NOTICE: This document contains correspondence generated during peer review and subsequent revisions but before transmittal to production for composition and copyediting:

- 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: 02/24/2023
To: "Emma Jean Qureshey" [redacted]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-23-122

RE: Manuscript Number ONG-23-122

Long-Acting Reversible Contraceptive (LARC) Uptake in High-Risk Pregnancies with Decision Aid versus Routine Care: One-Year Postpartum Follow-Up

Dear Dr. Qureshey:

Thank you for sending us your work for consideration for publication in Obstetrics & Gynecology. Your manuscript has been reviewed by the Editorial Board and by special expert referees. The Editors would like to invite you to submit a revised version for further consideration.

If you wish to revise your manuscript, please read the following comments submitted by the reviewers and Editors. Each point raised requires a response, by either revising your manuscript or making a clear argument as to why no revision is needed in the cover letter.

To facilitate our review, we prefer that the cover letter you submit with your revised manuscript include each reviewer and Editor comment below, followed by your response. That is, a point-by-point response is required to each of the EDITOR COMMENTS (if applicable), REVIEWER COMMENTS, and STATISTICAL EDITOR COMMENTS (if applicable) below.

The revised manuscript should indicate the position of all changes made. Please use the "track changes" feature in your document (do not use strikethrough or underline formatting).

Your submission will be maintained in active status for 21 days from the date of this letter. If we have not heard from you by 03/17/2023, we will assume you wish to withdraw the manuscript from further consideration.

EDITOR COMMENTS:

We would like to offer you the opportunity to revise your research letter based on the reviewers' feedback below.

In addition, please address the following points:
- The primary outcome was not significant (LARC use) and should be presented primarily alongside the contraception use as the secondary outcome.
- Please do not reference tables in the abstract. Please include the actual results you wish to highlight.
- Additional details on the methodology and the primary study can be included in an Online Supplement to preserve word count. Please include more details on the survey administration and the survey questions as they relate to the outcomes presented (for example, how was "satisfaction" measured?). See issues raised by Reviewer #1.
- The Acknowledgment section can be moved to the title page.
- The Discussion section should briefly mention limitations to this study and how that may affect interpretation/generalizability.
- In Table 1, please clarify in the legend what "past use of contraception" and "planned bilateral tubal ligation" refers to? What time interval was this assessed at?
- Please clarify how individuals who had a postpartum sterilization were analyzed in this analysis (as they would no longer have a need for contraception use).

Please also note the following:

* Help us reduce the number of queries we add to your manuscript after it is revised by reading the Revision Checklist at https://journals.lww.com/greenjournal/Documents/RevisionChecklist_Authors.pdf and making the applicable edits to your manuscript.

* Was this presented at SMFM? If so, please include on the title page the date and location of the presentation.

REVIEWER COMMENTS:

Reviewer #1:
In this research letter, the authors report on 1-year follow-up after a previously trial of a decisional aid vs. standard care for LARC. The authors find increased use of contraception (not LARC) in those who underwent the educational tool. My main issue with this research letter is that there are a lot of items left out that makes this research letter hard to follow. Comments are outlined below.

1) In the primary study, patient received LARC - however, LARC was similar between groups but overall contraception was not. What other forms of contraception are the authors referring to? Does this mean they got LARC and within the year discontinued LARC and found another method?
2) The Tables include permanent sterilization and BTL. How this factors into patients is not detailed. Are these patients included in the 1 year follow-up? If so, why would they be since this is permanent sterilization and not LARC.
3) How is high-risk defined?
4) The previous use of LARC or as in the tables short action contraception is confusing. Is this prior to the pregnancy in which they were counseled? Also how was previous contraception "surgical sterilization?"
5) Results - the primary outcome LARC at 1 year should be the first outcome presented, not contraception given that is a secondary outcome (albeit significant).
6) Details of how the surveys were given and conducted and time frames for f/u should be detailed

Reviewer #2:
This short manuscript, presented as a research letter, presents the interval data for a planned two-year study assessing continuation and satisfaction with LARC after use of a multimedia educational tool (MET) used to provide supplemental intervention in a high-risk pregnancy clinic for post-partum contraception. Though the Research Letter format prevents a deep discussion of some issues surrounding contraception use and satisfaction, the manuscript provides an informative, brief update on the outcomes. Though the increased use in contraceptives is modest, given that so many interventions have not shown a robust increase in use, it is an important contribution to the literature.

Line 54-57: It would also be interesting to discuss patient satisfaction with the tool itself. The parent study reports that 10 individuals reviewed the MET, but on-going satisfaction with the tool would be informative.

Line 72-73: The authors state that satisfaction between the groups was similar. A brief discussion of this, if more data is available, would be interesting to the reader.

Reviewer #3:
This research letter aims to provide data at one year postpartum in participants of a RCT testing educational modality for LARCs adoption. The purpose and data are of interest.

The letter follows OnG guidelines, which require some redundancy in a short communication. Replace the references to Tables in the unstructured Abstract with the most relevant p-values being cited.

Two additional suggestions are
1) to spell out what SUSTAIN means or stands for;
2) round to 2 decimal places for p-values in the tables.

STATISTICAL EDITOR COMMENTS:
Lines 70-73: Since LARC usage was the primary outcome, that result should be stated first in Results and Discussion. That is, by the original design, the primary outcome became NS at the one year mark. Need to modify the sentence, the difference is purely arithmetic, there is NS difference. One of the secondary outcomes (overall contraception use) became statistically significant at one year.

lines 65-68: However, the follow-up appears to be skewed towards those who previously had LARC, so that may have biased the measurement of overall contraceptive use at 1 year. Please mention in the discussion.

Table 2: Need to clearly separate the primary outcome from all others.

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Sincerely,
Mark A. Clapp, MD, MPH
Editorial Fellow

The Editors of Obstetrics & Gynecology

Emma Qureshey, MD
Department of Obstetrics, Gynecology & Reproductive Sciences
McGovern Medical School

March 7th, 2023

Jason D. Wright, MD
Editor-in-Chief, Obstetrics & Gynecology
409 12th Street SW,
Washington, DC 20024-2188

***RE:* LARC Uptake in High-Risk Pregnancies with Decision Aid versus Routine Care: One-Year Postpartum Follow-Up**

Dear Dr. Wright:

Thank you for considering the above-mentioned manuscript in Obstetrics & Gynecology. We have received your thoughtful comments and would like to submit the manuscript with suggested changes and edits as below;

EDITOR COMMENTS:
- The primary outcome was not significant (LARC use) and should be presented primarily alongside the contraception use as the secondary outcome.
This is presented in Results, line 73-75 and was added to line 88 in the discussion
- Please do not reference tables in the abstract. Please include the actual results you wish to highlight.
Fixed, lines 26-28 in abstract
- Additional details on the methodology and the primary study can be included in an Online Supplement to preserve word count. Please include more details on the survey administration and the survey questions as they relate to the outcomes presented (for example, how was "satisfaction" measured?). See issues raised by Reviewer #1.
- The Acknowledgment section can be moved to the title page.
Done
- The Discussion section should briefly mention limitations to this study and how that may affect interpretation/generalizability.
- In Table 1, please clarify in the legend what "past use of contraception" and "planned bilateral tubal ligation" refers to? What time interval was this assessed at?
Done
- Please clarify how individuals who had a postpartum sterilization were analyzed in this analysis (as they would no longer have a need for contraception use).

These individuals were included in the analysis as they received the same education at the time of enrollment which may have influenced their decision to ultimately go through with permanent sterilization (information on high-risk pregnancy, pregnancy planning, etc).

Reviewer #1:
In this research letter, the authors report on 1-year follow-up after a previously trial of a decisional aid vs. standard care for LARC. The authors find increased use of contraception (not LARC) in those who underwent the educational tool. My main issue with this research letter is that there are a lot of items left out that makes this research letter hard to follow. Comments are outlined below.

1) In the primary study, patient received LARC - however, LARC was similar between groups but overall contraception was not. What other forms of contraception are the authors referring to? Does this mean they got LARC and within the year discontinued LARC and found another method?
Please see Table 2 legend for additional forms of contraception. This is a great question regarding the differences in LARC in the initial 12 week time period versus one year follow and has been added briefly to the discussion in lines 89-91 but will be further investigated at the 2 year follow-up.
2) The Tables include permanent sterilization and BTL. How this factors into patients is not detailed. Are these patients included in the 1 year follow-up? If so, why would they be since this is permanent sterilization and not LARC.
These individuals were included in the analysis as they received the same education at the time of enrollment which may have influenced their decision to ultimately go through with permanent sterilization (information on high-risk pregnancy, pregnancy planning, etc).
3) How is high-risk defined?
There were a variety of conditions that categorized a pregnancy as high-risk, poor pregnancy outcomes in a prior pregnancy, maternal chronic conditions, fetal conditions, etc. This is available as a supplemental document in the parent trial and we are happy to provide again if this is felt to be necessary.
4) The previous use of LARC or as in the tables short action contraception is confusing. Is this prior to the pregnancy in which they were counseled? Also how was previous contraception "surgical sterilization?"
This was clarified in the legend for Table 1. There was one patient in the trial who had previously undergone surgical sterilization (which failed).
5) Results - the primary outcome LARC at 1 year should be the first outcome presented, not contraception given that is a secondary outcome (albeit significant).
Agree and adjusted
6) Details of how the surveys were given and conducted and time frames for f/u should be detailed
This was added to lines 54-55 and 79-81

Reviewer #2:
This short manuscript, presented as a research letter, presents the interval data for a planned two-year study assessing continuation and satisfaction with LARC after use of a multimedia educational tool (MET) used to provide supplemental intervention in a high-risk pregnancy clinic for post-partum contraception. Though the Research Letter format prevents a deep discussion of some issues surrounding contraception use and satisfaction, the manuscript provides an informative, brief update on the outcomes. Though the increased use in contraceptives is modest, given that so many interventions have not shown a robust increase in use, it is an important contribution to the literature.

Line 54-57: It would also be interesting to discuss patient satisfaction with the tool itself. The parent study reports that 10 individuals reviewed the MET, but on-going satisfaction with the tool would be informative.
We agree that this would be an interesting addition and something we have considered for future investigations.

Line 72-73: The authors state that satisfaction between the groups was similar. A brief discussion of this, if more data is available, would be interesting to the reader.

Re-worded for clarity in lines 79-81, the satisfaction was assessed via a simple, "Are you happy with your current method of contraception" with a yes/no answer.

Reviewer #3:
This research letter aims to provide data at one year postpartum in participants of a RCT testing educational modality for LARCs adoption. The purpose and data are of interest.

The letter follows OnG guidelines, which require some redundancy in a short communication. Replace the references to Tables in the unstructured Abstract with the most relevant p-values being cited.

Two additional suggestions are
1) to spell out what SUSTAIN means or stands for;
2) round to 2 decimal places for p-values in the tables.

All suggestions were implemented, lines 42-43 and both Table 1 and Table 2.

STATISTICAL EDITOR COMMENTS:
Lines 70-73: Since LARC usage was the primary outcome, that result should be stated first in Results and Discussion. That is, by the original design, the primary outcome became NS at the one year mark. Need to modify the sentence, the difference is purely arithmetic, there is NS

difference. One of the secondary outcomes (overall contraception use) became statistically significant at one year.

The primary outcome of LARC usage was moved in the discussion above the secondary outcome of overall contraceptive usage.

lines 65-68: However, the follow-up appears to be skewed towards those who previously had LARC, so that may have biased the measurement of overall contraceptive use at 1 year. Please mention in the discussion.

This is an important point and was added to the discussion.

Table 2: Need to clearly separate the primary outcome from all others.
Separated in Table 2

We have not published, posted or submitted any related papers from this analysis and are not planning to submit to another journal unless final negative decision is received.

As you know, long-acting reversible contraceptives are safe and effective methods to avoid unintended pregnancies but according to national surveys, LARC methods are used infrequently (~10-17%). There are several known barriers to LARC usage including misconceptions about safety and inability for providers to comprehensively educate due to time constraints. To address these important clinical barriers, we performed a randomized clinical trial evaluating the rates of LARC usage postpartum following a high-risk pregnancy in those who received education via a multimedia tool versus routine care. This was previously published in your journal. We are now reporting on the one-year postpartum follow-up data. We believe these findings will be of interest to the readers of your journal.

We know of no conflicts of interest associated with this publication. 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 there are not any discrepancies from the study as planned and registered. This trial was registered with Clinical trials.gov https://clinicaltrials.gov/ct2/show/results/NCT04291040?view=results *on March 2nd, 2020 (NCT04291040) prior to initial participant enrollment on July 9th 2020. As Corresponding Author, I confirm that the manuscript has been read and approved for submission by all the named authors. IRB approval was obtained from both institutions involved (HSC-MS-20-0022).*
Data-sharing will not be available until the planned follow-up is completed at 12 and 24 month interval from completion of primary outcome.

This study was funded in part by a research grant from the Investigator-Initiated Studies program of Organon. The sponsor's involvement as described in the manuscript is

accurate. The opinions expressed in this paper are those of the authors and do not necessarily represent Organon.

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

We hope you find our manuscript suitable for publication and look forward to hearing from you.

Sincerely,

Emma J. Qureshey, MD
Department of Obstetrics, Gynecology and Reproductive Sciences
McGovern Medical School, the University of Texas Health Science Center at Houston
Houston, TX
[redacted]