

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.*

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: Aug 23, 2018
To: "Elizabeth G. Clement" [REDACTED]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-18-1233

RE: Manuscript Number ONG-18-1233

The Language of First Trimester Nonviable Pregnancy: Patient Reported Preferences and Clarity

Dear Dr. Clement:

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 Sep 13, 2018, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1: Thank you for the opportunity to review the manuscript for this work. Language does, indeed, matter and can be vastly more important when pregnancy outcome isn't as expected, hoped or intended.

TITLE

Short Title

Line 17: Change to "The Language of First Trimester Pregnancy Demise"

PRECIS

ABSTRACT

line 24: omit comma

line 25: omit "the" before patient experience and "that" before patients hear

line 26: omit comma

line 27: replace "clinician communication" with "patient-clinician communication"

line 29: the original trial was randomized. Please add.

line 30: gestational age (GA) limits? It is important to define here what GA you classified as "early" for the trial. It is unclear if a patient with an IUFD at 17, 22, 30 weeks would also prefer "early pregnancy loss".

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line 37: on first read, the term "clarity" was not all that clear (pun sort of intended). Perhaps, adjusting the objectives to reflect you asked about patients linear understanding of each the terms would make use of "clarity" here more impactful. (in case the reader reads nothing but the abstract, you define/describe in the manuscript well)

line 43: same comment about GA. "in this diverse cohort of women with nonviable pregnancy in the first trimester, most preferred the term miscarriage...."

TEXT

Intro

line 52: omit comma

line 55: please add citation for the PB #150

line 56: omit "many"

line 60: replace "clinician-patient" with the more patient-centered "patient-clinician"

line 61: change to "with the language of first trimester pregnancy demise"

M&M

overall comment: Too much use of passive voice. Ex. "was constructed, was approved, were asked" instead of "we constructed, IRB approved, we asked". Please revise this section to active voice.

line 69: change "terminology" to "language" to be consistent

Comment: The original trial randomized 300 women. How did you decide which 155 to approach for this survey?

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Comment, line 74: the choice of a VAS to quantify a term promoting patient comprehension is interesting here. Are there published data suggesting comprehension of medical diagnoses is linear? In publications of research using VAS, it is imperative to include the anchors of the VAS in the manuscript. Were the anchors used in this study (patient-facing) really "least clear" to "most clear"? How were the anchors chosen? If based on other published literature, please cite. If not based on published literature, include rationale for choice of anchors in the manuscript as your conclusions for half of this submission rest, really, on these anchors.

Results

Overall comment: Too much use of passive voice again (see above comment). Please revise this section to active voice.

line 87: change "identified" to "self-identified" if participants self-reported ethnicity

line 92: omit comma.

line 95: you also, presumably, excluded the two participants that selected "none of the above" as their preferred term. Please include in this sentence/section of you did, in fact, exclude these participants as well.

Comment: Two participants selected "None of the above" terms as their preference. Did they offer alternative language/definition?

Comment, line 97: you don't present the mean/median and SD clarity score on the 100 mm VAS by term (just the aRR in figure 1b). It's important to include these data, esp if this study would be the first to examine this outcome in the ob/gyn literature.

Line 102: you did not submit a "Table 2". Did you mean Figure 1b?

Discussion

Line 111: replace "early" with "first trimester"

Comment, paragraph 2: again, GA is an important note here. You present no data that suggest these findings would be generalizable outside the first trimester. Granted, most pregnancy loss occurs in the first trimester.

Line 150: change to "are acceptable in the first trimester".

Line 154: change "providers" to "clinicians" to be consistent

Table 1

Comment: What is "other" level of education?

Reviewer #3: The authors present survey results of an assessment to identify patient-desired terms for nonviable pregnancy in the first trimester. The data are derived from a recent RCT of treatments for this condition. This is important

information for women's health providers because it is a common condition and there is no consensus on preferred language from those who experience the condition. This subject matter is of interest to the journal's readers. The condensed writing is greatly appreciated and could be further improved in the discussion section.

The following comments are intended to assist in more clearly communicating the results.

In the abstract addressing the following will improve consistency.

- 1) Line 26-27 - "terms that patients hear during the treatment course..." stated first in the objectives and last in the results. Keep the order the same in the abstract and the main body of the paper. Same sequence throughout, please.
- 2) Line 29 - how were the survey questions provided? (electronically?) And at what time point in the course of the study?
- 3) Line 40 "having heard all 4 terms..." what are the 4 terms? To this point, there are just 2.
- 4) Line 43 - This is a "diverse" cohort but in the abstract you have not provided any information about that other than they came from 3 states. Consider deleting the term or clarifying in the results by providing demographic information on the cohort.

The background is brief and to the point.

- 5) One addition to consider is a statement about how common miscarriage is, supporting the need to pursue clarity on this topic.

Methods

- 6) There is no explanation how you got from the 300 participants in original RCT to 155.
- 7) Line 70 - There wasn't a separate consent for this survey was there? Please clarify.
- 8) Line 72 - what was the language requesting "the most preferred term?"
- 9) Line 73-74 - What were the anchors on the 100-point VAS? If it was "least clear" and "most clear" than please use quotations.
- 10) Was there an open-ended question about other terms participants may have heard?
- 11) What was the specific goal of the regression model? Please state this clearly.
The results are clearly presented.
- 12) The Discussion section is the longest section (at least twice as long as any other section). This could be half the length and not sacrifice any points.
- 13) Table 1 - why not use the same terms to clarify prior miscarriage "no vs. yes" and prior induced abortion "0 vs. 1"?

Reviewer #4: This paper purports to "improve communication" and to allow health care practitioners "to provide patient-centered pregnancy care" by using the terms "miscarriage" or "early pregnancy loss" instead of "spontaneous abortion" or "early pregnancy failure". The study group is small, comprising only 145 women across three geographic locations, and results rely on a six-item survey. These patients were asked what term they prefer when discussing their loss of a first-trimester nonviable pregnancy. Predictably, "spontaneous abortion" is not preferred by many, likely because it contains a word that religious groups and conservative politicians have co-opted and transformed into something profane. It is not at all surprising that a woman does not want to say that she had an abortion right after she suffers a spontaneous pregnancy loss. Further, "abortion" is, indeed, a medical-ese term, and most non-medical people tend to use common language rather than medical terminology when faced with a choice.

The authors go on to find that these women also prefer "miscarriage" or "early pregnancy loss" to "early pregnancy failure". Again, this is hardly surprising, since most people do not wish to associate themselves with "failure"; it is a pejorative term. Interestingly, the authors did find that the distribution of nomenclature preference varied significantly by ethnicity, study site, and prior history of induced abortion. For example, women who had had one prior induced abortion were only 1/3 as likely to prefer "miscarriage" as women who had never had an induced abortion. Also, as is pointed out in the Discussion, there was no standardization among patients as to what terms they heard most often, or what terminology was used primarily by their treating practitioner(s). It is certainly feasible that a woman who heard "miscarriage" multiple times, while only hearing other terms once or twice, may record on a survey that she prefers the term "miscarriage". In fact, the authors write that "Spontaneous abortion was the least commonly heard term".

While the authors may have made some valid observations in this study, the implication that the preferential use of two certain terms (instead of two otherwise correct terms) denotes compassion or better "patient-centered pregnancy care" is

arguably presumptuous and judgmental, and not statistically verifiable.

Reviewer #5: Multisite survey of women (a sub study) participating in a comparative effectiveness trial of medical management of early pregnancy loss (RCT published in NEJM 2018)) Survey asking women about the preferred phrases used when discussing their early pregnancy loss 93% return of a 6 question survey.

Miscarriage, early pregnancy loss, spontaneous abortion, early pregnancy failure were the four phrases surveyed
Simple in concept and scope and patient centered/ Demographics: NY, Pennsylvania and California (both coasts) certainly not representative of the south or midwest
Nicely written, reads well

STATISTICAL EDITOR COMMENTS:

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

lines 67-68: How was the study "piloted for external validity"? It seems that the only groups evaluated were those cited, not to any external reference group.

lines 43-45, Table 1: Although the response rate is excellent, the groups are from 3 sites. How does the racial/ethnic, education level and other characteristics make this cohort representative generally of women who experienced a miscarriage and therefore representative of all such women's preference for terminology?

lines 97-102: I do not have a Table 2 in my copy, but there is figure 1a and 1b. What were the response rates to the VAS score for clarity?

The Table should include the unadjusted RRs to contrast with the aRRs. I assume that the response counts justify adjustment for 5 covariates, but should justify if needed.

EDITOR COMMENTS:

1. Thank you for your submission to Obstetrics & Gynecology. In addition to the comments from the reviewers above, you are being sent a notated PDF that contains the Editor's specific comments. Please review and consider the comments in this file prior to submitting your revised manuscript. These comments should be included in your point-by-point response cover letter.

The notated PDF is uploaded to this submission's record in Editorial Manager. If you cannot locate the file, contact Randi Zung and she will send it by email - rzung@greenjournal.org.

- The objective for the abstract should be a simple "to" statement without background.

- What "all 4 terms"? You've only provided 2 so far.

- preferred it to what?

- please reference the reVITALize GYN terminology as well. These are the accepted terminology and definitions for ACOG, many other organizations that participated in the reVITALize project and for the Green Journal

- I'm not certain that I understand this. You say that the terminology transitioned in the 1980's but not give evidence of this transition til 2015. Did anything occur between 1980 and 2015 that suggested a transition in terminology? Do patients know that the terminology has changed AND experience continued use of the disbanded terminology: If not, why is it surprising that they are dissatisfied?

- There is not a lack of official consensus about this. There may be a lack of uptake of the reVITALize terminology.

- Although I think the reviewer who was concerned about "patient centered care" may have missed the mark a bit, the way you have framed this "clinician-patient communication" is a good alternative to the. patient centered care terminology if you choose to make that difference.

- was this a preplanned study or not?

- validity testing requires further fleshing out.
- Other than language, what were criteria for offering a participant a survey? Were all English language speakers offered participation? If not, why not?
- for both the primary and this embedded study?
- how were these 4 terms chosen?
- you haven't mentioned the method for defining "preferred term"
- For data presented in the text, please provide the raw numbers as well as data such as percentages, effect size (OR, RR, etc) as appropriate and 95% CI's.
- 30.3 years....
- how was intendedness of pregnancy determined? Was that information from the primary study? Please in the methods be clear about sources of data that you used that were from the primary study.
- so is clarity that only criterium for acceptability?

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. Please submit Author Agreement Forms for the following authors:

Sarah Horvath, MD
 Arden McAllister, MPH
 Nathanael C. Koelper, MPH
 Mary Sammel, PhD
 Courtney A. Schreiber, MD, MPH

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

4. In order for an administrative database study to be considered for publication in Obstetrics & Gynecology, the database used must be shown to be reliable and validated. In your response, please tell us who entered the data and how the accuracy of the database was validated. This same information should be included in the Materials and Methods section of the manuscript.

5. All submissions that are considered for potential publication are run through CrossCheck for originality. We believe part of this submission may have been presented at a meeting. Would you please include the meeting presentation on your title page?

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 appendixes).

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. 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 express outcome data as both absolute and relative effects since information presented this way is much more useful for clinicians. In both the Abstract and the Results section of the manuscript, please give actual numbers and percentages in addition to odds ratios (OR) or relative risk (RR). If appropriate, please include number needed to treat for benefits (NNTb) or harm (NNTh). When comparing two procedures, please express the outcome of the comparison in dollar amounts.

13. Please review the journal's Table Checklist to make sure that your tables conform to journal style. The Table Checklist is available online here: http://edmgr.ovid.com/ong/accounts/table_checklist.pdf.

14. The American College of Obstetricians and Gynecologists' (College) documents are frequently updated. These documents may be withdrawn and replaced with newer, revised versions. If you cite College documents in your manuscript, be sure the reference you are citing is still current and available. If the reference you are citing has been updated (ie, replaced by a newer version), please ensure that the new version supports whatever statement you are making in your manuscript and then update your reference list accordingly. If the reference you are citing has been withdrawn with no clear replacement, please contact the editorial office for assistance (obgyn@greenjournal.org). In most

cases, if a College document has been withdrawn, it should not be referenced in your manuscript (exceptions could include manuscripts that address items of historical interest). All College documents (eg, Committee Opinions and Practice Bulletins) may be found via the Resources and Publications page at <http://www.acog.org/Resources-And-Publications>.

15. Figure 1: Are these figures available at a higher resolution?

16. 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 Sep 13, 2018, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,
Nancy C. Chescheir, MD
Editor-in-Chief

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.

September 18, 2018

To the Editorial Office:

Please find attached our Original Article submission entitled, *The Language of First Trimester Nonviable Pregnancy: Patient Reported Preferences and Clarity*. In this manuscript, we present cross-sectional data gathered within a randomized trial of medical management of early pregnancy loss.

We make this submission solely to *Obstetrics & Gynecology*; the manuscript is not under consideration elsewhere and will not be submitted elsewhere while it is under your review. All authors have made substantial contributions to the analysis and interpretation of data as well as to manuscript revision and have approved the final manuscript. As lead author, I affirm that this manuscript is an honest, accurate, and transparent account of the study being reported and no important aspects of the study have been omitted; and that any discrepancies from the study as planned have been explained. This study was approved by the Institutional Review Boards of all three sites.

Thank you for considering our manuscript for publication in *Obstetrics & Gynecology*. We appreciate the reviewers' and editors' comments; we have addressed these comments point by point below.

Sincerely on behalf of all authors,

Elizabeth G. Clement, MD

A large black rectangular redaction box covering the signature and any handwritten notes or contact information that might have been present.

REVIEWER COMMENTS:

Reviewer #1: Thank you for the opportunity to review the manuscript for this work. Language does, indeed, matter and can be vastly more important when pregnancy outcome isn't as expected, hoped or intended.

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Response: Thank you, revised as suggested.

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line 30: gestational age (GA) limits? It is important to define here what GA you classified as "early" for the trial. It is unclear if a patient with an IUFD at 17, 22, 30 weeks would also prefer "early pregnancy loss".

Response: Thank you, the definition has been added to the revised manuscript.

lines 31-2: omit "computed and" I'm not sure "computed" adds value (needless words).

Response: Thank you, revised as suggested.

lines 34-35: what is your "response" rate? results should include the 155 you approached (in addition to the 145 that completed the survey). again, participants' GA is pertinent to results for generalizability.

Response: Thank you, revised as suggested

line 37: on first read, the term "clarity" was not all that clear (pun sort of intended). Perhaps,

adjusting the objectives to reflect you asked about patients linear understanding of each the terms would make use of "clarity" here more impactful. (in case the reader reads nothing but the abstract, you define/describe in the manuscript well)

Response: Thank you, revised as suggested in the abstract and objectives sections.

line 43: same comment about GA. "in this diverse cohort of women with nonviable pregnancy in the first trimester, most preferred the term miscarriage...."

Response: Thank you, revised as suggested.

TEXT

Intro

line 52: omit comma

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line 55: please add citation for the PB #150

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line 56: omit "many"

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overall comment: Too much use of passive voice. Ex. "was constructed, was approved, were asked" instead of "we constructed, IRB approved, we asked". Please revise this section to active voice.

Response: Thank you, revised as suggested.

line 69: change "terminology" to "language" to be consistent

Response: Thank you, revised as suggested.

Comment: The original trial randomized 300 women. How did you decide which 155 to approach for this survey?

Response: The survey was developed and then implemented as a protocol modification after the larger trial had already begun enrollment. All English-speaking participants enrolling between November 2015 and May 2017 were approached for the survey. We have revised this in the text as suggested.

line 72: add comma after "single"

Response: Thank you, revised as suggested.

Comment, line 74: the choice of a VAS to quantify a term promoting patient comprehension is interesting here. Are there published data suggesting comprehension of medical diagnoses is linear? In publications of research using VAS, it is imperative to include the anchors of the VAS in the manuscript. Were the anchors used in this study (patient-facing) really "least clear" to "most clear"? How were the anchors chosen? If based on other published literature, please cite. If not based on published literature, include rationale for choice of anchors in the manuscript as your conclusions for half of this submission rest, really, on these anchors.

Response: The anchors were "least clear" and "most clear". This has been added to the abstract.

The VAS scale has been shown to be a valid scale type for assessing patient satisfaction (see citation 13). While we aim here to assess patient perceived clarity, we do not formally assess comprehension with this survey. We are asking patient perception of clarity and patient preference, which are satisfaction metrics.

A visual analog scale has potential advantages and disadvantages as compared to an ordinal likert scale. The usage of a linear visual analog scale was done with the goal to potentially discern slightly subtler distinctions than an ordinal scale. (See citations 14, 15, and 16) Potential disadvantages include potential lower survey completion rates due to increased time to complete the survey. (Citation 16) There is some thought that favoring likert scales historically may be a function of paper and pen surveys and the greater difficulty in data collection with VAS scales. (citation 14) This survey was developed on the digital platform of RedCap, facilitating ease of data collection. Funke and Rieps found that while mean ratings between VAS and a 5-point likert scale showed a small absolute difference, the VAS had an ability to detect smaller differences. (citation 15)

We have added the citations supporting the utilization of the VAS scale to the manuscript.

The data as presented in the manuscript did not use the continuous VAS measures because the distributions of these data in our sample were largely bimodal (responses clustered at the low end of the scale "least clear" and the high end "most clear"). Instead we derived a new dichotomous clarity variable for each term where the term was 0 if the VAS score was <50 and 1 when clarity score was ≥ 50mm. We have clarified this in the methods section.

Results

Overall comment: Too much use of passive voice again (see above comment). Please revise this section to active voice.

Response: Thank you, revised as suggested.

line 87: change "identified" to "self-identified" if participants self-reported ethnicity

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line 95: you also, presumably, excluded the two participants that selected "none of the above" as their preferred term. Please include in this sentence/section of you did, in fact, exclude these participants as well.

Response: Yes, they were excluded. Revised as suggested

Comment: Two participants selected "None of the above" terms as their preference. Did they offer alternative language/definition?

Response: The two participants who selected "none of the above" as their preference did not offer alternative language. This has been added to the manuscript.

Comment, line 97: you don't present the mean/median and SD clarity score on the 100 mm VAS by term (just the aRR in figure 1b). it's important to include these data, esp if this study would be the first to examine this outcome in the ob/gyn literature.

Response: Thank you. As noted above, VAS measures were dichotomized for each term to indicate clear yes/no. We present n and percent who indicated each term was clear in the manuscript and in table 2.

Line 102: you did not submit a "Table 2". Did you mean Figure 1b?

Response: Yes, revised as suggested.

Discussion

Line 111: replace "early" with "first trimester"

Response: Thank you, revised as suggested.

Comment, paragraph 2: again, GA is an important note here. You present no data that suggest these findings would be generalizable outside the first trimester. Granted, most pregnancy loss occurs in the first trimester.

Response: Thank you, we have added a reference to the population consisting of women with a pregnancy demise in the first trimester in the discussion of generalizability.

Line 150: change to "are acceptable in the first trimester".

Response: Thank you, revised as suggested.

Line 154: change "providers" to "clinicians" to be consistent

Response: Thank you, revised as suggested.

Table 1

Comment: What is "other" level of education?

Response: Thank you for noting this. On review of the data, those who noted "other" free texted in their level of education and all have now been reclassified in the appropriate predesignated category. Table 1 has been edited now that those respondents have been reclassified.

Reviewer #3: The authors present survey results of an assessment to identify patient-desired terms for nonviable pregnancy in the first trimester. The data are derived from a recent RCT of treatments for this condition. This is important information for women's health providers because it is a common condition and there is no consensus on preferred language from those who experience the condition. This subject matter is of interest to the journal's readers. The

condensed writing is greatly appreciated and could be further improved in the discussion section.

The following comments are intended to assist in more clearly communicating the results.

In the abstract addressing the following will improve consistency.

1) Line 26-27 - "terms that patients hear during the treatment course..." stated first in the objectives and last in the results. Keep the order the same in the abstract and the main body of the paper. Same sequence throughout, please.

Response: Thank you for this comment, we have revised the order for consistency throughout the manuscript.

2) Line 29 - how were the survey questions provided? (electronically?) And at what time point in the course of the study?

Response: Survey questions were completed either on paper or electronic tablet, and this took place at the baseline visit. This information has been added to the manuscript.

3) Line 40 "having heard all 4 terms..." what are the 4 terms? To this point, there are just 2.

Response: This sentence has been revised, thank you.

4) Line 43 - This is a "diverse" cohort but in the abstract you have not provided any information about that other than they came from 3 states. Consider deleting the term or clarifying in the results by providing demographic information on the cohort.

Response: Thank you, we have revised to remove the reference to "diverse".

The background is brief and to the point.

5) One addition to consider is a statement about how common miscarriage is, supporting the need to pursue clarity on this topic.

Response: Thank you. We have noted this in the first line of the introduction.

Methods

6) There is no explanation how you got from the 300 participants in original RCT to 155.

Response: We have given timelines to demonstrate that the trial began recruitment prior to the initiation of this survey, and stated that all participants enrolling during the November 2015 to May 2017 timeline were given the survey. This occurred due to the timing of survey development in relation to the trial, and this has been clarified in the text.

7) Line 70 - There wasn't a separate consent for this survey was there? Please clarify.

Response: No, this has been clarified in the manuscript.

8) Line 72 - what was the language requesting "the most preferred term?"

Response: The language has been added.

9) Line 73-74 - What were the anchors on the 100-point VAS? If it was "least clear" and "most clear" than please use quotations.

Response: These were the anchors and quotations have been added.

10) Was there an open-ended question about other terms participants may have heard?

Response: No, there was no open-ended question about other terms.

11) What was the specific goal of the regression model? Please state this clearly.

The results are clearly presented.

Response: Thank you. We have added the following language to the paper to reflect the rationale: Multivariable models were created in order to determine if terminology preferences vary depending on demographic characteristics.

12) The Discussion section is the longest section (at least twice as long as any other section). This could be half the length and not sacrifice any points.

Response: Thank you, we have edited the discussion section to improve brevity.

13) Table 1 - why not use the same terms to clarify prior miscarriage "no vs. yes" and prior induced abortion "0 vs. 1"?

Response: Thank you, revised as suggested.

Reviewer #4: This paper purports to "improve communication" and to allow health care practitioners "to provide patient-centered pregnancy care" by using the terms "miscarriage" or "early pregnancy loss" instead of "spontaneous abortion" or "early pregnancy failure". The study group is small, comprising only 145 women across three geographic locations, and results rely on a six-item survey. These patients were asked what term they prefer when discussing their loss of a first-trimester nonviable pregnancy. Predictably, "spontaneous abortion" is not preferred by many, likely because it contains a word that religious groups and conservative politicians have co-opted and transformed into something profane. It is not at all surprising that a woman does not want to say that she had an abortion right after she suffers a spontaneous pregnancy loss. Further, "abortion" is, indeed, a medical-ese term, and most non-medical people tend to use common language rather than medical terminology when faced with a choice.

The authors go on to find that these women also prefer "miscarriage" or "early pregnancy loss" to "early pregnancy failure". Again, this is hardly surprising, since most people do not wish to associate themselves with "failure"; it is a pejorative term. Interestingly, the authors did find that the distribution of nomenclature preference varied significantly by ethnicity, study site, and prior history of induced abortion. For example, women who had had one prior induced abortion were only 1/3 as likely to prefer "miscarriage" as women who had never had an induced abortion. Also, as is pointed out in the Discussion, there was no standardization among patients as to what terms they heard most often, or what terminology was used primarily by their treating practitioner(s). It is certainly feasible that a woman who heard "miscarriage" multiple times, while only hearing other terms once or twice, may record on a survey that she prefers the term

"miscarriage". In fact, the authors write that "Spontaneous abortion was the least commonly heard term".

While the authors may have made some valid observations in this study, the implication that the preferential use of two certain terms (instead of two otherwise correct terms) denotes compassion or better "patient-centered pregnancy care" is arguably presumptuous and judgmental, and not statistically verifiable.

Response: Thank you for your thoughts. We have highlighted some of the limitations of our methodology in our discussion section and think that this paper provides a first step towards understanding patient perceptions of language when receiving the diagnosis of an early pregnancy loss.

Reviewer #5: Multisite survey of women (a sub study) participating in a comparative effectiveness trial of medical management of early pregnancy loss (RCT published in NEJM 2018)) Survey asking women about the preferred phrases used when discussing their early pregnancy loss 93% return of a 6 question survey.

Miscarriage, early pregnancy loss, spontaneous abortion, early pregnancy failure were the four phrases surveyed

Simple in concept and scope and patient centered/ Demographics: NY, Pennsylvania and California (both coasts) certainly not representative of the south or midwest
Nicely written, reads well

STATISTICAL EDITOR COMMENTS:

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

lines 67-68: How was the study "piloted for external validity"? It seems that the only groups evaluated were those cited, not to any external reference group.

Response: We pretested our survey for external validity with 12 voluntary participants approached in the waiting room of a family planning clinic, half pregnant and half not pregnant, but none with a known diagnosis of an abnormal pregnancy. We then performed pilot test for internal validity within the PreFair trial on 23 participants which allowed us to make our ultimate modifications. We have added this language to our methods section.

lines 43-45, Table 1: Although the response rate is excellent, the groups are from 3 sites. How does the racial/ethnic, education level and other characteristics make this cohort representative generally of women who experienced a miscarriage and therefore representative of all such women's preference for terminology?

Response: Our respondents are from three sites in three different states and are a racially and socioeconomically diverse group. This is highlighted in our discussion section.

lines 97-102: I do not have a Table 2 in my copy, but there is figure 1a and 1b.

Table 2 references Figure 1b, this had been added to the manuscript

What were the response rates to the VAS score for clarity?

Response: our response rates for the VAS scores were the same as for our survey in general. (145/155, 93.5%).

The Table should include the unadjusted RRs to contrast with the aRRs. I assume that the response counts justify adjustment for 5 covariates, but should justify if needed.

Response: Table 2 includes response frequencies along with unadjusted and adjusted measures of association. While the sample size for this study is relatively small (n=145) we modeled clarity (yes/no) for each term in a joint model which accounted for correlation among the repeated measures within each subject. We believe that this multivariable model can support the inclusion of 5 covariates, while any one outcome modeled separately may not.

EDITOR COMMENTS:

1. Thank you for your submission to Obstetrics & Gynecology. In addition to the comments from the reviewers above, you are being sent a notated PDF that contains the Editor's specific comments. Please review and consider the comments in this file prior to submitting your revised manuscript. These comments should be included in your point-by-point response cover letter.

The notated PDF is uploaded to this submission's record in Editorial Manager. If you cannot locate the file, contact Randi Zung and she will send it by email - rzung@greenjournal.org.

- The objective for the abstract should be a simple "to" statement without background.

Response: Thank you, revised as suggested

- What "all 4 terms"? You've only provided 2 so far.

Response: Thank you, we have revised this language.

- preferred it to what?

Response: This language has been clarified.

- please reference the reVITALize GYN terminology as well. These are the accepted terminology and definitions

for ACOG, many other organizations that participated in the reVITALize project and for the Green Journal

Response: Thank you, revised as suggested.

- I'm not certain that I understand this. You say that the terminology transitioned in the 1980's but not give

evidence of this transition til 2015. Did anything occur between 1980 and 2015 that suggested a

transition in
terminology?

Response: Moscrop 2013 (citation #5) Reviewed medical literature in this time period and found that published medical literature on this topic shifted their language from spontaneous abortion to miscarriage in the 1980s. However, there is no other literature or evaluation of the usage in clinical practice. This distinction has now been clarified in the manuscript. The manuscript has been edited to reflect what can be objectively documented regarding language usage.

Do patients know that the terminology has changed AND experience continued use of the disbanded terminology: If not, why is it surprising that they are dissatisfied?

Response: I do not know if patients know that the terminology has changed, but I'm not sure that it's clear how intentional our language shifts have been. Our survey data show that patients continue to hear the "disbanded terminology". In fact, I do not think any of the terminology has been truly disbanded as there are ICD10 codes exist for spontaneous abortion, incomplete abortion, threatened abortion, but not for early pregnancy loss.

- There is not a lack of official consensus about this. There may be a lack of uptake of the reVITALize

terminology. Response: The ACOG practice bulletin states "In the first trimester, the terms miscarriage, spontaneous abortion, and early pregnancy loss are used interchangeably, and there is no consensus on terminology in the literature. However, early pregnancy loss is the term that will be used in this Practice Bulletin." This is different that the reVITALize terminology. This has been expanded upon in the manuscript.

- Although I think the reviewer who was concerned about "patient centered care" may have missed the mark a bit, the way you have framed this "clinician-patient communication" is a good alternative to the patient centered care terminology if you choose to make that difference.

Response: Thank you, manuscript has been revised to reflect "patient-clinician communication" rather than "patient centered care"

- was this a preplanned study or not?

This survey was developed concurrently with the primary study and implemented after the start of the primary study; the manuscript has been edited to reflect the timing.

- validity testing requires further fleshing out.

Response: Thank you, we have elaborated on validity testing in our methods.

- Other than language, what were criteria for offering a participant a survey? Were all English language speakers offered participation? If not, why not?

Response: All English language speakers were offered participation in the survey. The total number eligible is due to the timing in the study when the survey was introduced. Otherwise the inclusion criteria were the inclusion criteria for the PreFair clinical trial. This has been clarified

in the manuscript.

- for both the primary and this embedded study?

Response: Non-english speakers were included in the primary study, but not in our embedded study.

- how were these 4 terms chosen?

Response: The first three terms, *early pregnancy loss*, *spontaneous abortion*, and *miscarriage* are mentioned in the 2015 ACOG practice bulletin as the alternate acceptable terms. *early pregnancy failure* was included as review of the medical literature on this diagnosis included this term/phrase. This has been added to the methods section.

- you haven't mentioned the method for defining "preferred term"

Response: Thank you. We asked patients "What word would you prefer your doctors use to describe your diagnosis?" in our survey and this has been added to our methods section.

- For data presented in the text, please provide the raw numbers as well as data such as percentages, effect size (OR, RR, etc) as appropriate and 95% CI's.

Response: Thank you. We have modified the results section to add the raw data within the text as appropriate.

- 30.3 years....

Response: Edited in manuscript.

- how was intendedness of pregnancy determined? Was that information from the primary study? Please in the

methods be clear about sources of data that you used that were from the primary study.

Response: Yes, all demographic data was obtained from the primary study. This has been added to the manuscript.

- so is clarity that only criterium for acceptability?

Response: This survey aimed to identify which phrases currently used by clinicians are perceived as clear and preferable from the perspective of the patient.

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. Please submit Author Agreement Forms for the following authors:

Sarah Horvath, MD
Arden McAllister, MPH
Nathanael C. Koelper, MPH
Mary Sammel, ScD
Courtney A. Schreiber, MD, MPH

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

4. In order for an administrative database study to be considered for publication in Obstetrics & Gynecology, the database used must be shown to be reliable and validated. In your response, please tell us who entered the data and how the accuracy of the database was validated. This

same information should be included in the Materials and Methods section of the manuscript.

Response: Thank you. The data was collected as part of a clinical trial using RedCap, not using an administrative database. This has been added to the manuscript.

5. All submissions that are considered for potential publication are run through CrossCheck for originality. We believe part of this submission may have been presented at a meeting. Would you please include the meeting presentation on your title page?

Response: Thank you, this has been added to the title page

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 appendixes).

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. 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 express outcome data as both absolute and relative effects since information presented this way is much more useful for clinicians. In both the Abstract and the Results section of the manuscript, please give actual numbers and percentages in addition to odds ratios (OR) or relative risk (RR). If appropriate, please include number needed to treat for benefits (NNTb) or harm (NNTh). When comparing two procedures, please express the outcome of the comparison in dollar amounts.

13. Please review the journal's Table Checklist to make sure that your tables conform to journal style. The Table Checklist is available online here: http://edmgr.ovid.com/ong/accounts/table_checklist.pdf.

14. The American College of Obstetricians and Gynecologists' (College) documents are frequently updated. These documents may be withdrawn and replaced with newer, revised versions. If you cite College documents in your manuscript, be sure the reference you are citing is still current and available. If the reference you are citing has been updated (ie, replaced by a newer version), please ensure that the new version supports whatever statement you are making in your manuscript and then update your reference list accordingly. If the reference you are citing has been withdrawn with no clear replacement, please contact the editorial office for assistance (obgyn@greenjournal.org). In most cases, if a College document has been withdrawn, it should not be referenced in your manuscript (exceptions could include manuscripts that address items of historical interest). All College documents (eg, Committee Opinions and Practice Bulletins) may be found via the Resources and Publications page at <http://www.acog.org/Resources-And-Publications>.

Response: Thank you. We cite Practice Bulletin 150, which has since been replaced by Practice Bulletin 200. We have chosen to keep Practice Bulletin 150 as our citation as the timing and publication of that bulletin guided the creation of our survey.

15. Figure 1: Are these figures available at a higher resolution?

Response: Yes, we have resubmitted Figure 1a and 1b

16. 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 Sep 13, 2018, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,
Nancy C. Chescheir, MD
Editor-in-Chief

Randi Zung

From: Clement, Elizabeth [REDACTED]
Sent: Tuesday, October 2, 2018 8:58 PM
To: Randi Zung
Subject: RE: Your Revised Manuscript 18-1233R1
Attachments: 18-1233R1 ms 10_2 EGC Revisions.docx; Sammel Author Agreement.pdf

Follow Up Flag: Follow up
Flag Status: Flagged

Categories: Blue Category

Dear Ms. Zung,

Thank you so much for these edits; attached are the revised manuscript and Mary Sammel's author agreement. Below are my responses point by point. Thank you for your consideration.

Best,

Elizabeth Clement

Dear Dr. Clement:

Your revised manuscript is being reviewed by the Editors. Before a final decision can be made, we need you to address the following queries. Please make the requested changes to the latest version of your manuscript that is attached to this email. Please track your changes and leave the ones made by the Editorial Office. Please also note your responses to the author queries in your email message back to me.

1. General: The Editor has made edits to the manuscript using track changes. Please review them to make sure they are correct.

Response: Thank you for the edits. All modifications made were appropriate and kept.

2. Please submit an Author Agreement form for Mary Sammel with both the "Disclosure of Potential Conflicts of Interest" and "Authorship" sections completed. The version we received doesn't have the boxes checked.

Response: This has been submitted in this email

3. Corresponding Author Information: This information was added from your manuscript record in Editorial Manager. It will be published on the title page if your manuscript is accepted. Please be sure this information is correct.

Response: This has been reviewed and is correct.

4. Abstract-Methods: Methods section needs to be beefed up. Please note that you surveyed all English-speaking participants in the RCT, at what point in the primary study was the survey given and that it was given both on paper and on tablet. Should mention that the survey questions used VAS method. Also that this was a preplanned sub-study.

Response: This has been modified to reflect the requested changes. Of note, we didn't survey all of the English-speaking participants, as the survey was developed concurrently with the clinical trial, and thus not fully implemented until after the initiation of the main study.

5. Abstract-Results: In the abstract, please provide absolute numbers as well as whichever effect size you are reporting + Confidence intervals. P values may be omitted for space concerns. By absolute values, I mean something like: xx (outcome in exposed)/yy(outcome in unexposed) (zz%) (Effect size= ; 95% CI=). An example might be: Outcome 1 was more common in the exposed than the unexposed 60%/20% (Effect size=3;95% CI 2.6-3.4)

Response: Thank you, edited as requested

6. Line 47: To avoid the issue of starting your sentence with a number, to incorporate moving the information about when and how the survey was administered to the methods section, and to use more active voice would you consider the following: We approached all 155 English-speaking participants in the parent study. Of these 145 (93.5) participated.

Response: This has been modified to reflect the requested changes. Of note, we didn't survey all of the English-speaking participants, as we started survey development concurrently with the initiation of the parent study, so the survey didn't go out until after initiation of the parent study. All English speaking participants who were recruited after the initiation of our substudy were approached.

7. Line 50: Heard more frequently in what setting? Give data.

Response: Participants reported hearing these terms in the process of receiving their diagnosis of the nonviable pregnancy in the first trimester. This has been edited with data, reflecting our survey responses.

8. Line 51: Where are these data stated in the body of your paper? If the data are not contained in the text, tables, or figures, please add them.

Response: These data are included in table 1. The numbers but not the percentiles had been included in the table, the table has been edited to include percentiles and the significant figures are edited to match in the abstract and the table.

9. Line 55 and elsewhere: Please express this p-value and all the p-values in your paper to no more than three decimal places.

Response: Edited as requested

10. Line 59: Could you limit the noun you use for this to "terminology" and "language" for consistency please?

Response: Edited as requested

11. Line 60: You haven't reported any way that the patient experience has been evaluated in the abstract results. The conclusion should reference the results.

Response: Edited as requested

12. Line 62: In your response to reviews you agreed to change patient-centered to patient-clinician communication.

Response: Edited as requested

13. Line 78: Reference 6 is now outdated and has been replaced with Practice Bulletin No. 200. Please review PB to make sure it states what you are citing. See <https://www.acog.org/Clinical-Guidance-and-Publications/Practice-Bulletins-List>.

Response: Thank you for editing the citation with PB 200. We had initially kept PB 150 for historical reasons as it in part prompted the study, but agree to change it to PB 200 given this is the current reference. PB 200 continues to include the citation as included in the paper, so no changes have been made to the body of our manuscript.

14. Line 97: Please note the change to REDCap, the official name.

Response: Noted, thank you for the edit.

15. Line 131 (Results): For data presented in the text, please provide the raw numbers as well as data such as percentages, effect size (OR, RR, etc) as appropriate and 95% CI's.

Response: This has been edited as requested

16. Line 135 and Line 149: The highlighted sentence belongs in Methods section. Please move this.

Response: These sentences have been moved as requested.

17. Line 170: Please change to "terminology" or "language" to be consistent with earlier edits.

Response: Edited as requested

18. Line 174: Would you consider "Results" rather than "connotations"?

Response: edited as requested.

19. Reference 6: Reference 6 is now outdated and has been replaced with Practice Bulletin No. 200. Please review PB to make sure it states what you are citing. See <https://www.acog.org/Clinical-Guidance-and-Publications/Practice-Bulletins-List>.

(The citation we added will be updated with page numbers in mid-October.)

Response: Thank you, cited text confirmed to be present in PB 200.

20. Table 2: Please express this p-value and all the p-values in your paper to no more than three decimal places.

Response: Thank you, edited as requested.

Elizabeth G. Clement, MD
Clinical Associate
Penn OB/GYN Associates
Department of Obstetrics and Gynecology
Hospital of the University of Pennsylvania

From: Randi Zung [RZung@greenjournal.org]
Sent: Friday, September 28, 2018 2:50 PM
To: Clement, Elizabeth
Subject: Your Revised Manuscript 18-1233R1

Dear Dr. Clement:

Your revised manuscript is being reviewed by the Editors. Before a final decision can be made, we need you to address the following queries. Please make the requested changes to the latest version of your manuscript that is attached to this email. Please track your changes and leave the ones made by the Editorial Office. Please also note your responses to the author queries in your email message back to me.

1. General: The Editor has made edits to the manuscript using track changes. Please review them to make sure they are correct.
2. Please submit an Author Agreement form for Mary Sammel with both the “Disclosure of Potential Conflicts of Interest” and “Authorship” sections completed. The version we received doesn’t have the boxes checked.
3. Corresponding Author Information: This information was added from your manuscript record in Editorial Manager. It will be published on the title page if your manuscript is accepted. Please be sure this information is correct.
4. Abstract-Methods: Methods section needs to be beefed up. Please note that you surveyed all English-speaking participants in the RCT, at what point in the primary study was the survey given and that it was given both on paper and on tablet. Should mention that the survey questions used VAS method. Also that this was a preplanned sub-study.
5. Abstract-Results: In the abstract, please provide absolute numbers as well as whichever effect size you are reporting + Confidence intervals. P values may be omitted for space concerns. By absolute values, I mean something like: xx (outcome in exposed)/yy(outcome in unexposed) (zz%) (Effect size= ; 95% CI=). An example might be: Outcome 1 was more common in the exposed than the unexposed 60%/20% (Effect size=3;95% CI 2.6-3.4)
6. Line 47: To avoid the issue of starting your sentence with a number, to incorporate moving the information about when and how the survey was administered to the methods section, and to use more active voice would you consider the following: We approached all 155 English-speaking participants in the parent study. Of these 145 (93.5) participated.
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(The citation we added will be updated with page numbers in mid-October.)
20. Table 2: Please express this p-value and all the p-values in your paper to no more than three decimal places.

To facilitate the review process, we would appreciate receiving a response by October 3.

Best,
Randi Zung

--
Randi Zung (Ms.)
Editorial Administrator | Obstetrics & Gynecology American College of Obstetricians and Gynecologists
409 12th Street, SW
Washington, DC 20024-2188
T: 202-314-2341 | F: 202-479-0830
<http://www.greenjournal.org><<http://www.greenjournal.org/>>

From: [REDACTED]
To: [Stephanie Casway](mailto:Stephanie.Casway@greenjournal.org)
Subject: Re: O&G Figure Revision: 18-1233
Date: Monday, September 24, 2018 3:08:47 PM

Hi Stephanie,

Thank you so much for this.

There are no changes to the caption for figure 1a.

For 1b, the changes are in bold below. Thank you!

B. Clarity rankings of diagnosis terms by women diagnosed with first-trimester nonviable pregnancy. Clarity measured on a 100 mm visual analog scale, and dichotomized such that >50 on VAS is considered “clear”. Absolute risk reduction adjusted for site, ethnicity, race, prior induced abortions, and planned pregnancy. dichotomous variable for each term”.

Best,

Elizabeth Clement, MD

Sent from my iPhone

On Sep 20, 2018, at 12:28 PM, Stephanie Casway
<SCasway@greenjournal.org<<mailto:SCasway@greenjournal.org>>> wrote:

Good Afternoon Dr. Clement,
Your figure has been edited, and PDFs of the figure and legend are attached for your review. Please review the figure and legend CAREFULLY for any mistakes.

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 be grateful to receive a reply no later than Monday, 9/24. 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>>

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