

# 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)\*
- Email correspondence between the editorial office and the authors\*

*\*The corresponding author has opted to make this information publicly available.*

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Questions about these materials may be directed to the *Obstetrics & Gynecology* editorial office:

[obgyn@greenjournal.org](mailto:obgyn@greenjournal.org).

**Date:** Jul 20, 2018  
**To:** "Sarita Sonalkar" [REDACTED]  
**From:** "The Green Journal" em@greenjournal.org  
**Subject:** Your Submission ONG-18-1137

RE: Manuscript Number ONG-18-1137

One-year effectiveness of intended postplacental versus intended delayed postpartum intrauterine devices

Dear Dr. Sonalkar:

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 Aug 10, 2018, we will assume you wish to withdraw the manuscript from further consideration.

#### REVIEWER COMMENTS:

Reviewer #1:

The authors used a computational algorithm to investigate a "what-if" question in order to provide recommendations for the real-world applications of the postplacental IUD.

#### Strengths:

1) Used the Monte Carlo method (mathematical model) and the decision analysis for the simulating scenarios of "postplacental IUD" patients and "delayed postpartum IUD" patients; 2) Used a prescriptive approach to conduct decision analysis; but acknowledged their limitation of missing descriptive decision-making information from patients (p14, line 304-309). A few suggestions would further strengthen this manuscript.

#### 1. Study goal and objective:

- a. The authors stated the objective was to "investigate the real-world effectiveness of immediate and delayed postpartum IUD placement" (p5, line 107-108). Given they used "a theoretical cohort" (p7, line 149), the authors are suggested to refine the study objective and/or the title to help readers understand this study was based on a computational modeling/analysis.
- b. Please provide a definition of "effectiveness".

#### 2. Methods:

- a. This study was primarily based on computational analysis, it thus would be necessary to specify the rationale behind the methodology. Please explain 1) Why Monte Carlo method was appropriate for this study; 2) Why one-way deterministic sensitivity analysis (DSA) was selected?
- b. If "effectiveness" is the output of the model, please specify (e.g. whether it comes with a computational formula).
- c. The authors conducted a literature review but did not report the results. Given the authors indicated "factors that we hypothesized would affect IUD effectiveness" (p6, line 118), it would strengthen the modeling foundation if they would use the literature review results to verify or support the hypothesis.

#### 3. Results:

- a. It would be helpful if the authors could add the model results with point estimates/probabilities to Figure 1a and 1b.
- b. Figure 2: if Y axis are parameters/inputs used in each analysis (to see how the results are affected), please specify.

Reviewer #2:

TITLE: One-year effectiveness of intended postplacental versus intended delayed postpartum intrauterine devices

Overall: This is an original research report of a decision analysis comparing postplacental IUD insertion to IUD insertion at the routine postpartum visit. This is a modeling paper and that needs to be emphasized more in the objectives, title and throughout the paper. The conclusions are overstated in the discussion.

Author Conflicts are reported and are not problematic.

IRB/Ethics approval: The authors submitted the study to their IRB and the study was deemed exempt.

TITLE: The title should include words clarifying that this is a modeling paper.

ABSTRACT - does the abstract match the paper? Does the abstract provide enough information? I usually review the abstract last:

1. Introduction: The use of a decision analysis/Monte-Carlo design needs to be stated right up front in the objective.
2. Methods: The primary outcomes/comparisons for the model need to be stated.
3. Results: How many women and how many years were entered as the baseline for the model? All percentages should display the numerator and denominator with the percentage.

INTRODUCTION:

4. Line 107: Please state clearly that this is a modeling paper and not a "real-world". Real word implies that women were followed prospectively after IUDs were placed.

MATERIALS AND METHODS:

5. Line 118: Restate so that it's clear, or else clarify that IUD effectiveness (or not) is the same as probability of pregnancy (Line 113).
6. Overall the Materials and methods reads as one very long paragraph. Readers of the green journal may not be terribly familiar with the methods of modeling so in addition to writing towards reviewers the authors should think about how they write the paper so someone less familiar with modeling could learn from the paper.
7. Line 133: This should be a new paragraph. The concept of Base Case values needs to be more clearly stated.
8. Lines 133-140: Did you take into account the likely differences in expulsion rates between copper and Levonorgestrel IUDs?
9. Line 141: Explain what a node is
10. Line 148: How many women entered the model? How many cycles did you run?
11. Line 150: this is the first I have seen postplacental after cesarean and postplacental after vaginal delivery. This needs further explanation about the details and the differences. If you were running two separate models based on vaginal or cesarean delivery that should be stated in the introduction.
12. Line 153: Explain deterministic sensitivity analysis.

RESULTS:

13. Lines 200 - 202: These results are important but can you put it in more clear clinical language? Your model predicted X number of women would become pregnant - rather than use the word effectiveness?
14. Line 208: Please clarify how these numbers compare to effectiveness?

DISCUSSION:

15. Line 251: Please be more cautious about presenting the results. The pregnancy rates between immediate and delayed IUD insertion, after accounting for everything else really wasn't that much lower. This is in keeping with the literature and should be clearly stated. What does this paper add to the primary research literature? The conclusion is still the same that it's individual risk/benefit.
16. Line 268: Compared to what? 88/1000 compared to what?
17. Line 312: This seems like the most important new information from your paper but unfortunately it's buried in the discussion
18. Use the Green Journal's writing guide to assist with writing a good discussion. [edmgr.ovid.com/ong/accounts/guidetowriting.pdf](http://edmgr.ovid.com/ong/accounts/guidetowriting.pdf)

TABLES AND FIGURES

19. Table 1: Why did you use only one base case value instead of a range? A range would be much more informative for this complicated topic. The base literature are so varied from many different types of populations. Yet the base cases are all taken from just a small number of papers.
20. The tables should stand alone. Table 2 needs a more descriptive title and footnotes

Reviewer #3:

This well-written manuscript reports on an evidence-based decision model comparing the one-year probability of pregnancy following intended post-placental versus intended delayed postpartum (PP) IUD placement. The authors did a broad search of published studies and reports on IUD usage and subsequent outcomes for both immediate, post-placental use, and more traditional use at the PP visit. Utilizing appropriate decision analysis methodology, they were able to show that the probability of unintended pregnancy remained higher with delayed PP placement, versus post-placental placement.

The authors utilized a number of clinical studies and clinical models to create their decision model.

The references are recognized as significant studies and modeling. They also utilized economic models of decision analysis and incorporated these studies in their model.

Several questions should be addressed by the authors in regards to this manuscript:

1. In Table 1, the authors cite a base case % of post-placental IUD placement of 70%. Please clarify the source of this estimate
2. There are fairly broad estimates of the return rate for traditional post-partum appointments, and possible IUD placement at that time. These estimates often reflect the patient population studied. The authors used 81.6% return rate with a range of 65-90%. Reference #6, which is an economic comparison of immediate versus delayed IUD placement, uses a return rate of 81%, which includes all patients, not just those who did not receive immediate IUD placement. The authors may wish to compare/contrast these rates.
3. The authors correctly note that expulsion rates are quite higher with post-placental IUD placement. The authors may wish to address methods to reduce this rate, and further support use of post-placental IUD placement.

Reviewer #4:

This study is a very interesting first step in evaluating the true effectiveness of post-placental IUD placement versus intended interval placement. Prior studies have shown both a higher expulsion rate with post-placental placement as well as a higher probability of certain groups of women not returning for their post-partum IUD placement. However, there is not much data on what these two competing factors mean in practice. This study used a statistical decision model to predict the probability based on influencing criteria they identified and utilizing data available from prior studies. While this provides some very useful information, it does remain a statistical prediction model. As pointed out by the authors, ultimately an RTC should be undertaken to further evaluate this question.

Introduction:

- 1) Overall, the introduction does a good job of setting up why this is an important question to answer.
- 2) Consider adding a comment the lack of insurance payment for post-partum LARC in many locations and the impact this may have on placement in patients particularly at risk for not following up at 6 weeks postpartum. This is where the much of the literature supporting immediate post-partum LARC is focused and a brief mention would be worthwhile.
- 3) Lines 100-102: It would be beneficial to include expulsion rates in this section rather than waiting until later in the paper.
- 4) Line 105: Recommend including the numeric range in which women attend a postpartum visit rather than stating it is variable.
- 5) It is important to note that this study looked at one-year probabilities. The logical, and important, next step would be the looking at the actual rates within these groups.

Materials and Methods:

- 1) What was the reasoning behind choosing a 1-year probability vs a 2-year probability, given that the WHO recommends a 2-year pregnancy interval as noted in the introduction. As this is a prediction model not an RTC it seems that this would have been a possible alternative. The decision for 1 year should be discussed.
- 2) Line 114-115: Why was the "intent to receive" versus "actually received" utilized to define the 2 groups. As some women who intend to receive an immediate post-placental IUD cannot due to unforeseen circumstances such as Triple I or hemorrhage, this would presumably increase the close interval pregnancy rate in this group. Mentioning the reasoning behind this choice would be beneficial.
- 3) Line 121: It would be beneficial to explain the reasoning for including next contraceptive use (and its efficacy etc.) after IUD discontinuation as a variable for IUD effectiveness.
- 4) Lines 121-126: Was there consideration of including intrapartum events (i.e. hemorrhage, triple I) as variables affecting placement and therefore efficacy?
- 5) Line 184-185: What was the estimated probability of IUD placement at the postpartum visit. This should be included in the text, if not here than in the intro.

Results

- 1) Lines 240-243: These numbers do not match the table referenced. 96.1% is the number scenario #3 for delayed PP IUDs per the table so should be listed first. Per the table, 89% is scenario #2 for the delayed PP IUD. Neither is the number for post-placental IUD placement.

Discussion:

Very good discussion and excellent final points. The discussion helps highlight the importance of this study and its context. Some of the information could be introduced sooner the highlight the "so what" factor, but otherwise very well done.

Reviewer #5:

This is an interesting analysis and the decision tree and its assumptions are explained. It is of note that it appears the biggest potential source of variability is whether the patient returns to clinic, rather than events/probabilities after that decision point. If the probability of returning were sufficiently differential for vaginal or cesarean deliveries, then apparently the simulations of Fig 3 could be quite different. That aspect might be explored further as a sensitivity analysis. That is, not as individual probabilities, but as a ratio of probabilities.

#### EDITOR'S NOTE:

It is common for cost effectiveness trials to make a statement something like " in 84% of 10,000 Monte Carlo simulations we found such and such" in the both the abstract and results section. Please edit for something similar w /your data.

Also, as I understand it, the primary node that determines whether post placental or post partum visit placement is cost effective is related to whether a woman returns for her pp visit, this point deserves some further discussion. It looks like there is a difference on this point by whether a woman delivers vaginally or by cesarean and if there is a differential in return rates for women w/ these two delivery routes, that could alter your results. At the end of the day, it doesn't seem like it would make a difference to the clinician if its cost effective w/ vaginal but not cesarean (or vice versa) because for the individual woman, the issue is whether to put it in after placental delivery or not. Could you explore this? some in your discussion?

#### EDITOR COMMENTS:

1. Thank you for your submission to Obstetrics & Gynecology. The reviewer comments should be included in your point-by-point response cover letter.

2. 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:

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

3. Each author on this manuscript must submit a completed copy of our revised author agreement form (updated in the August 2014 issue). Please have Dr. McAllister submit a form.

Please note:

a) Any material included in your submission that is not original or that you are not able to transfer copyright for must be listed under I.B on the first page of the author agreement form.

b) All authors must disclose any financial involvement that could represent potential conflicts of interest in an attachment to the author agreement form.

c) All authors must indicate their contributions to the submission by checking the applicable boxes on the author agreement form.

d) The role of authorship in Obstetrics & Gynecology is reserved for those individuals who meet the criteria recommended by the International Committee of Medical Journal Editors (ICMJE; <http://www.icmje.org>):

\* Substantial contributions to the conception or design of the work;

OR

the acquisition, analysis, or interpretation of data for the work;

AND

\* Drafting the work or revising it critically for important intellectual content;

AND

\* Final approval of the version to be published;

AND

\* Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

The author agreement form is available online at <http://edmgr.ovid.com/ong/accounts/agreementform.pdf>. Signed forms should be scanned and uploaded into Editorial Manager with your other manuscript files. Any forms collected after your revision is submitted may be e-mailed to [obgyn@greenjournal.org](mailto:obgyn@greenjournal.org).

4. Based on the forms that have been submitted, Dr. Schreiber has not met the criteria for authorship. Dr. Schreiber should resubmit a revised author agreement form because they filled it out erroneously the first time. Please check the 'yes' or 'no' box in the disclosure section.

5. 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.

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 will be transitioning as much as possible to use of the reVITALize definitions, and we encourage authors to familiarize themselves with them. The obstetric data definitions are available at <http://links.lww.com/AOG/A515>, and the gynecology data definitions are available at <http://links.lww.com/AOG/A935>.

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 appendices).

Please limit your Introduction to 250 words and your Discussion to 750 words.

8. Specific rules govern the use of acknowledgments in the journal. Please edit your acknowledgments or provide more information in accordance with 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 signature on the journal's author agreement form verifies that permission has been obtained from all named persons.
- \* If all or part of the paper was presented at the Annual Clinical and Scientific Meeting of the American College of Obstetricians and Gynecologists or at any other organizational meeting, that presentation should be noted (include the exact dates and location of the meeting).

9. The most common deficiency in revised manuscripts involves the abstract. Be sure there are no inconsistencies between the Abstract and the manuscript, and that the Abstract has a clear conclusion statement based on the results found in the paper. Make sure that the abstract does not contain information that does not appear in the body text. If you submit a revision, please check the abstract carefully.

In addition, the abstract length should follow journal guidelines. The word limits for different article types are as follows: Original Research articles, 300 words; Reviews, 300 words; Case Reports, 125 words; Current Commentary articles, 250 words; Clinical Practice and Quality, 300 words; Procedures and Instruments, 200 words. Please provide a word count.

10. Only standard abbreviations and acronyms are allowed. A selected list is available online at <http://edmgr.ovid.com/ong/accounts/abbreviations.pdf>. Abbreviations and acronyms cannot be used in the title or précis. Abbreviations and acronyms must be spelled out the first time they are used in the abstract and again in the body of the manuscript.

11. 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.

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](http://edmgr.ovid.com/ong/accounts/table_checklist.pdf).

13. Please revise your figures:

Figure 1: Please update Figure 1A and 1B to Figures 1 and 2 due to space considerations.

Figure 2: Please update to Figure 3. Figure is okay

Figure 3: Please update to Figure 4. Figure is okay

When you submit your revision, art saved in a digital format should accompany it. If your figure was created in Microsoft Word, Microsoft Excel, or Microsoft PowerPoint formats, please submit your original source file. Image files should not be copied and pasted into Microsoft Word or Microsoft PowerPoint.

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

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

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

Figures should be no smaller than the journal column size of 3 1/4 inches. Art that is low resolution, digitized, adapted from slides, or downloaded from the Internet may not reproduce. Refer to the journal printer's web site (<http://cjs.cadmus.com/da/index.asp>) for more direction on digital art preparation.

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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, that each author has given approval to the final form of the revision, and that the agreement form signed by each author and submitted with the initial version remains valid.

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 Aug 10, 2018, 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

If you would like your personal information to be removed from the database, please contact the publication office.

Sarita Sonalkar, M.D., M.P.H.  
Department of Obstetrics and Gynecology

July 30<sup>th</sup>, 2018

Editor-in-Chief  
*Obstetrics and Gynecology*

Dear Editor,

Thank you for your consideration of the revision of our Original Research Article, “A decision analysis model of one-year effectiveness of intended postplacental versus intended delayed postpartum intrauterine devices” for submission to the journal *Obstetrics and Gynecology*.

Dr. Sonalkar, Ms. Hunter, and Dr. Schreiber contributed to the concept and design of the study. Dr. Sonalkar and Ms. Hunter contributed to the data collection and analysis. All authors contributed to the interpretation of the data. All authors contributed to drafting and revising the manuscript for intellectual content. All authors have approved the final version of the manuscript. Dr. Sonalkar 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 have been explained.

Again, we respectfully request that the suggested reference limit of 30 be waived for this original research, as our data was obtained from previously published work, and all references should be cited in order to allow readers to understand the methodology.

Dr. Sonalkar is supported by an NIH Women’s Reproductive Health Research Career Development award (K12-HD001265-18). Dr. Schreiber receives research funding from Medicines360, ContraMed, Bayer Pharmaceuticals, and the National Institutes of Health, and has served as a consultant for Bayer Pharmaceuticals. Ms. Hunter, Dr. Gurney, and Ms. McAllister do not report any conflicts of interest.

The University of Pennsylvania Institutional Review Board determined that this research was non-human subjects research, and did not require IRB review. The paper is not under consideration at any other journal.

Our detailed responses to the reviewers are noted below, and we have included a tracked changes version of the manuscript as well as revised figures in our re-submission.

Best wishes,



Sarita Sonalkar, M.D., M.P.H.  
Hospital of the University of Pennsylvania



Responses to reviewers RE: Manuscript Number ONG-18-1137

A decision analysis model of one-year effectiveness of intended postplacental versus intended delayed postpartum intrauterine devices

*Reviewer #1:*

*The authors used a computational algorithm to investigate a "what-if" question in order to provide recommendations for the real-world applications of the postplacental IUD.*

*Strengths:*

*1) Used the Monte Carlo method (mathematical model) and the decision analysis for the simulating scenarios of "postplacental IUD" patients and "delayed postpartum IUD" patients; 2) Used a prescriptive approach to conduct decision analysis; but acknowledged their limitation of missing descriptive decision-making information from patients (p14, line 304-309). A few suggestions would further strengthen this manuscript.*

*1. Study goal and objective:*

*a. The authors stated the objective was to "investigate the real-world effectiveness of immediate and delayed postpartum IUD placement" (p5, line 107-108). Given they used "a theoretical cohort" (p7, line 149), the authors are suggested to refine the study objective and/or the title to help readers understand this study was based on a computational modeling/analysis.*

Thank you for this important suggestion.

We have revised the title to read, "A decision analysis model of one-year effectiveness of intended postplacental versus intended delayed postpartum intrauterine devices."

Page 5, Line 113: We have revised the objective to read, "Our objective was to use decision analysis to model the effectiveness of immediate and delayed postpartum IUD placement.

*b. Please provide a definition of "effectiveness".*

Page 5, Line 110: We added the following sentence: The term "effectiveness" refers to how well a method works in actual practice, as opposed to "efficacy," which refers to how well a method works in clinical trials<sup>31</sup>."

*2. Methods:*

*a. This study was primarily based on computational analysis, it thus would be necessary to specify the rationale behind the methodology. Please explain 1) Why Monte Carlo method was appropriate for this study;*

Page 6 line 122: We added, "The Monte Carlo simulation method accounts for the probability distribution of outcomes with inherent uncertainty, using decision trees."

*2) Why one-way deterministic sensitivity analysis (DSA) was selected?*

We used both deterministic and probabilistic sensitivity analyses to assess the effect of variations each of inputs individually (deterministic sensitivity analysis) and variations in all the inputs simultaneously (probabilistic sensitivity analysis).

Page 8 line 180: we added, “Deterministic sensitivity assesses how changes in the model inputs affect model outputs, varying a single parameter at a time across its range.”

*b. If "effectiveness" is the output of the model, please specify (e.g. whether it comes with a computational formula).*

We have revised this sentence to more clearly state the output of the model:

Page 7 line 175: “Our simulation models computed the mean effectiveness of postplacental and delayed postpartum IUD insertion in the base case scenario.”

*c. The authors conducted a literature review but did not report the results. Given the authors indicated "factors that we hypothesized would affect IUD effectiveness" (p6, line 118), it would strengthen the modeling foundation if they would use the literature review results to verify or support the hypothesis.*

The literature review was used to provide the base case and ranges (the inputs) for our model, as noted in Table 1. All articles obtained from the literature review are cited in table 1. However, as most of the articles did not report as a primary outcome the one-year probability of pregnancy, we are unable to use the literature review or comment on whether the review itself verifies or supports the hypothesis.

### *3. Results:*

*a. It would be helpful if the authors could add the model results with point estimates/probabilities to Figure 1a and 1b.*

We have added a small table in to Figure 1a and 1b with the base case model output.

*b. Figure 2: if Y axis are parameters/inputs used in each analysis (to see how the results are affected), please specify.*

We added the following text as a Y-axis label in Figure 2, “Model inputs with uncertainty.”

Reviewer #2:

*TITLE: One-year effectiveness of intended postplacental versus intended delayed postpartum intrauterine devices*

*Overall: This is an original research report of a decision analysis comparing postplacental IUD insertion to IUD insertion at the routine postpartum visit. This is a modeling paper and that needs to be emphasized more in the objectives, title and throughout the paper. The conclusions are overstated in the discussion.*

*Author Conflicts are reported and are not problematic.*

*IRB/Ethics approval: The authors submitted the study to their IRB and the study was deemed exempt.*

*TITLE: The title should include words clarifying that this is a modeling paper.*

As edited in response to Reviewer 1, we have changed the title to the following: “A decision analysis model of one-year effectiveness of intended postplacental versus intended delayed postpartum intrauterine devices.”

*ABSTRACT - does the abstract match the paper? Does the abstract provide enough information? I usually review the abstract last:*

1. *Introduction: The use of a decision analysis/Monte-Carlo design needs to be stated right up front in the objective.*

Page 3 line 66: We have revised the text of the Objective to read as follows: “To compare, using decision analysis methodology, the one-year probability of pregnancy after intended postplacental intrauterine device (IUD) insertion with intended delayed insertion at an outpatient postpartum visit (delayed postpartum placement).”

2. *Methods: The primary outcomes/comparisons for the model need to be stated.*

We revised the text of the Methods to more explicitly state the primary outcome and comparisons as follows:

Page 3, Line 69: “We developed an evidence-based decision model with the primary outcome of one-year probability of pregnancy. We compared one-year probability of pregnancy following intended postplacental or intended delayed postpartum IUD placement.”

3. *Results: How many women and how many years were entered as the baseline for the model? All percentatges should display the numerator and denominator with the percentage.*

The theoretical cohort sample sizes are added to this section; the number of years is one, as we modeled a one-year probability. Percentages in this section are derived from probability outputs from the model and thus denominators of the percentages would simply be the percentage value over 100 and thus denominators were not included.

#### *INTRODUCTION:*

4. *Line 107: Please state clearly that this is a modeling paper and not a "real-world". Real word implies that women were followed prospectively after IUDs were placed.*

As requested by Reviewer 1, We have reworded page 5 line 113, to read as follows: “Thus, our objective in this study was to model, with decision analysis, the effectiveness of immediate and delayed postpartum IUD placement.”

#### *MATERIALS AND METHODS:*

5. *Line 118: Restate so that it's clear, or else clarify that IUD effectiveness (or not) is the same as probability of pregnancy (Line 113).*

We have added the following sentence on page 6, line 125: “Probability of pregnancy in our model is considered to be the inverse of IUD effectiveness, and we chose a one-year endpoint so that our effectiveness estimates could be compared with established one-year estimates of contraceptive efficacy.

6. *Overall the Materials and methods reads as one very long paragraph. Readers of the green journal may not be terribly familiar with the methods of modeling so in addition to writing towards reviewers the authors should think about how the write the paper so someone less familiar with modeling could learn from the paper.*

Thank you for this comment. We have broken up the Materials and Methods section into additional paragraphs and have explained the modeling concepts as suggested by this and other reviewers.

7. *Line 133: This should be a new paragraph. The concept of Base Case values needs to be more clearly stated.*

The concept of the base case value has more clearly been stated in page 7, lines 148 as follows: “For each event, two authors (T.H., S.S.) reviewed each article and the most likely probability, called the “base case value,” was selected from the trial that was methodologically superior, based on robustness of study design, and sample size.”

8. *Lines 133-140: Did you take into account the likely differences in expulsion rates between copper and Levonorgestrel IUDs?*

We did take into account the differences in copper and levonorgestrel IUD expulsion for vaginal postplacental placement (Table 1). We have included the following sentence: Page 7 line 156: “When data were available, we incorporated likely differences in outcomes of copper versus levonorgestrel IUDs, and vaginal versus Cesarean deliveries.”

9. *Line 141: Explain what a node is*

We have included additional information about decision tree construction and the definition of a node in page 8, line 163: “We constructed three decision trees as maps of the possible outcomes after 1) intended postplacental IUD placement after vaginal delivery, 2) intended postplacental IUD placement after Cesarean delivery, and 3) intended delayed postpartum IUD placement. Each branch point is called a “node,” and the outcomes of each node incorporate the base case probabilities determined from the literature (Figure 1).”

10. *Line 148: How many women entered the model?*

We have included the following sentence on page 8 line 176: “Our models used a theoretical cohort of 2,500,000 for the delayed postpartum and vaginal postplacental models, and 1,250,000 women for the Cesarean model.”

*How many cycles did you run?*

For the probabilistic sensitivity analysis, we ran 10,000 cycles, as noted on page 9, line 185.

11. *Line 150: this is the first I have seen postplacental after cesarean and postplacental after vaginal delivery. This needs further explanation about the details and the differences. If you were running two separate models based on vaginal or cesarean delivery that should be stated in the introduction.*

Thank you for this point. We have revised the last sentence of the introduction, page 5, line 114 as follows, “We compared the one-year probabilities of pregnancy after intended postplacental IUD insertion after vaginal or Cesarean delivery with intended delayed postpartum insertion, incorporating factors that influence successful device placement and retention.”

In addition, on page 8, line 163, the following sentence was added, “We constructed three decision trees as maps of the possible outcomes after 1) intended postplacental IUD placement after vaginal delivery, 2) intended postplacental IUD placement after Cesarean delivery, and 3) intended delayed postpartum IUD placement.”

12. *Line 153: Explain deterministic sensitivity analysis.*

As requested by reviewer 1, we have included the following sentence on page 8 line 180: “Deterministic sensitivity assesses how changes in the model inputs affect model outputs, varying a single parameter at a time across its range.”

## **RESULTS:**

13. *Lines 200 - 202: These results are important but can you put it in more clear clinical language? Your model predicted X number of women would become pregnant - rather than use the word effectiveness?*

We have revised this paragraph to focus primarily on the modeled percentages of women expected to become pregnant at one year.

Page 10, line 225: “Based on these values, our decision model predicts that among a theoretical cohort of 2,500,000 women intending to receive a postplacental IUD following vaginal delivery,

1,250,000 women intending a postplacental IUD after Cesarean delivery, and 2,500,000 women intending a delayed postpartum IUD, 17.3%, 11.2%, and 24.6%, respectively, would become pregnant by one year after delivery (Table 2)."

14. *Line 208: Please clarify how these numbers compare to effectiveness?*

The details and numbers in this section have been removed to adhere to word count requirements.

#### DISCUSSION:

15. *Line 251: Please be more cautious about presenting the results. The pregnancy rates between immediate and delayed IUD insertion, after accounting for everything else really wasn't that much lower. This is in keeping with the literature and should be clearly stated. What does this paper add to the primary research literature? The conclusion is still the same that it's individual risk/benefit.*

Thank you for this important comment. We added the following sentence to the first paragraph of the discussion:

"Given that effectiveness is only one of many important qualities of a contraceptive method, these results should be interpreted in the larger clinical context in which postpartum contraception counseling occurs."

16. *Line 268: Compared with what? 88/1000 compared to what?*

This prior paper by Washington et al found that postplacental IUD placement resulted in prevention of 88/1000 additional pregnancies at 2 years as compared to delayed postpartum IUD placement. We have revised this section of the discussion to describe the 1-year pregnancy rates, which is a more relevant comparison to our study. In addition, we have highlighted one significant difference in assumptions between the prior study and ours: the prior study assumed that all women who intended a postplacental IUD actually received one. However, many women intending a postplacental IUD are ultimately ineligible due to complications of pregnancy: our study used a base case estimate of 70% of women desiring a postplacental IUD to actually receive one.

17. *Line 312: This seems like the most important new information from your paper but unfortunately it's buried in the discussion*

Thank you for this comment. We have brought this information into the second paragraph of the discussion section.

#### TABLES AND FIGURES

19. *Table 1: Why did you use only one base case value instead of a range? A range would be much more informative for this complicated topic. The base literature are so varied from many different types of populations. Yet the base cases are all taken from just a small numbers of papers.*

The base case was used in the primary analysis; ranges were used in the sensitivity analyses in order to incorporate the important variations in estimates that the reviewer brings up.

20. *The tables should stand alone,. Table 2 needs a more descriptive title and footnotes. The title and legend for Table 2 have been revised to be more descriptive.*

Title: Summary of one-year IUD effectiveness estimates in three modeled scenarios: 1) the primary decision model, 2) a scenario in which all women return for postpartum follow-up, and 3) a scenario in which all women receive their intended IUD.

Table 2 legend: The base case scenario, or Scenario 1, uses the primary decision model estimates derived from the literature to provide estimates of IUD effectiveness after intended postplacental

placement after vaginal delivery, intended postplacental placement after Cesarean delivery, and intended delayed postpartum placement. Scenario 2 models a theoretical setting in which all women would present for postpartum follow-up; here, we set the percentage of women returning for postpartum follow-up to 100%. This allows for practice-level assessment of benefit of a postplacental IUD program. Scenario 3 models a theoretical setting in which all women would receive their intended IUD; here, we set the percent of women who return for follow-up and the percent of women who receive their intended IUD at 100%. This allows for individual-level assessment of the benefit of a postplacental IUD.

*Reviewer #3:*

*This well-written manuscript reports on an evidence-based decision model comparing the one-year probability of pregnancy following intended post-placental versus intended delayed postpartum(PP) IUD placement. The authors did a broad search of published studies and reports on IUD usage and subsequent outcomes for both immediate, post-placental use, and more traditional use at the PP visit. Utilizing appropriate decision analysis methodology, they were able to show that the probability of unintended pregnancy remained higher with delayed PP placement, versus post-placental placement.*

*The authors utilized a number of clinical studies and clinical models to create their decision model.*

*The references are recognized as significant studies and modeling. They also utilized economic models of decision analysis and incorporated these studies in their model.*

*Several questions should be addressed by the authors in regards to this manuscript:*

*1. In Table 1, the authors cite a base case % of post-placental IUD placement of 70%. Please clarify the source of this estimate*

Thank you for this important question. Our base case value of 70% is derived from the study by Jatlaoui et al (2014) as referenced. In that study, 177 women were enrolled in a prospective cohort study of postplacental IUD insertion after vaginal delivery, and 35 were excluded due to Cesarean delivery. Of the 142 eligible women, 99 had an IUD placed. 43 women did not have an IUD placed for a variety of reasons including withdrawal of consent, infection, precipitous delivery, and hemorrhage.

*2. There are fairly broad estimates of the return rate for traditional post-partum appointments, and possible IUD placement at that time. These estimates often reflect the patient population studied. The authors used 81.6% return rate with a range of 65-90%. Reference #6, which is an economic comparison of immediate versus delayed IUD placement, uses a return rate of 81%, which includes all patients, not just those who did not receive immediate IUD placement. The authors may wish to compare/contrast these rates.*

Our base case value for returning to a postpartum appointment is derived from Chen et al 2017. Chen et al 2017's return rate is from a population of a cohort of postpartum patients in a U.S. health system, not just those who did not receive postpartum IUD placement. Thus, our estimate of return for a postpartum visit is from a population that may be similar to that of the Washington et al's paper, but possibly more relevant as it is a more recent cohort. That being said, we agree with the reviewer that an additional compare/contrast with our paper and the Washington et al paper is warranted, and we have added the following language into the discussion, page 13, line 291:

“Our study is similar to a 2015 cost-effectiveness study in which postplacental and delayed IUD placement resulted in 27/1000 and 78/1000 unintended pregnancies at one year, respectively. However, we incorporated additional nodes in our decision tree, including the proportion of women who did not receive an intended postplacental IUD. We also provided data regarding differential effectiveness of a postplacental IUD placed after Cesarean versus vaginal delivery.”

3. *The authors correctly note that expulsion rates are quite higher with post-placental IUD placement. The authors may wish to address methods to reduce this rate, and further support use of post-placental IUD placement.*

We appreciate the reviewer’s clinical concern regarding interventions to decrease expulsion rates for postplacental IUDs. However, to our knowledge, no clinical intervention has been shown to result in a decrease in postplacental IUD expulsion rates. Follow-up and ultrasound evaluation is likely warranted for women who receive a postplacental IUD, but this is beyond the scope of our manuscript.

*Reviewer #4:*

*This study is a very interesting first step in evaluating the true effectiveness of post-placental IUD placement versus intended interval placement. Prior studies have shown both a higher expulsion rate with post-placental placement as well as a higher probability of certain groups of women not returning for their post-partum IUD placement. However, there is not much data on what these two competing factors mean in practice. This study used a statistical decision model to predict the probability based on influencing criteria they identified and utilizing data available from prior studies. While this provides some very useful information, it does remain a statistical prediction model. As pointed out by the authors, ultimately an RTC should be undertaken to further evaluate this question.*

*Introduction:*

1) *Overall, the introduction does a good job of setting up why this is an important question to answer.*

Thank you for this comment.

2) *Consider adding a comment the lack of insurance payment for post-partum LARC in many locations and the impact this may have on placement in patients particularly at risk for not following up at 6 weeks postpartum. This is where the much of the literature supporting immediate post-partum LARC is focused and a brief mention would be worthwhile.*

Thank you for this suggestion. We added reference to insurance reimbursement for postpartum long-acting reversible contraception on page 15, line 324: “Health systems should work to improve access to postplacental IUDs, which is often limited by lack of infrastructure and insurance reimbursement for immediate postpartum LARC”, and included a reference to the Hofler et al paper, Implementing immediate postpartum LARC programs. *Obstet Gynecol* 2017 (129; 3-9) .

3) *Lines 100-102: It would be beneficial to include expulsion rates in this section rather than waiting until later in the paper.*

*We have include expulsion rates and their references in the Introduction as follows:*

Page 5, line 102: “Although postplacental IUD placement ensures that women leave the hospital with contraception, this timing of placement results in higher proportion of expulsion, with rates ranging from 5.8-24%, as compared to expulsion rates of 2.9-3.5% with interval IUDs.

4) *Line 105: Recommend including the numeric range in which women attend a postpartum visit rather than stating it is variable.*

We have included the proportion from the literature of the proportion of women who attend postpartum follow up as follows:

Page 5, line 107: “However, the proportion of women who attend a postpartum visit ranges from 65-90%; of women intending IUD placement at this visit, the proportion who have an IUD placed varies from 22.6-100%.”

5) *It is important to note that this study looked at one-year probabilities. The logical, and important, next step would be the looking at the actual rates within these groups.*

Thank you for this comment. We agree that a prospective study is necessary to answer this question.

#### *Materials and Methods:*

1) *What was the reasoning behind choosing a 1-year probability vs a 2-year probability, given that the WHO recommends a 2-year pregnancy interval as noted in the introduction. As this is a prediction model not an RTC it seems that this would have been a possible alternative. The decision for 1 year should be discussed.*

Although we considered choosing 2-year probability of pregnancy given the birth spacing recommendations by WHO, we chose a 1-year probability for two reasons: 1) to provide comparative effectiveness values to established and well-known estimates of contraceptive efficacy, and 2) because the included studies in our review provided data to one year or less.

We added the following into the Materials and Methods

Page 6, Line 126: “we chose a one-year endpoint so that our effectiveness estimates could be compared with established one-year estimates of contraceptive efficacy”

2) *Line 114-115: Why was the "intent to receive" versus "actually received" utilized to define the 2 groups. As some women who intend to receive an immediate post-placental IUD cannot due to unforeseen circumstances such as Triple I or hemorrhage, this would presumably increase the close interval pregnancy rate in this group. Mentioning the reasoning behind this choice would be beneficial.*

Thank you for this comment. We have now included an explanation of our reasoning on page 6 line 123: “We chose to compare intended IUD placement rather than actual IUD placement to model the common clinical and life circumstances in both groups that limit access to IUDs.”

3) *Line 121: It would be beneficial to explain the reasoning for including next contraceptive use (and its efficacy etc.) after IUD discontinuation as a variable for IUD effectiveness.*

Thank you for this important question. Prior conceptualizations of 1-year effectiveness assume a 1-year continuation, but many women discontinue their chosen method. In the case of postplacental IUDs, the high expulsion rates often necessitate contraceptive switching. Thus, in our conceptualization of effectiveness, we wanted to include all potential factors that would affect IUD effectiveness, including switching.

We have included the following sentence on page 6, line 135: “We included estimates of contraceptive discontinuation and switching into our effectiveness model in order to simulate the common experiences of women who have IUD expulsion or choose to discontinue a method, to provide a realistic estimate of pregnancy probability.”

4) *Lines 121-126: Was there consideration of including intrapartum events (i.e. hemorrhage, triple I) as variables affecting placement and therefore efficacy?*



Thank you for this question. Although we did not include these clinical variables, we did include the probability that an intended postplacental IUD would be placed (70%), based on the study by Jatlaoui et al (2014). In that study, 177 women were enrolled in a prospective cohort study of postplacental IUD insertion after vaginal delivery, and 35 were excluded due to Cesarean delivery. Of the 142 eligible women, 99 had an IUD placed. 43 women did not have an IUD placed for a variety of reasons including withdrawal of consent, infection, precipitous delivery, and hemorrhage. We have included language on page 6, line 138 to describe this reasoning.

5) *Line 184-185: What was the estimated probability of IUD placement at the postpartum visit. This should be included in the text, if not here than in the intro.*

Thank you for this suggestion. We included the following text in the Introduction, page 5 line 109-110: “of those women who attend a postpartum visit, the proportion who have an IUD placed varies in the literature from 22.6-100%<sup>13,28,29</sup>”

### *Results*

1) *Lines 240-243: These numbers do not match the table referenced. 96.1% is the number scenario #3 for delayed PP IUDs per the table so should be listed first. Per the table, 89% is scenario #2 for the delayed PP IUD. Neither is the number for post-placental IUD placement. Sorry for the confusion in the construction of this sentence. The numbers are correct as written but the sentence structure was confusing. We have revised the paragraph for clarity to read as follows:*

In the scenario in which all women were assumed to return to clinic for their 6-week follow up visit (Scenario 2), and in the scenario in which all women received their intended IUD (Scenario 3), one-year effectiveness rates for delayed postpartum IUDs were 89.0% and 96.1%, respectively (Table 2), and were higher than the one-year effectiveness rates for postplacental IUD placement.

### *Discussion:*

*Very good discussion and excellent final points. The discussion helps highlight the importance of this study and its context. Some of the information could be introduced sooner the highlight the "so what" factor, but otherwise very well done.*

Thank you for this comment. As per the comments of another reviewer, we have moved some of the pertinent information higher in the discussion.

### *Reviewer #5:*

*This is an interesting analysis and the decision tree and its assumptions are explained. It is of note that it appears the biggest potential source of variability is whether the patient returns to clinic, rather than events/probabilities after that decision point. If the probability of returning were sufficiently differential for vaginal or cesarean deliveries, then apparently the simulations of Fig 3 could be quite different. That aspect might be explored further as a sensitivity analysis. That is, not as individual probabilities, but as a ratio of probabilities.*

The reviewer brings up an interesting point. There are data that women who undergo Cesarean delivery are more likely to return for postpartum follow-up (point estimate of return for follow-up 72%) as compared to women who have a vaginal delivery (point estimate of return to follow up of 65%; Wilcox et al. 2016) However, across the range of estimates used in our model for the proportion of women who return for follow-up (65-90%), postplacental placement (either after vaginal or Cesarean delivery) results in a higher effectiveness estimate than delayed IUD placement, as shown in Figure 2. The sensitivity analyses presented in our manuscript incorporate the ranges. If we were to use different base case values for proportion of women who attend postpartum follow-up for vaginal and Cesarean deliveries, it is possible that the two distributions

in Figure 3 (vaginal and Cesarean delivery distributions) would be closer to each other, but there would not be a significant change in the overall result. In fact, with our current base case value of 81.6% return for follow-up, our analyses are conservative. Thus we respectfully request to maintain the current sensitivity analyses in our manuscript.

EDITOR'S NOTE:

*It is common for cost effectiveness trials to make a statement something like "in 84% of 10,000 Monte Carlo simulations we found such and such" in the both the abstract and results section. Please edit for something similar w /your data.*

We have edited the results in the abstract to state:

One-year probabilities of pregnancy among a theoretical cohort of 2,500,000 women intending to receive a postplacental IUD following vaginal delivery and 1,250,000 women intending to receive a postplacental IUD following Cesarean delivery are 17.3% and 11.2% respectively; the one-year probability of pregnancy among a theoretical cohort of 2,500,000 women intending to receive a delayed postpartum IUD is 24.6%.

*Also, as I understand it, the primary node that determines whether post placental or post partum visit placement is cost effective is related to whether a woman returns for her pp visit, this point deserves some further discussion. It looks like there is a difference on this point by whether a woman delivers vaginally or by cesarean and if there is a differential in return rates for women w/ these two delivery routes, that could alter your results. At the end of the day, it doesn't seem like it would make a difference to the clinician if its cost effective w/ vaginal but not cesarean (or vice versa) because for the individual woman, the issue is whether to put it in after placental delivery or not. Could you explore this? some in your discussion?*

We have included a discussion of this topic as brought up by Reviewer 5 on page 15 line 342 as follows:

"We did not include in our analyses differential published estimates for proportion of women who attend postpartum follow-up after vaginal versus Cesarean delivery<sup>30</sup>. However, our sensitivity analyses incorporate these estimates, and postplacental placement (either after vaginal or Cesarean delivery) resulted in a higher effectiveness than delayed IUD placement across the range of estimates for the proportion of women who return for follow-up (65-90%)."

EDITOR COMMENTS:

*1. Thank you for your submission to Obstetrics & Gynecology. The reviewer comments should be included in your point-by-point response cover letter.*

*2. 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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*to author queries.*

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

We opt in to publishing the response letter and subsequent email correspondence.

*3. Each author on this manuscript must submit a completed copy of our revised author agreement form (updated in the August 2014 issue). Please have Dr. McAllister submit a form.*

Ms. McAllister's form is now included

*Please note:*

*a) Any material included in your submission that is not original or that you are not able to transfer copyright for must be listed under I.B on the first page of the author agreement form.*

*b) All authors must disclose any financial involvement that could represent potential conflicts of interest in an attachment to the author agreement form.*

*c) All authors must indicate their contributions to the submission by checking the applicable boxes on the author agreement form.*

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*4. Based on the forms that have been submitted, Dr. Schreiber has not met the criteria for authorship. Dr. Schreiber should resubmit a revised author agreement form because they filled it out erroneously the first time. Please check the 'yes' or 'no' box in the disclosure section.*

Dr. Schreiber's revised author agreement is included in the submission.

*5. 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.*

This statement has been included in the cover letter.

*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 will be transitioning as much as possible to use of the reVITALize definitions, and we encourage authors to familiarize themselves with them. The obstetric data definitions are available at <http://links.lww.com/AOG/A515>, and the gynecology data definitions are available at <http://links.lww.com/AOG/A935>.*

We have adhered to these definitions in this draft.

*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 appendixes).*

The manuscript is 22 pages and 5498 words.

*Please limit your Introduction to 250 words and your Discussion to 750 words.*

The Introduction has 246 words. The Discussion has 727 words.

*8. Specific rules govern the use of acknowledgments in the journal. Please edit your acknowledgments or provide more information in accordance with 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 signature on the journal's author agreement 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).*

This information is included in the acknowledgements.

*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 limits for different article types are as follows: Original Research articles, 300 words; Reviews, 300 words; Case Reports, 125 words; Current Commentary articles, 250 words; Clinical Practice and Quality, 300 words; Procedures and Instruments, 200 words. Please provide a word count.*  
The abstract has 279 words.

*10. Only standard abbreviations and acronyms are allowed. A selected list is available online at <http://edmgr.ovid.com/ong/accounts/abbreviations.pdf>. Abbreviations and acronyms cannot be used in the title or précis. Abbreviations and acronyms must be spelled out the first time they are used in the abstract and again in the body of the manuscript.*  
We have adhered to the abbreviation guidelines.

*11. The journal does not use the virgule symbol (/) in sentences with words. Please rephrase your text to avoid using "and/or," or similar constructions throughout the text. You may retain this symbol if you are using it to express data or a measurement.*  
We have removed "and/or" from our revision.

*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](http://edmgr.ovid.com/ong/accounts/table_checklist.pdf).*

*We have reviewed the checklist.*

*13. Please revise your figures:*

*Figure 1: Please update Figure 1A and 1B to Figures 1 and 2 due to space considerations.*

*We have updated these figures.*

*Figure 2: Please update to Figure 3. Figure is okay*

*Figure 3: Please update to Figure 4. Figure is okay*

*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.*

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**From:** [REDACTED]  
**To:** [Stephanie Casway](#)  
**Cc:** [REDACTED]  
**Subject:** Re: O&G Figure Revision: 18-1137  
**Date:** Monday, August 13, 2018 5:33:04 PM

---

Stephanie,

There are still some changes to be made.

Figure 2 was missing nodes following “Continuation”, which we added into the figure we sent to you today. These additional nodes were labeled “correctly positioned” and “partial expulsion.”

In Figure 3, we added units (%) to the figure legend on the y-axis.

Liz and Tegan please chime in if there is anything else you noticed.

Sarita

Sent from my iPad

On Aug 13, 2018, at 2:19 PM, Stephanie Casway <[SCasway@greenjournal.org](mailto:SCasway@greenjournal.org)> wrote:

Good Afternoon Sarita,

Thank you so much for your review. Attached you will find updated PDFs of Figures 1, 2, and 4, as well as the legend. Note that we added symbols to Figures 1 and 2 and added the gray bar at 0 for Figure 4. I did not see any changes to Figure 3; however, please let me know if I am missing something. The legend has been updated as well.

Please let me know if these edits are okay, or if any more are needed. Thank you so much for your help!

**From:** [REDACTED]  
**Sent:** Monday, August 13, 2018 1:20 PM  
**To:** Stephanie Casway <[SCasway@greenjournal.org](mailto:SCasway@greenjournal.org)>  
**Cc:** [REDACTED]  
**Subject:** Re: O&G Figure Revision: 18-1137

Hi Stephanie,

Please find attached updated figure legends and figures (figures both as pdf and powerpoint). Please check to see if the formatting has come through properly - we had some differences among the co-authors as to whether the powerpoint figures had all the elements formatted correctly.

Thank you!

Sarita

On Tue, Aug 7, 2018 at 9:09 PM Stephanie Casway <[SCasway@greenjournal.org](mailto:SCasway@greenjournal.org)>

wrote:

Good Afternoon Dr. Sonalkar,

Your figures and legend have been edited, and PDFs of the figures and legend are attached for your review. Please review the figures CAREFULLY for any mistakes.

PLEASE NOTE: Any changes to the figures must be made now. Changes 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 be grateful to receive a reply no later than Thursday, 8/9. Thank you for your help.

Best wishes,

Stephanie Casway, MA  
Production Editor  
*Obstetrics & Gynecology*  
American College of Obstetricians and Gynecologists  
409 12th St, SW  
Washington, DC 20024  
Ph: (202) 314-2339  
Fax: (202) 479-0830  
[scasway@greenjournal.org](mailto:scasway@greenjournal.org)

<18-1137 Legend.pdf>

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<18-1137 Fig 2 (8-13-18 v2).pdf>

<18-1137 Fig 4 (8-13-18 v2).pdf>