 AM
To: Guthrie, Kate [redacted]
Cc: Connie Fei Lu [redacted]
Subject: RE: figures in your Green Journal manuscript (19-205)

Thank you. It's no trouble, really – we take the time to redraw most of our art to incorporate journal style. Thank you for your edits. I will have our production editor make the changes on Monday when she returns to the office, and I will send you the edited versions.

From: Guthrie, Kate [redacted]
Sent: Thursday, April 11, 2019 10:04 AM
To: Denise Shields <DShields@greenjournal.org>
Cc: Connie Fei Lu [redacted]
Subject: RE: figures in your Green Journal manuscript (19-205)

Good morning, Denise,
First, I want to say I'm sorry you went through all this trouble… We had powerpoint slides for each of the figures, but were never asked to send them. (The submission instructions said to embed them in the manuscript draft and that they would ask for separate figures later…)

I am attaching them here, so you can at least now use them as a reference.
I am also attaching our responses to all your inquiries.

Please let me know if you need anything else, or if anything doesn't make sense. You are always welcome to call me: 401.580.2217.

Many thanks!
Dr K Guthrie

From: Denise Shields [mailto:DShields@greenjournal.org]
Sent: Friday, April 05, 2019 3:54 PM
To: [redacted]
Subject: figures in your Green Journal manuscript (19-205)

Re: "A Qualitative Study of the Contraceptive Effect on Women's Sexual Experiences"

Dear Dr. Guthrie,

Your figures and legend have been edited and they are attached for your review. Please review the attachments CAREFULLY for any mistakes. **There are questions in the figure legends for you to answer.**

PLEASE NOTE: Any changes to the figures must be made now. Changes made at later stages are expensive and time-consuming and may result in the delay of your article's publication.

To avoid a delay, I would appreciate a reply no later than Tuesday, 4/9. Thank you for your help.

Best,
Denise

Denise Shields
Senior Manuscript Editor
Obstetrics & Gynecology
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