OBSTETRICS & GYNECOLOGY

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- Comments from the reviewers and editors (email to author requesting revisions)
- Response from the author (cover letter submitted with revised manuscript)*

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

Personal or nonessential information may be redacted at the editor's discretion.

Questions about these materials may be directed to the *Obstetrics & Gynecology* editorial office: obgyn@greenjournal.org.

Date: Dec 05, 2019
To: "Elsie Taveras" [redacted]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-19-1729

RE: Manuscript Number ONG-19-1729

Effects of the First 1,000 Days Systems-Change Intervention on Maternal Gestational Weight Gain

Dear Dr. Taveras:

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 14 days from the date of this letter. If we have not heard from you by Dec 19, 2019, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1:

1. I thank the journal for the opportunity to review this study

2. Abstract - Methods - line 58 no need to elaborate on statistical methods. Consider removing

3. Results - I prefer to represent data in medians and IQR as it provides a better view of the study population.

4. Please refer for BMI obesity categories when reffering for >35, >30 etc.

5. 4 .Introduction - . Well written introduction .consider to refer for bariatric surgeries as a mean for obesity treatment pre-pregnancy.

6. Materials and methods - well written

7. Line 229-230 - please delete no significant results

8. Line 232 - better define BMI categories in methods than in the results.

9. Line 233 - please provide OR (not just aOR) for the decrease in prevalence.

10. Discussion - consider to comment on bariatric surgeris in the field of obstetrics.

11. No limitation paragraph? No limitation in the study?

12. TABLES - please consider to show data in MEDIAN IQR - this is not a deal breaker, albeit important in my opinion.

13. It would be interested to evaluate adverse maternal and neonatal outcomes among the study cohort.

Reviewer #2: The authors present their work describing a systems change intervention utilizing the First 1000 days

program in order to impact maternal gestational weight gain.

The following items should be addressed:
1. Introduction: the portions of the introduction in lines 78-81 regarding the impact of childhood obesity and the value of early intervention are outside the scope of this study; the authors should reframe and describe some of the available evidence regarding the impact of increased gestational weight gain and maternal obesity, given that the primary outcome is maternal and not any neonatal outcomes, and the study is not powered or designed to address neonatal outcomes or childhood obesity rates.

2. Methods line 181-205 - what sample size would be required to detect a difference in the pre- and post-intervention groups?

3. Results line 208-209 and figure 3 - how many women received care and did not deliver at an affiliate hospital? What are the differences between women who delivered at other hospitals vs those who were included in the study?

4. Results - What were the actual differences in gestational weight gain between the groups (in pounds)? How much more or less than the IOM guidelines did the women's weight change over their pregnancy before and after the intervention? The overweight group did have statistically significant decrease in excess GWG, however the confidence interval is wide and nearly reaches 1.0 in both the adjusted and unadjusted analyses. Therefore it would be helpful for readers to see what actual changes were noted in order to determine if this difference is also clinically significant.

5. Results - how many women in each group developed gestational diabetes, or had pre-existing diabetes?

Reviewer #3: The authors present a study evaluating excessive pregnancy weight gain before and after implementation of the First 1,000 Days Program in their area. The study is certainly timely and important with the current obesity epidemic. I have only a few questions/recommendations:

1) The definition of excessive weight gain needs to be in the paper as it is the primary outcome. Did they use >35 lbs for normal weight, >25 lbs for overweight, and >20 lbs for obese women?

2) I realize that the numbers would not be large, but did they look at obesity by category? There may have been benefit from the program for women in Class I versus Class III.

3) While the other sections of the paper are well written and robust, the results section has too little information. What was the range of total weight gain and the average for each BMI group? Did any have too little weight gain after the program was implemented? For Table II, please give the numbers not just the percentile for excessive weight gain for each group.

4) While I understand that the paper is addressing excessive weight gain in high risk for obesity women, pregnancy is THE risk factor for future overweight and obesity for all women. The authors need to address why there was no improvement in normal weight women who still had close to 30% rates of excessive weight gain.

STATISTICAL EDITOR COMMENTS:

The Statistical Editor makes the following points that need to be addressed:
lines 213-215: What were the outcomes for the women who delivered during the "washout period".

Table 2: Should cite the n as well as the % of women in each BMI category with excess GWG. No need to include the column of p-values, since the CIs for aORs are given. Also, since the primary outcome was reduction in excess GWG (lines 157-158) and lines 193-194, the decision was made a priori to stratify by BMI category, why was $p < .05$ or 95% CIs boundaries used as the inference threshold? It seems that there were really 3 primary outcomes being tested (one for each BMI category in Table 2) and only one, the overwgt group, was statistically significant. However, if the Authors had corrected for testing 3 (or even two) hypotheses, the difference would no longer have been significant. Furthermore, why was there not a power/sample size calculation done, based on what would have constituted a clinically significant difference in rates of excess GWG to assure the reader that the groups were of adequate size? Based on the proportions and counts from Tables 1 and 2, the difference in proportion of excess GWG for the overwgt BMI class was 9.4% with 95% CI [0.8-17.8%].

Table 3: These should be labelled as secondary outcomes (lines 237-238). Should explain for the reader in text how the p for trend (0.09) relates to the CIs of [0.43, 0.96]. Also, since there were n = 928 women in the post-implementation period, Table 3 cites n = 261 exposed to systems-change only and n = 533 who were exposed to system changes plus

coaching. Those groups sum to n = 794. What category of exposure was the remaining 928-794= 134 women? Also, need to either include in Table 3 or elsewhere a fully enumeration of the n(%) for excess GWG for the BMI categories in the columns with headings N = 261 and N = 533 (and the unaccounted for N = 134)

Fig 3: Was the demographic profile of the women who were excluded or who had missing data differ from those in the final analyzed groups in ways that might have affected the generalizability of the conclusions?

EDITOR'S COMMENTS:

You are reporting on what seems like a massive project to benefit mothers and their children with respect to prevention of obesity. It is always a judgement call on the part of authors and editors for these big projects to decide how to divide up the manuscripts that stem for these big projects. You of course have the benefit of seeing all the outcomes, but what you've presented herein is that for about 1/3 of your patients (those who were overweight) before the project about 55% gained too much weight and afterwards, about 45% did so. (about 50% pre and post) Confidence interval for your aOR's is wide and approaches 1. No other group (normal weight or obese) had an associated benefit. If I were a clinical director, I might look at this and consider this to be very little benefit for what seems like an expensive array of interventions. If you are only presenting this data in this paper, the conclusion should really be--we did this big intervention and not much really changed for mothers' weight gain. If, however, you have additional data (some of which I'm suggesting below in my comments) that can describe results in broader terms, then perhaps there is a real benefit of the project (or perhaps not). As authors, you can decide whether to add additional information (assuming its not already reported in other papers) but as an editor, based on what you've reported here, I need you to alter your conclusions to reflect the very modest nature of your positive results.

Line 45: We no longer require that authors adhere to the Green Journal format with the first submission of their papers. However, any revisions must do so. I strongly encourage you to read the instructions for authors (the general bits as well as those specific to the feature-type you are submitting). The instructions provide guidance regarding formatting, word and reference limits, authorship issues, and other things. Adherence to these requirements with your revision will avoid delays during the revision process, as well as avoid re-revisions on your part in order to comply with the formatting.

Line 56: how do you define “women at highest risk of excess GWG”? Please add here. Was FTD offered to women w BMI < 25?

Line 62: Please provide crude OR’s prior to adjusted OR’s. Thank you for providing the raw data and not just the OR’s!

Line 68: Your conclusion seems a bit overstated, even as it is technically correct. About half of women who were overweight both pre and post FTD gained excess weight and there was no effect in obese women. Perhaps you could soften your statement by saying something like “…was associated with a modest reduction of excess GWG among women who were overweight, but not obese at the start of pregnancy”. Word count would likely need to be addressed. The precis would need to be edited to address this as well.

Line 80-82: I’m a bit confused by this. The focus of this report is on maternal weight gain, not infant weight or childhood weight status. I’m not sure what the relevance to maternal weight gain is with your statement that intervention works best “in the earliest stateges of life”, which clearly are not possible when addressing a woman’s weight gain in pregnancy. It seems this sentence is conflating what I think your overall program goals were, which is addressing not only the mother’s weight status but that of her child.

Line 88: Could you expand a bit on what a “collective impact” approach is? Our readership will likely not be famililar. Just a sentence or two please.

Do you have data regarding rates of gestational diabetes in the pre-post groups? Given the rather modest effects on GWG shown in your study, reporting on outcomes that may be associated with improved nutrition, exercise, sleep etc that you target in your program may strengthen (or not) the argument that the program was beneficial in terms of maternal outcomes.

Line 91: please avoid causal language like ‘effects” here and throughout your paper. Similarly, line 108 “The program improves weight gain”…. Line 233..exposure resulted in….. Line 241. These are a few examples.

Line 128: What health behaviors and socio-contextual factors are you talking about here? Can you include these in a box or table, or Supplemental Digital content?

Line 132: what was considered high weight gain in early pregnancy?

Line 137: should be “and reducing fast food consumption” for parallel sentence construction. .,

Line 170 or thereabouts. Did you include only singleton births?

Line 180: At the end of the methods section, I’m still unclear if women who were normal weight were included in the FTD program. You indicate that you excluded underweight women due to low numbers and that implies that you included normal weight women. Were there GWG values tracked even if they did not get the full scope of the FTD program? Since this was a major campaign at the 2 clinic sites, if the normal weight women did not get full scope of FTD, they were exposed to the in-clinic messaging described, perhaps increased emphasis by clinic staff on nutrition information (ie, Hawthorne effect).

Line 207: PRESENTATION OF STATS INFORMATION—please note this applies throughout the manuscript, including abstract, main text and tables.

P Values vs Effect Size and Confidence Intervals: While P values are a central part of inference testing in statistics, when cited alone, often the strength of the conclusion can be misunderstood. Whenever possible, the preferred citation should be in terms of an effect size, such as odds ratio or relative risk or the mean difference of a variable between two groups, expressed with appropriate confidence intervals. When such syntax is used, the P value has only secondary importance and often can be omitted or noted as footnotes in a Table format. Putting the results in the form of an effect size makes the result of the statistical test more clinically relevant and gives better context than citing P values alone. This is true for the abstract as well as the manuscript.

Please provide absolute values for variables, in addition to assessment of statistical significance.

We ask that you provide crude OR’s followed by adjusted OR’s for all variables.

Line 230: We do no allow authors to describe variables or outcomes in terms that imply a difference (such us of the terms “trend” or “tendency” or “marginally different”) unless there is a statistical difference. Please edit here and throughout.

Line 234: please note as well that there was no difference for those who started pregnancy in normal weight range.

Line 247-248: Same issue as pointed out in my comments in the abstract section. Yes, its a 10% reduction in rate of excessive GWG in this 1/3 of your patient population but contextualized with the whole population, this is rather modest.

Line 252: you also found no associations for improved weight gain profiles in women who started at normal weight —Overall, for 2/3 of your patients, there was no benefit.

Line 252-256 seems rather fatalistic. As I read this, it seems like you are saying that for the obese women, no prenatal intervention could be beneficial. Maybe the FTD program could be modified for those with greater problems in excess caloric intake? The Peaceman trial mentioned later does seem to have shown a benefit for obese women.

Line 258: You’ve given us no data about the “ability to influence changes you list in this sentence. You’ve only given us data about weight gain outcomes, not the process changes associated with these outcomes. If you want to expand on your reporting to support this statement, it could be retained.

Line 262: Why do you think the FTD program was only associated w/ a 10% reduction in excess GWG when the Cochrane report showed a 20% reduction? If the prior studies showed that providers’ advice was associated with benefit, why are you suggesting providers can’t do this?

Line 291: reasonable to point out that this trial showed a similar reduction of excessive weight gain as your does (about 14% in the Peaceman trial vs 10% in yours) although the Peaceman trial reported this for all participants, obese and overweight which should be emphasized. As noted in my prior comments (and by other reviewers) the lack of information about other outcomes besides Apgar scores limits your report. The Peaceman trial is a good example of what additional information would strengthen your report—cesarean birth rate, preeclampsia and GDM rates, macrosomia, prematurity rates.

Line 306: “women with overweight” seems to be missing a word. Do you mean “women who are overweight by BMI” ?

EDITOR COMMENTS:

1. The Editors of Obstetrics & Gynecology are seeking to increase transparency around its peer-review process, in line with efforts to do so in international biomedical peer review publishing. If your article is accepted, we will be posting this revision letter as supplemental digital content to the published article online. Additionally, unless you choose to opt out, we

will also be including your point-by-point response to the revision letter. If you opt out of including your response, only the revision letter will be posted. Please reply to this letter with one of two responses:
A. OPT-IN: Yes, please publish my point-by-point response letter.
B. OPT-OUT: No, please do not publish my point-by-point response letter.

2. As of December 17, 2018, Obstetrics & Gynecology has implemented an "electronic Copyright Transfer Agreement" (eCTA) and will no longer be collecting author agreement forms. When you are ready to revise your manuscript, you will be prompted in Editorial Manager (EM) to click on "Revise Submission." Doing so will launch the resubmission process, and you will be walked through the various questions that comprise the eCTA. Each of your coauthors will receive an email from the system requesting that they review and electronically sign the eCTA.

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

3. Our journal requires that all evidence-based research submissions be accompanied by a transparency declaration statement from the manuscript's lead author. The statement is as follows: "The lead author* affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained." *The manuscript's guarantor.

If you are the lead author, please include this statement in your cover letter. If the lead author is a different person, please ask him/her to submit the signed transparency declaration to you. This document may be uploaded with your submission in Editorial Manager.

4. Clinical trials submitted to the journal as of July 1, 2018, must include a data sharing statement. The statement should indicate 1) whether individual deidentified participant data (including data dictionaries) will be shared; 2) what data in particular will be shared; 3) whether additional, related documents will be available (eg, study protocol, statistical analysis plan, etc.); 4) when the data will become available and for how long; and 5) by what access criteria data will be shared (including with whom, for what types of analyses, and by what mechanism). Responses to the five bullet points should be provided in a box at the end of the article (after the References section).

5. All submissions that are considered for potential publication are run through CrossCheck for originality. The following lines of text match too closely to previously published works.

Please add variance to lines 145-154 (We created a text message…to fathers).

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

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

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

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

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. In your Abstract, manuscript Results sections, and tables, the preferred citation should be in terms of an effect size, such as odds ratio or relative risk or the mean difference of a variable between two groups, expressed with appropriate confidence intervals. When such syntax is used, the P value has only secondary importance and often can be omitted or noted as footnotes in a Table format. Putting the results in the form of an effect size makes the result of the statistical test more clinically relevant and gives better context than citing P values alone.

If appropriate, please include number needed to treat for benefits (NNTb) or harm (NNTh). When comparing two procedures, please express the outcome of the comparison in U.S. dollar amounts.

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

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

14. Figures

Figure 1: Okay, please resubmit current file with the revision.

Figure 2: Please upload a high res version of this image (tiff, eps, jpeg). Please provide a letter of permission to use this in print and electronic formats.

Figure 3: Okay, please resubmit current file with the revision.

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

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

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

* A confirmation that you have read the Instructions for Authors (http://edmgr.ovid.com/ong/accounts/authors.pdf), and
* A point-by-point response to each of the received comments in this letter.

If you submit a revision, we will assume that it has been developed in consultation with your co-authors and that each author has given approval to the final form of the revision.

Again, your paper will be maintained in active status for 14 days from the date of this letter. If we have not heard from you by Dec 19, 2019, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

Nancy C. Chescheir, MD
Editor-in-Chief

2018 IMPACT FACTOR: 4.965
2018 IMPACT FACTOR RANKING: 7th out of 83 ob/gyn journals

[redacted]

January 6, 2020

Dr. Nancy C. Chescheir
Editor-in-Chief, *Obstetrics & Gynecology*

Re: Resubmission of manuscript #ONG-19-1729, "Effects of the First 1,000 Days Systems-Change Intervention on Maternal Gestational Weight Gain"

Dear Dr. Chescheir,

Thank you very much for the opportunity to address the reviewer's comments and resubmit our manuscript for publication in *Obstetrics & Gynecology*. We thank the reviewers and editors for their thoughtful feedback, and have attached our responses to their comments. We have made a number of revisions based on suggestions, which we hope will make this article stronger, and confirm we have read the Instructions for Authors.

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.

Figure 2 and Appendix 3 are intervention materials developed by the research team for the research study. If the manuscript is accepted for publication, *Obstetrics & Gynecology*, has our permission to use these figures in print and electronic formats.

We appreciate your continued interest in this manuscript and we look forward to hearing from you.

Sincerely,

Elsie M. Taveras, MD, MPH

Tiffany Blake-Lamb, MD

REVIEWER COMMENTS:

Reviewer #1:

1. Abstract - Methods - line 58 no need to elaborate on statistical methods. Consider removing.

   We have removed the sentence in the abstract, line 57.

2. Results - I prefer to represent data in medians and IQR as it provides a better view of the study population.

   We have kept the data presentation in means and standard deviations because gestational weight gain in our sample shows a normal distribution. We would be happy to change to medians and IQR if the Editor prefers this change.

3. Please refer to BMI obesity categories when referring for >35, >30 etc.

   As suggested in comment #6, on page 9 (lines 232-235) we now define body mass index categories as written below. We changed subsequent references in the paper to refer to the weight category (normal weight, overweight, obesity).

   "Women with a BMI ≥ 18.5 to < 25 kg/m^2 were considered to be normal weight, women with a BMI ≥25 to <30 kg/m^2 were considered to have overweight, and women with a BMI ≥30 kg/m^2 were considered to have obesity."

4. Introduction - Well written introduction consider to refer for bariatric surgeries as a mean for obesity treatment pre-pregnancy.

   We thank the reviewer for this comment and agree there is increasing evidence that bariatric surgery for obesity treatment prior to pregnancy can improve pregnancy outcomes. However, since our intervention begins during prenatal care and pertains specifically to reducing excess weight gain during pregnancy, discussion of pre-pregnancy interventions for obesity is beyond the scope of our manuscript.

5. Line 229-230 - please delete no significant results

   We chose to keep the pertinent negative results in the manuscript in the interest of fully reporting the study findings.

6. Line 232 - better define BMI categories in methods than in the results.

   We have updated the methods to better define the BMI categories, page 9 (lines 232-235).

7. Line 233 - please provide OR (not just aOR) for the decrease in prevalence.

   As suggested by the reviewer, we have included the unadjusted OR, page 13 (line 338).

8. Discussion - consider to comment on bariatric surgeries in the field of obstetrics.

    Please see response to #4 above.

9. No limitation paragraph? No limitation in the study?

    Limitations are included within the Discussion, pages 15-16 (lines 422-469).

10. TABLES - please consider to show data in MEDIAN IQR - this is not a deal breaker, albeit important in my opinion.

    Please see response #2 above.

11. It would be interested to evaluate adverse maternal and neonatal outcomes among the study cohort.

    We thank the reviewer for this suggestion and have included additional potential adverse outcomes to Table 2 including: preterm birth, Cesarean delivery, large-for-gestational age, macrosomia, and small-for-gestational age.

Reviewer #2:

12. Introduction: the portions of the introduction in lines 78-81 regarding the impact of childhood obesity and the value of early intervention are outside the scope of this study; the authors should reframe and describe some of the available evidence regarding the impact of increased gestational weight gain and maternal obesity, given that the primary outcome is maternal and not any neonatal outcomes, and the study is not powered or designed to address neonatal outcomes or childhood obesity rates.

    The First 1,000 Days Program was designed with the primary goal of reducing excess gestational weight gain for women during pregnancy and excess weight gain for infants during the first two years of life, however the current study pertains only to the pregnancy portion of the program. We agree that this distinction was not clearly delineated in our Introduction, and we have edited to better reflect the focus of the current study on maternal outcomes.

13. Methods line 181-205 - what sample size would be required to detect a difference in the pre- and post-intervention groups?

    We have included a sample size and power calculation on page 10 (lines 259-262). To demonstrate a difference of 13% in the prevalence of excess GWG among women with a pre-pregnancy BMI $\geq$ 25 kg/m^2 between the pre and post-intervention groups, a sample of 191 women per group would be required (alpha of 0.05 and a power of 0.80).

14. Results line 208-209 and figure 3 - how many women received care and did not deliver at an affiliate hospital? What are the differences between women who delivered at other hospitals vs those who were included in the study?

We thank the reviewer for this question and have added the below clarification to page 9 (lines 232-235) indicating only women who delivered at a Partners HealthCare affiliated hospital were included in the study. It was not possible to examine differences among women that delivered at a hospital outside of the Partners HealthCare system because we did not have access to their electronic health record data. This is also outlined in the top box of Figure 3.

"In order to collect complete data from the electronic health record, women were required to deliver a singleton birth at a Partners HealthCare affiliated hospital between September 1, 2015 – May 31, 2018 to be included in analyses."

15. Results - What were the actual differences in gestational weight gain between the groups (in pounds)? How much more or less than the IOM guidelines did the women's weight change over their pregnancy before and after the intervention? The overweight group did have statistically significant decrease in excess GWG, however the confidence interval is wide and nearly reaches 1.0 in both the adjusted and unadjusted analyses. Therefore, it would be helpful for readers to see what actual changes were noted in order to determine if this difference is also clinically significant.

    We agree with the reviewer and have added continuous weight differences for each group to Tables 1 and 2.

16. Results - how many women in each group developed gestational diabetes, or had pre-existing diabetes?

    While gestational diabetes was documented in the electronic health record, we were unable to confirm the reliability of the information pre-intervention or correct for missingness in the EHR as we did for gestational weight gain. Thus, we have not included GDM results in the current paper.

Reviewer #3:

17. The authors present a study evaluating excessive pregnancy weight gain before and after implementation of the First 1,000 Days Program in their area. The study is certainly timely and important with the current obesity epidemic.

    We thank the reviewer for the positive comments about the study.

18. The definition of excessive weight gain needs to be in the paper as it is the primary outcome. Did they use >35 lbs for normal weight, >25 lbs for overweight, and >20 lbs for obese women?

    We defined the primary outcome as gestational weight gain above the 2009 National Academy of Medicine guidelines according to pre-pregnancy body mass index. This sentence is included on page 9 (lines 245-247).

19. I realize that the numbers would not be large, but did they look at obesity by category? There may have been benefit from the program for women in Class I versus Class III.

The reviewer is correct that our sample sizes did not allow a robust stratified analysis of more detailed obesity categories and we chose to not include these results in the article. For example, cell sizes for Class III obesity was only 13 (2.0%) women pre-implementation and 13 (1.4%) post-implementation.

20. While the other sections of the paper are well written and robust, the results section has too little information. What was the range of total weight gain and the average for each BMI group? Did any have too little weight gain after the program was implemented? For Table II, please give the numbers not just the percentile for excessive weight gain for each group.

In response to the reviewer's suggestion, we have added several new results to the text and table including mean gestational weight gain in table 2 and several secondary birth outcomes.

21. While I understand that the paper is addressing excessive weight gain in high risk for obesity women, pregnancy is THE risk factor for future overweight and obesity for all women. The authors need to address why there was no improvement in normal weight women who still had close to 30% rates of excessive weight gain.

The reviewer raises an important question about plausible reasons why our results were essentially null among women who entered pregnancy at a normal weight. While women in the normal weight category were likely exposed to the systematic intervention components, they would not have been eligible for the individualized coaching and patient navigation. Thus, it is possible that the "dose" of intervention received by these normal weight women was insufficient to result in reduced GWG. We have included this explanation in the discussion section on page 16 (lines 451-460) .

STATISTICAL EDITOR COMMENTS:

22. Lines 213-215: What were the outcomes for the women who delivered during the "washout period".

Women in the washout period received varying degrees of the intervention, so we did not evaluate the impact of the intervention on their gestational weight gain. These women were slightly less likely to have public insurance (46% vs 54%), but otherwise did not differ from women in our analytic sample in terms of their age, parity, race/ethnicity, or pre-pregnancy BMI. There were also no differences in terms of their cesarean section rates, preterm birth or large for gestational age rates, or in their infant's birthweight or gestational age at delivery.

- Table 2: Should cite the n as well as the % of women in each BMI category with excess GWG. No need to include the column of p-values, since the CIs for aORs are given. Also, since the primary outcome was reduction in excess GWG (lines 157-158) and lines 193-194, the decision was made a priori to stratify by BMI category, why was $p < .05$ or 95% CIs boundaries used as the inference threshold? It seems that there were really 3 primary outcomes being tested (one for each BMI category in Table 2) and only one, the overwgt group, was statistically significant. However, if the Authors had corrected for testing 3 (or even two) hypotheses, the difference would no longer have been significant. Furthermore, why was there not a power/sample size calculation done, based on what would have constituted a clinically significant

difference in rates of excess GWG to assure the reader that the groups were of adequate size? Based on the proportions and counts from Tables 1 and 2, the difference in proportion of excess GWG for the overwgt BMI class was 9.4% with 95% CI [0.8-17.8%].

In response to the reviewer, we have included n and % in each BMI category. We have also removed the p-values from Table 2. Additionally, we have included our sample size and power calculations on page 10 (lines 259-262). The purpose of our multivariable analysis was to test the association of the First 1000 days program with excess gestational weight gain for each BMI group irrespective of the others. Therefore, we did not adjust for multiple comparisons among the pre-pregnancy BMI groups.

- Table 3: These should be labelled as secondary outcomes (lines 237-238). Should explain for the reader in text how the p for trend (0.09) relates to the CIs of [0.43, 0.96]. Also, since there were n = 928 women in the post-implementation period, Table 3 cites n = 261 exposed to systems-change only and n = 533 who were exposed to system changes plus coaching. Those groups sum to n = 794. What category of exposure was the remaining 928-794= 134 women? Also, need to either include in Table 3 or elsewhere a fully enumeration of the n (%) for excess GWG for the BMI categories in the columns with headings N = 261 and N = 533 (and the unaccounted for N = 134)

In response to the reviewer, we have labeled the additional outcomes in Table 3 as secondary. We have also added a footnote to Table 3 to clarify the statistical test used for the trend analysis and how it relates to the confidence intervals of the point estimates presented in the table.

The pre/post implementation samples were defined based on delivery date, with a conservative washout period to ensure the pre/post groups received no intervention or the full systems change intervention. The program assessed dose (systems-change only vs. systems change + coaching) based on engagement in the program during prenatal care. Due to the fact that women started prenatal care and delivered at varying gestational ages, the samples do not perfectly match. In Figure 3, we have depicted this with the two grey boxes around each sample.

- Fig 3: Was the demographic profile of the women who were excluded or who had missing data differ from those in the final analyzed groups in ways that might have affected the generalizability of the conclusions?

Women excluded for missing data did not differ from women included in the study in terms of age, parity, race/ethnicity, public insurance status, or pre-pregnancy BMI. (see table below). We have included this in the text on page 12 (lines 317-319).

Participant Characteristics	**Overall N= 1571**	**Excluded N=141**	**P-value**
Age, years	30.0 (5.9)	28.9 (6.0)	0.05
Parity	1.2 (1.1)	1.0 (1.4)	0.14
Race/ethnicity, n (%)			

White, non-Hispanic	420 (26.7)	32 (27.8)	0.86
Hispanic/Latino	835 (53.2)	57 (49.5)	
Black, non-Hispanic	123 (7.8)	11 (9.6)	
Asian or Other, non-Hispanic	193 (12.3)	15 (13.0)	
Public Insurance, n (%)	847 (53.9)	68 (48.2)	0.19
Pre-Pregnancy BMI, kg/m^2	28.1 (6.1)	27.5 (7.3)	0.53
Pre-Pregnancy BMI Category[a], n (%)			
≥ 18.5 to < 25 kg/m^2	538 (34.3)	19 (44.1)	0.33
≥ 25 to < 30 kg/m^2	532 (33.9)	14 (32.6)	
≥ 30 kg/m^2	501 (31.9)	10 (23.2)	
Gestational age at delivery, weeks	39.2 (1.8)	39.0 (2.1)	0.22

EDITOR'S COMMENTS:

- You are reporting on what seems like a massive project to benefit mothers and their children with respect to prevention of obesity. It is always a judgement call on the part of authors and editors for these big projects to decide how to divide up the manuscripts that stem for these big projects. You of course have the benefit of seeing all the outcomes, but what you've presented herein is that for about 1/3 of your patients (those who were overweight) before the project about 55% gained too much weight and afterwards, about 45% did so. (about 50% pre and post) Confidence interval for your aOR's is wide and approaches 1. No other group (normal weight or obese) had an associated benefit. If I were a clinical director, I might look at this and consider this to be very little benefit for what seems like an expensive array of interventions. If you are only presenting this data in this paper, the conclusion should really be--we did this big intervention and not much really changed for mothers' weight gain. If, however, you have additional data (some of which I'm suggesting below in my comments) that can describe results in broader terms, then perhaps there is a real benefit of the project (or perhaps not). As authors, you can decide whether to add additional information (assuming its not already reported in other papers) but as an editor, based on what you've reported here, I need you to alter your conclusions to reflect the very modest nature of your positive results.

  The editor raises an important point about the modest nature of our results and we have made efforts to qualify our language and interpretation throughout the manuscript. We have also included more detailed gestational weight gain outcomes to the revised draft as well as added several secondary outcomes to rule out adverse or unintended consequences. In addition, we have reported all null outcomes in the interest of being fully transparent about our findings.

  The editor also asks about additional outcome data. In a subset of women in the post-implementation phase only (N=286), we also conducted surveys in the first and third trimesters of pregnancy to assess implementation process outcomes, e.g. awareness and satisfaction with the program and exposure to various components of the program (see supplemental table,

Appendix 1). These results indicate that the program was delivered with high fidelity and was well-accepted by the participants. We opted not to include this table in the original manuscript as we were already near the maximum word count but have now added it as supplemental content. In addition to the gestational weight gain outcome included in this manuscript, we have a number of birth outcomes which we have now added to the paper. We also have extensive postpartum and infant growth outcomes including effects of program participation on rapid infant weight gain that we do intend to publish separately.

Finally, we wanted to make a comparison of our study to the NIH-funded trials reported in the Peaceman et al. manuscript. We aimed to make systematic and sustainable changes within the community health centers that were pragmatic, feasible to implement in low-resource settings, and accepted by each of the sectors we worked with. In contrast to the NIH-funded LIFE-Moms trials, our intervention components were not expensive and were easily integrated into clinical workflow. For example, one of our changes was to implement universal screening of social determinants of health for all women seeking prenatal care in the community health centers. We trained the front desk staff to implement this component and this screening is now part of routine practice at the health centers. This was not a costly intervention and has been sustained. On the other hand, several of the LIFE-Moms studies implemented expensive components that would be difficult to integrate and sustain in low-resource settings, e.g. meal replacement. Thus, while our results are more modest than those presented in the Peaceman article, we were encouraged by the results that could have incremental effects if combined with additional, more expensive efforts like those in the Peaceman article.

We hope the editor will find our revisions responsive to the reviewer's comments.

- Line 45: We no longer require that authors adhere to the Green Journal format with the first submission of their papers. However, any revisions must do so. I strongly encourage you to read the instructions for authors (the general bits as well as those specific to the feature-type you are submitting). The instructions provide guidance regarding formatting, word and reference limits, authorship issues, and other things. Adherence to these requirements with your revision will avoid delays during the revision process, as well as avoid re-revisions on your part in order to comply with the formatting.

  We have reviewed the instructions to authors carefully and have made all the required formatting changes to the revised manuscript.

- Line 56: how do you define "women at highest risk of excess GWG"? Please add here. Was FTD offered to women w BMI < 25?

  We have added clarification to the abstract that we defined women at high risk of excess GWG based on pre-pregnancy BMI or first trimester weight gain ≥ 2 kg as per NAS/IOM guidelines (lines 54-55). All women who received prenatal care at the participating health centers, including those with a BMI < 25, were eligible for the systems change intervention. Only women considered to be high risk were offered additional health coaching.

- Line 62: Please provide crude OR's prior to adjusted OR's. Thank you for providing the raw data and not just the OR's!

We have made this change as suggested on page 3 (line 61)

- Line 68: Your conclusion seems a bit overstated, even as it is technically correct. About half of women who were overweight both pre and post FTD gained excess weight and there was no effect in obese women. Perhaps you could soften your statement by saying something like "…was associated with a modest reduction of excess GWG among women who were overweight, but not obese at the start of pregnancy". Word count would likely need to be addressed. The precis would need to be edited to address this as well.

  We thank the editor for this comment and have made the suggested change to the conclusion and have also qualified our language throughout the manuscript.

- Line 80-82: I'm a bit confused by this. The focus of this report is on maternal weight gain, not infant weight or childhood weight status. I'm not sure what the relevance to maternal weight gain is with your statement that intervention works best "in the earliest stages of life", which clearly are not possible when addressing a woman's weight gain in pregnancy. It seems this sentence is conflating what I think your overall program goals were, which is addressing not only the mother's weight status but that of her child.

  The editor is correct and we have now edited these lines in response. Please also see response to #12 above.

- Line 88: Could you expand a bit on what a "collective impact" approach is? Our readership will likely not be familiar. Just a sentence or two please.

  We have added a definition of Collective Impact, along with applicable citations, to page 5 (lines 116-118).

  Briefly, the First 1,000 Days program was co-created by a diverse set of stakeholders working in early life clinical and public health services, including Obstetrics, Pediatrics, Adult Medicine, Behavioral Health, Nutrition, Community Health, the Women, Infants and Children (WIC) program, and the Maternal, Infant and Childhood Home Visiting program. Recognizing that system-wide changes to achieve improved health outcomes require a highly structured and collaborative effort, the program used a "Collective Impact" approach to create the infrastructure for sustainable, systems-level changes. Collective Impact (CI) is defined as "the commitment of a group of important actors from different sectors to a common agenda for solving a specific social problem".

- Do you have data regarding rates of gestational diabetes in the pre-post groups? Given the rather modest effects on GWG shown in your study, reporting on outcomes that may be associated with improved nutrition, exercise, sleep etc that you target in your program may strengthen (or not) the argument that the program was beneficial in terms of maternal outcomes.

  We agree that gestational diabetes shares many of the same risk factors as excess gestational weight gain during pregnancy, and we would have liked to include GDM data in our study, however the medical record system in use at our study sites in the pre-intervention period only

had data available on GDM diagnosis for 18% of the sample, thus we chose not to report on this variable. Please also see response to #16 above.

- Line 91: please avoid causal language like 'effects" here and throughout your paper. Similarly, line 108 "The program improves weight gain"…. Line 233..exposure resulted in….. Line 241. These are a few examples.

  The above mentioned lines have been edited with more exact language. We have also reviewed throughout the paper and made edits where appropriate.

- Line 128: What health behaviors and socio-contextual factors are you talking about here? Can you include these in a box or table, or Supplemental Digital content?

  Figure 2 includes an example of the intervention content, including the five social-behavioral goals of the program. These goals are further outlined on pages 7-8 (lines 182-190) in the text of the manuscript. Within the text on page 7, we have made reference to Figure 2.

  In addition, we have added a supplemental figure (Appendix 3) showing the individually-tailored Community Resource Guide, and a supplemental table (Appendix 2) outlining the Social Determinants of Health we screened for. The guide was mailed or emailed to all patients, with the content tailored to their needs based on what Social Determinants of Health they screened positive for.

- Line 132: what was considered high weight gain in early pregnancy?

  Excess first trimester weight gain was defined as ≥ 2 kgs based on National Academy of Medicine/IOM guidelines. We included this on page 7 (line 178).

- Line 137: should be "and reducing fast food consumption" for parallel sentence construction.

  We have updated this sentence on page 8 (line 186) to correct the sentence construction.

- Line 170 or thereabouts. Did you include only singleton births?

  That is correct, we only included singleton births in the analytic sample. We have included "singleton birth" in the sentence outlining inclusion criteria on page 9 (lines 239-242, 249).

- Line 180: At the end of the methods section, I'm still unclear if women who were normal weight were included in the FTD program. You indicate that you excluded underweight women due to low numbers and that implies that you included normal weight women. Were there GWG values tracked even if they did not get the full scope of the FTD program? Since this was a major campaign at the 2 clinic sites, if the normal weight women did not get full scope of FTD, they were exposed to the in-clinic messaging described, perhaps increased emphasis by clinic staff on nutrition information (ie, Hawthorne effect).

  We thank the editor for allowing us to clarify this language in the text. All women who were seen for prenatal care, including those with a normal pre-pregnancy body mass index, were

exposed to the systematic changes we made in the community health center. However, normal weight women did not receive individualized health coaching. Underweight women were also exposed to the program but because of small sample sizes we excluded them from our *analyses*. We have clarified this in the Methods section, on pages 9-10 (lines 256-258).

- Line 207: PRESENTATION OF STATS INFORMATION—please note this applies throughout the manuscript, including abstract, main text and tables.

  a. P Values vs Effect Size and Confidence Intervals: While P values are a central part of inference testing in statistics, when cited alone, often the strength of the conclusion can be misunderstood. Whenever possible, the preferred citation should be in terms of an effect size, such as odds ratio or relative risk or the mean difference of a variable between two groups, expressed with appropriate confidence intervals. When such syntax is used, the P value has only secondary importance and often can be omitted or noted as footnotes in a Table format. Putting the results in the form of an effect size makes the result of the statistical test more clinically relevant and gives better context than citing P values alone. This is true for the abstract as well as the manuscript.

  We have included all confidence intervals for the effect estimates in the paper and in the tables. We have removed the p-values from Table 2 as well (see response above to comment #23.)

  b. Please provide absolute values for variables, in addition to assessment of statistical significance.

  We include absolute values for variables throughout.

  c. We ask that you provide crude OR's followed by adjusted OR's for all variables.

  We have included unadjusted and adjusted ORs throughout.

- Line 230: We do not allow authors to describe variables or outcomes in terms that imply a difference (such us of the terms "trend" or "tendency" or "marginally different") unless there is a statistical difference. Please edit here and throughout.

  We have removed reference to the non-significant LGA results, page 12 (line 329).

- Line 234: please note as well that there was no difference for those who started pregnancy in normal weight range.

  We have added a sentence stating we saw no change among other groups of women on page 13 (lines 339-340).

- Line 247-248: Same issue as pointed out in my comments in the abstract section. Yes, its a 10% reduction in rate of excessive GWG in this 1/3 of your patient population but contextualized with the whole population, this is rather modest. Line 252: you also found no associations for improved weight gain profiles in women who started at normal weight—Overall, for 2/3 of your patients, there was no benefit.

Please see response to #26 above.

- Line 252-256 seems rather fatalistic. As I read this, it seems like you are saying that for the obese women, no prenatal intervention could be beneficial. Maybe the FTD program could be modified for those with greater problems in excess caloric intake? The Peaceman trial mentioned later does seem to have shown a benefit for obese women.

  We thank the editor for allowing us to clarify this language in the text. Our intention was not to be fatalistic but rather to say that more intensive interventions would be needed for women with obesity than those delivered in the current First 1000 days program. We have modified this language in the text on page 14 (lines 371-376). Additionally, we intend to use the findings of our current work to modify the intensity of our program to make it more effective for this particularly vulnerable population of women.

- Line 258: You've given us no data about the "ability to influence changes you list in this sentence. You've only given us data about weight gain outcomes, not the process changes associated with these outcomes. If you want to expand on your reporting to support this statement, it could be retained.

  The editor is correct. This statement unintentionally implied knowledge of process changes that we did not report in the previous submission. We are now adding process outcomes as supplemental content. See response to #26 above.

- Line 262: Why do you think the FTD program was only associated w/ a 10% reduction in excess GWG when the Cochrane report showed a 20% reduction? If the prior studies showed that providers' advice was associated with benefit, why are you suggesting providers can't do this?

  We have moved the comparison with the Cochrane report to a subsequent paragraph in the Discussion section on pages 14-15 (lines 383-411), and have offered a possible reason why the Cochrane data and the Peaceman data (as noted in the following comment) may differ from our findings. We did not intend to suggest that providers are not able to provide GWG counseling, and the sentence has been revised to better reflect the intended meaning.

- Line 291: reasonable to point out that this trial showed a similar reduction of excessive weight gain as your does (about 14% in the Peaceman trial vs 10% in yours) although the Peaceman trial reported this for all participants, obese and overweight which should be emphasized. As noted in my prior comments (and by other reviewers) the lack of information about other outcomes besides Apgar scores limits your report. The Peaceman trial is a good example of what additional information would strengthen your report—cesarean birth rate, preeclampsia and GDM rates, macrosomia, prematurity rates.

  Please see response to comment #26 above. We have now included additional outcomes to the article including several of those reported in the Peaceman manuscript.

- Line 306: "women with overweight" seems to be missing a word. Do you mean "women who are overweight by BMI" ?

We have clarified the language to say women who were overweight at the start of pregnancy, page 16 (line 471).

EDITOR COMMENTS:

- The Editors of Obstetrics & Gynecology are seeking to increase transparency around its peer-review process, in line with efforts to do so in international biomedical peer review publishing. If your article is accepted, we will be posting this revision letter as supplemental digital content to the published article online. Additionally, unless you choose to opt out, we will also be including your point-by-point response to the revision letter. If you opt out of including your response, only the revision letter will be posted. Please reply to this letter with one of two responses:
  A. OPT-IN: Yes, please publish my point-by-point response letter.
  B. OPT-OUT: No, please do not publish my point-by-point response letter.

  We acknowledge that if the article is accepted the Editors will post this revision letter as supplemental digital content. We would like to OPT-IN for our point-by-point responses to the revision letter being published.

- As of December 17, 2018, Obstetrics & Gynecology has implemented an "electronic Copyright Transfer Agreement" (eCTA) and will no longer be collecting author agreement forms. When you are ready to revise your manuscript, you will be prompted in Editorial Manager (EM) to click on "Revise Submission." Doing so will launch the resubmission process, and you will be walked through the various questions that comprise the eCTA. Each of your coauthors will receive an email from the system requesting that they review and electronically sign the eCTA.

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

  We have confirmed that disclosures are correctly listed on the manuscript's title page.

- 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.

  As requested, we have added this statement to the cover letter.

- Clinical trials submitted to the journal as of July 1, 2018, must include a data sharing statement. The statement should indicate 1) whether individual deidentified participant data (including data dictionaries) will be shared; 2) what data in particular will be shared; 3) whether additional, related documents will be

available (eg, study protocol, statistical analysis plan, etc.); 4) when the data will become available and for how long; and 5) by what access criteria data will be shared (including with whom, for what types of analyses, and by what mechanism). Responses to the five bullet points should be provided in a box at the end of the article (after the References section).

Thank you, this is included on page 35.

- All submissions that are considered for potential publication are run through CrossCheck for originality. The following lines of text match too closely to previously published works.

  Please add variance to lines 145-154 (We created a text message…to fathers).

  We have edited the language as requested on page 8 (lines 194-204).

- Standard obstetric and gynecology data definitions have been developed through the reVITALize initiative, which was convened by the American College of Obstetricians and Gynecologists and the members of the Women's Health Registry Alliance. Obstetrics & Gynecology has adopted the use of the reVITALize definitions. Please access the obstetric and gynecology data definitions at https://www.acog.org/About-ACOG/ACOG-Departments/Patient-Safety-and-Quality-Improvement/reVITALize. If use of the reVITALize definitions is problematic, please discuss this in your point-by-point response to this letter.

  We have reviewed the list of standard definitions. Our only variation is in the exact definition of GWG. ACOG recommends using last recorded gestational weight minus last recorded weight prior to pregnancy. In order to best standardize GWG between the pre/post intervention groups, we used first trimester weight given that pre-pregnancy weights were not available for many women. We have described our calculation method for GWG in detail on page 10 (lines 253-256).

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

  We have confirmed the word count is within the required limit.

- Specific rules govern the use of acknowledgments in the journal. Please note the following guidelines:
  * All financial support of the study must be acknowledged.
  * Any and all manuscript preparation assistance, including but not limited to topic development, data collection, analysis, writing, or editorial assistance, must be disclosed in the acknowledgments. Such acknowledgments must identify the entities that provided and paid for this assistance, whether directly or indirectly.
  * All persons who contributed to the work reported in the manuscript, but not sufficiently to be authors, must be acknowledged. Written permission must be obtained from all individuals named in the acknowledgments, as readers may infer their endorsement of the data and conclusions. Please note that your response in the journal's electronic author form verifies that permission has been obtained from all

named persons.
* If all or part of the paper was presented at the Annual Clinical and Scientific Meeting of the American College of Obstetricians and Gynecologists or at any other organizational meeting, that presentation should be noted (include the exact dates and location of the meeting).

All financial support for the study is included on page 1. All persons who contributed to the work in the manuscript are either listed as authors, or are acknowledged with their permission.

- 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.

  We have carefully reviewed the abstract to make sure it matches the text, and is within the word count.

- 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 confirmed there are no abbreviations or acronyms in the title or précis. Abbreviations and acronyms have been spelled out the first time in the abstract and body of the manuscript. Some acronyms have been removed per the guidance that only standard abbreviations and acronyms are allowed.

- 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 the symbol (/) from sentences with words.

- In your Abstract, manuscript Results sections, and tables, the preferred citation should be in terms of an effect size, such as odds ratio or relative risk or the mean difference of a variable between two groups, expressed with appropriate confidence intervals. When such syntax is used, the P value has only secondary importance and often can be omitted or noted as footnotes in a Table format. Putting the results in the form of an effect size makes the result of the statistical test more clinically relevant and gives better context than citing P values alone.

  If appropriate, please include number needed to treat for benefits (NNTb) or harm (NNTh). When comparing two procedures, please express the outcome of the comparison in U.S. dollar amounts. Please standardize the presentation of your data throughout the manuscript submission. For P values, do not

exceed three decimal places (for example, "P = .001"). For percentages, do not exceed one decimal place (for example, 11.1%").

We have confirmed the paper meets the above specifications.

- 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.

  We have confirmed the table meets the above specifications and conforms with the journal style.

- Figures

  Figure 1: Okay, please resubmit current file with the revision.

  Figure 2: Please upload a high res version of this image (tiff, eps, jpeg). Please provide a letter of permission to use this in print and electronic formats.

  Figure 3: Okay, please resubmit current file with the revision.

  We have added a supplemental figure (Appendix 3). All files are included with the revision. We have added permission to use and print Figure 2 and Appendix 3 in the cover letter.

- Authors whose manuscripts have been accepted for publication have the option to pay an article processing charge and publish open access. With this choice, articles are made freely available online immediately upon publication. An information sheet is available at http://links.lww.com/LWW-ES/A48. The cost for publishing an article as open access can be found at http://edmgr.ovid.com/acd/accounts/ifauth.htm.
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  * A confirmation that you have read the Instructions for Authors (http://edmgr.ovid.com/ong/accounts/authors.pdf), and
  * A point-by-point response to each of the received comments in this letter.

  If you submit a revision, we will assume that it has been developed in consultation with your co-authors and that each author has given approval to the final form of the revision.

  We have added confirmation that we have read the Instructions for Authors to the cover letter, and have included a point-by-point response to all comments.