Date: Oct 12, 2018
To: "Han-Yang Chen" [redacted]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-18-1726

RE: Manuscript Number ONG-18-1726

Maternal and Neonatal Morbidity among Low-Risk Nulliparous Women at 39 to 41 Weeks

Dear Dr. Chen:

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 Nov 02, 2018, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1: Maternal and Neonatal Morbidity among Low-Risk Nulliparous women at 39-41 weeks

Authors used a large national database US Vital Statistics Data from 2011-2015 reported by CDC 2011-2015

Compared composite maternal and neonatal morbidity at 39,40,41 weeks

Can you explain definition of 39 weeks and how you categorized the week assigned to the patient. Example is 39 weeks 39-0/7-39-6/7 weeks? was 40 weeks 40-0/7-40-6/7 weeks and was 41 weeks 41-0/7-41-6/7 weeks. This description is important. Explain how you took a continuous variable and codified it into a categorical variable

Materials and Methods: your definition of composite maternal morbidity is somewhat troubling to me: 1 ICU admission, maternal blood transfusion ruptured uterus or unplanned hysterectomy. You have combined mild and severe in unusual ways. Severe maternal morbidity (SMM) includes unexpected outcomes of labor and delivery that result in significant short- or long-term consequences to a woman's health.

It is well know that transfusion is driving the SMM rate nationwide. Transfusion is common enough that it doesn't need to be in a composite score unless you define it as >4 units which is less common. Why any transfusion and not >4 units as in an SMM. There were no neuro, pulmonary, sepsis indications unless the intent was to use ICU as a surrogate. Given that women end up in the ICU for all sorts of reasons and often more than one reason.

Example an ICU admission because of an unplanned hysterectomy or severe hemorrhage would this count as one or two complications.In other words could one patient be counted more than one complication?

Neonatal comorbidity: Please explain how you found the data for death less than 27 days. Is it on a birth certificate?

The composite morbidities do not seem to paint a comprehensive clinical picture and seem more happenstance than deliberate

Discussion: Needs to be developed

Clinical Perspective on the noted increase in morbidity would be an excellent translation for the reader. Example For every week of gestation blood transfusion of any kind increased from 1.89 per 1000 women at 39 weeks to 2.29 at 40 weeks to 3.07 at 41 weeks. Can you discuss the clinical significance of this? How does this relate to a 1.6% overall transfusion rate in pregnancy in all women. This does not even equate into 1/1000 increase in risk each week. We need to be careful how

we talk about risk

What were the major contributors to each of the composite score for both the mother and baby: please discuss and give some perspective. The increases are small from week to week and although they are statistically significant we must translate this for the reader into a clinical significance. How many were ICU vs blood transfusion

Could gestational age be a surrogate for a combined maternal/fetal genetic advantage in evolution. In other words the pregnancies that are easiest and most natural will deliver at 39+ weeks

Does delivering at 39 weeks through IOL really change the maternal-fetal outcomes or will the unanticipated outcomes be worse than the small increase in risk seen with each week

Will we see more chorioamnionitis, more antibiotic use, more c Difficile, more unintended harm from prolonged LOS instead of IOL is testing women starting at 38 weeks, doing an ultrasound looking at fluid and Doppler's an alternative to mitigation of neonatal risk

Since clinically we speak in weeks and days and do not lump all comers into a week, a more continuous variable approach. Does risk change every day just a little.

Reviewer #2: This is a population-based cohort study using data from the U.S. vital statistics dataset (2011-2015), where births from low-risk nulliparous women who labored (and ultimately had a vaginal delivery or cesarean delivery) were compared based on the gestational age at delivery (39 to 41 weeks). This data was adjusted for maternal age, race/ethnicity, education, marital status, pre-pregnancy BMI, prenatal care, smoking, infant sex, and delivery year. Only births that were reported using updated 2003 revision of birth certificates were used. Composite maternal and neonatal morbidity were significantly higher with delivery at 40 and 41 weeks as compared to 39 weeks.

1. Novelty: Though there are other articles that attempt to answer questions like these, they are either randomized trials that are much smaller in size or other observational studies that use a slightly different cohort.

2. Methodology:

i. From the methods section, it is unclear if patients that presented laboring with malpresentation (i.e. breech) were excluded. Given the potential risks with such a cohort, it may be worthwhile to exclude these.

ii. The methods section does not describe what dating criteria were used to assess for gestational age at time of delivery; as this is a large public dataset, I recognize this information may not be available. In my opinion, this should be cited as a limitation of this study.

iii. Why do you believe that the composite neonatal morbidity was so much higher in this study than what was cited in the ARRIVE trial?

iv. Given that maternal obesity is tied to various poor maternal outcomes, is it possible for the data to be further adjusted for class of obesity (class I, II, III)?

3. Significance: This study is interesting and helps to provide relevant data that clinicians can use when attempting to counsel low-risk patients on elective labor induction vs expectant management at term.

4. Presentation:

i. There were several grammatical errors noted throughout the text that should be corrected in order to minimize distractions to the reader. A few examples include:

a. On line 63, hysterectomy is misspelled.
b. On line 142, the section should be entitled "Discussion"
c. On line 155, the word "to" is seen twice in a row.

ii. The manuscript is an appropriate length to convey the information.

iii. In Table 2 (as well as the body of the text, I would use the term "uterine rupture" rather than "ruptured uterus."

iv. In Figure 1, I would consider changing the title of the figure to something more descriptive than the term "flow chart" (i.e. Eligibility and study sample size).

v. Number and quality of references seems appropriate.

Reviewer #3: This manuscript addresses some areas of weakness in the ARRIVE trial in that the rarer outcomes were difficult to assess. By using birth certificate data over a 5 year period, this allowed for significant improvement in the

evaluation of the rare outcomes (hysterectomy, seizures, death). While this data set is likely the only way to fully explore these data in a national setting, it does present some limitations that were well addressed in the discussion section, e.g.- limitations of data collected, variability in the states mandated information on the birth certificate, induction vs. expectant management and applicability to multiparous patients.

I found this manuscript to be timely, topical and supports the information presented in the ARRIVE trial so, in that way, it is not novel but complementary.

One area that is difficult to read is the section on page 9 line 122-124 where a double negative is unclear.

I do question have some hesitation regarding some of the outcomes and the accuracy of the information that can be obtained from birth certificate data regarding in particular the number of hysterectomies and the rate of transfusion. The rate of overall transfusion was only listed at 0.22%, which is surprising given the hemorrhage risk has been quoted as between 5-15%. This likely is associated with under reporting on birth certificates, but there should be no significant difference between the groups that I could see. Additionally, it is surprising that the number of hysterectomies for this time frame is also 408, 0.01%), understanding that these are low risk nullips. Despite this, I do not see an easy alternative for evaluating these rare outcomes other than a country with a national birth registration database (eg- Netherlands, UK).

Reviewer #4: Chen et al present the results of a large cohort study utilizing US national birth certificate data to determine the association of maternal and neonatal morbidity among healthy nulliparous women who deliver at 39, 40, and 41 weeks' gestation. The authors find increasing rates of cesarean delivery, composite maternal morbidity and composite neonatal morbidity with advancing gestation of delivery.

Furthermore, significant relationships were seen among many of the individual components that made up the composite outcome. The authors conclude that these findings, when used together with other recent studies, can help counseling patients regarding delivery timing and induction.

Questions and comments for the authors.

1. The data from this cohort are quite impression. The mode of delivery findings support the findings seen in the ARRIVE trial and due to the large number of subjects included, you were able to make conclusions regarding maternal and neonatal outcomes. Importantly, many of the outcomes demonstrate a dose-response of such with gestational age of delivery. I appreciate that you appropriately acknowledge the limitations of the 'induction' label in the revised birth certificate data. It is my understanding from reference 20 that the included study variables and outcomes are more valid in birth certificate data. Would it be helpful to the readers to report the "accuracy" in birth certificate data regarding the reported variables?

2. How were your covariates in your regression model chosen? Many of these variables differed on univariate analysis by gestational age of delivery. Were these chosed a priori or following univariate analysis.

3. What proportion of the population were coded as "unknown" for pre-pregnancy BMI, prenatal care, and smoking during pregnancy? It may be helpful to readers to report this rate such that they can get an idea on the potential impact of this.

STATISTICAL EDITOR COMMENTS:

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

Table 1: Need to enumerate all missing or unknown characteristics (eg, Maternal Race/Ethnicity)

Table 2: There were some missing data for the maternal morbidities listed. Should enumerate all missing data. (especially important if missing data were more clustered in 41 wk cohort) The samples are larger and the counts of adverse events are also. However, there were 10 covariates used as adjustors, so for some of the aRRs, the model is likely over fitted (eg, 41 wk ruptured uterus (n = 46) or 41 wk unplanned hysterectomy (n = 87)). In the first case, it is NS anyway, but in the second case, should be cited as limitation to generalizing from these data.

Table 3: Again, some data were missing for neonatal morbidities and those should all be enumerated. (especially important if missing data were more clustered in 41 wk cohort).

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.

- Mention the composite outcomes in your methods. Also mention as requested by one reviewer how "weeks' are defined.

- If you are going to report outcomes at 40 and 41 weeks separately, then please give us the % in each gestational age group and don't lump 40-41 weeks. If you are "lumping" them in your analysis, then indicate that in methods.

- While you do show an apparent "dose response" for the composite outcome, please temper your conclusions based on the small effect sizes. (Please note that effect sizes (RR, OR) within the zone of potential bias should be noted as weak. Those effect sizes in the zone of potential interest should be emphasized. (Ref: False alarms and pseudo-epidemics. The limitations of observational epidemiology. Grimes DA, Schulz KF. Ob Gyn 2012;120:920-7)

- Do you have primary and secondary outcomes? IF so, please state.

- perfectly stated. Thanks.

- again, please state what you mean be weeks. (39 wk 0 - 39 wk 6 days?) etc

- Did you consider looking at fetal deaths?

- Any transfusion? Why did you pick these morbidities? Why not use the CDC definition?

- 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.

- This would be more clearly written by just giving the rates at the different gestational ages first and then if you want to add the."18% higher" comparisons, do that. For instance, "The overall rate of composite maternal morbidity in the three gestational age categories were 2.76/1,000 live births (39 weeks), 2,82/1000 live births (40 weeks) and 3.67/1,000 live births (41 weeks).

- Same structure as above for maternal composite outcomes

- When delivery occured after 39 weeks, the rate of ...

- pleasE put this in context. Similar to ARRIVE data? Cesarean rate is not one of your stated outcomes--while its important data, it shouldn't be your leading statement in your results or your discussion. these should be organized with primary outcome then secondary outcomes presented in that order.

- why didn't you include all of these or did you consider admit to NICU and intubation x 6 hours or more to be surrogates for meconium aspiration? Or were these not part of the birth certificate data?

- Important to reiterate here that the differences are quite small--yes, present but not large absolute differences.

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. 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. 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.

5. 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.

6. Please note your potential 2019 SMFM presentation on the title page of the revised manuscript. If it is accepted, please let the Editorial Office know as soon as possible.

7. 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).

8. 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.

9. 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.

10. 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.

11. 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.

12. 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.

13. 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 Nov 02, 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

November 7, 2018

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

RE: Manuscript Number ONG-18-1726
Maternal and Neonatal Morbidity among Low-Risk Nulliparous Women at 39 to 41 Weeks (Revised title: Neonatal and Maternal Morbidity among Low-Risk Nulliparous Women at 39 to 41 Weeks)

Dear Dr. Chescheir:

Thank you kindly for considering the above-mentioned manuscript for publication in *Obstetrics & Gynecology*.

Per reviewers' comments, we have revised the manuscript. In the following pages, you will find our point-by-point response to the suggestions by reviewers. We are attaching:

1. Revised manuscript (with references and tables) with track changes
2. Clean copy of the manuscript (with references and tables)
3. Figure file

Please note that in the comments below, the reference to "line_____" refers to manuscript with track changes and not the clean copy.

"The lead author (OAB) 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." Dr Ashimi Balogun is manuscript's guarantor. In addition, we will "OPT-IN" to publish the response letter and subsequent email correspondence related to author queries.

Please also note that the abstract of this paper was accepted for a poster presentation at 2019 SMFM. We truly appreciate the opportunity to publish our work in your journal and please do not hesitate contact me with any questions or concerns.

Sincerely,

Han-Yang Chen, PhD

REVIEWER COMMENTS:

Reviewer #1: Maternal and Neonatal Morbidity among Low-Risk Nulliparous women at 39-41 weeks.

Authors used a large national database US Vital Statistics Data from 2011-2015 reported by CDC 2011-2015

Compared composite maternal and neonatal morbidity at 39,40,41 weeks

1. Can you explain definition of 39 weeks and how you categorized the week assigned to the patient. Example is 39 weeks 39-0/7-39-6/7 weeks? was 40 weeks 40-0/7-40-6/7 weeks and was 41 weeks 41-0/7-41-6/7 weeks. This description is important. Explain how you took a continuous variable and codified it into a categorical variable

Response: We appreciate the reviewer's question regarding the definition of 39-41 weeks. We utilized the Period Linked Birth-Infant Death Data Files of U.S. Vital Statistics Data from 2011-2015, assembled by the National Center for Health Statistics and provided by the Centers for Disease Control and Prevention (CDC). In the dataset, the variable of gestational age was already categorized into weeks (for example, 39 weeks include 39-0/7 - 39-6/7 weeks). The dataset does not provide data of gestational age in days.

In the revised manuscript, we have responded to this question and another one by a reviewer by adding the following in the Methods (lines 108-112): The 2003 revision of the birth certificate replaced the "clinical estimate of gestation" with the "obstetric estimate of gestation." Detailed information of the methods for this obstetric estimate of gestation can be found elsewhere.14 The obstetric estimate of gestation is reported in completed weeks (i.e., 39 weeks includes deliveries from 39 weeks 0 days through 39 weeks 6 days).

2. Materials and Methods: your definition of composite maternal morbidity is somewhat troubling to me: 1 ICU admission, maternal blood transfusion ruptured uterus or unplanned hysterectomy. You have combined mild and severe in unusual ways. Severe maternal morbidity (SMM) includes unexpected outcomes of labor and delivery that result in significant short- or long-term consequences to a woman's health.

It is well know that transfusion is driving the SMM rate nationwide. Transfusion is common enough that it doesn't need to be in a composite score unless you define it as >4 units which is less common. Why any transfusion and not >4 units as in an SMM. There were no neuro, pulmonary, sepsis indications unless the intent was to use ICU as a surrogate. Given that women end up in the ICU for all sorts of reasons and often more than one reason.
Example an ICU admission because of an unplanned hysterectomy or severe hemorrhage would this count as one or two https://urldefense.proofpoint.com/v2/url?u=http-3A__complications.In&d=DwIGaQ&c=6vgNTiRn9_pqCD9hKx9JgXN1VapJQ8JVoF8oWH1AgfQ&r=

VJpPTo49T-0x_4_RRjEU3b5lnUBHGdeCz2XaTZN6HUE&m=8nP3Al3G5AJ42ac_JzARFQa2tXqA2YlXJuaySLXJjgM&s=qPwYd-atM5NtPBnkE2Zhab8bhfbmb9xt8gwupWsMmbA&e= other words could one patient be counted more than one complication?

Response: While severe morbidity may be defined as the reviewer suggests, we note that that there is variation in researchers' selection of the composite, which may be due to the topic, the rate of adverse outcomes, and the available data. The birth certificate, for example, does not provide the number of units transfused. Undeniably, the morbidity with transfusion of four units is worse than with one unit. Nevertheless, it is noteworthy that neither in the ARRIVE trial nor the current TXA trial (https://clinicaltrials.gov/ct2/show/NCT03364491) for prevention of postpartum hemorrhage during cesarean delivery defines adverse outcome as transfusion of at least four units of PRBC. Also, transfusion of four units or more is not the definition for maternal morbidity used in our study or the only approach to identifying maternal morbidity.

To address this concern of the reviewer we have revised the manuscript in the following manner:

1. **A sensitivity analysis of composite maternal morbidity without any transfusion also indicates that the adverse outcome for women who deliver at 40 and 41 weeks are higher than those that deliver at 39 weeks (Supplementary Table 1). This statement is in lines 196-197**
2. **Women or newborn with more than one morbidity were counted once. We have added the following (lines 120-121): "For determining the frequency of occurrence for both composites, newborns or women with more than one outcome were counted only once."**

3. Neonatal comorbidity: Please explain how you found the data for death less than 27 days. Is it on a birth certificate?

Response: We used the Period Linked Birth-Infant Death Data Files of U.S. Vital Statistics Data from 2011-2015, assembled by the National Center for Health Statistics and provided by the Centers for Disease Control and Prevention (CDC). In brief, infant deaths were linked to their corresponding birth certificates. The datasets provide a variable called "Age at Death in Days", which was used for categorized death less than 27 days.

In response to this question, we have added the following (lines 116-118): The determination of death within 27 days was made by linking birth and death certificates (which has the variable "Age at Death in Days").

4. The composite morbidities do not seem to paint a comprehensive clinical picture and seem more happenstance than deliberate

Response: As we have noted, we believe our composite morbidity outcome is not happenstance, but is a reasonable reflection – for this analysis – of the morbidity that accrues to women and children.

5. Discussion: Needs to be developed Clinical Perspective on the noted increase in morbidity would be an excellent translation for the reader. Example For every week of gestation blood transfusion of any kind increased from 1.89 per 1000 women at 39 weeks to 2.29 at 40 weeks to 3.07 at 41 weeks. Can you discuss the clinical significance of this? How does this relate to a 1.6% overall transfusion rate in pregnancy in all women. This does not even equate into 1/1000 increase in risk each week. We need to be careful how we talk about risk

Response: We appreciate the reviewer's comment that the rate of adverse outcomes is low, even if it increases significantly from 39 to 41 weeks. In response to this point, we have added the following in the discussion section (lines 245-249): "Even if the rate of actual morbidity is low among uncomplicated nullilparous, it is clinically important. The number of low-risk nulliparous women who deliver annually in the U.S. is upwards of 800,000,[1-4] and thus this low frequency will still result in a substantial number of individuals affected by a significantly morbid condition. As the results of ARRIVE trial[11] and observational studies[3,17,20] suggest, the chance of these adverse outcomes is modifiable."

6. What were the major contributors to each of the composite score for both the mother and baby: please discuss and give some perspective. The increases are small from week to week and although they are statistically significant we must translate this for the reader into a clinical significance. How many were ICU vs blood transfusion.

Response: In Tables 2 and 3 we provide the contribution of each component to the composite

7. Could gestational age be a surrogate for a combined maternal/fetal genetic advantage in evolution. In other words the pregnancies that are easiest and most natural will deliver at 39+ weeks.

Response: The data from US Vital Statistic does not permit such an understanding and any understanding would be purely speculative. Thus, for this point, we would prefer not to modify our manuscript. Nevertheless, we would note that this speculation would not seem to be supported by the data, given that women who deliver after 39 weeks seem to have worse outcomes (which does not seem to reflect the "easiest" pregnancies).

8. Does delivering at 39 weeks through IOL really change the maternal-fetal outcomes or will the unanticipated outcomes be worse than the small increase in risk seen with each week. Will we see more chorioamnionitis, more antibiotic use, more c Difficile, more unintended harm from prolonged LOS instead of IOL is testing women starting at 38 weeks, doing an ultrasound looking at fluid and Doppler's an alternative to mitigation of neonatal risk.

Response: We appreciate the reviewer's concerns about induction of labor unexpectedly altering maternal-neonatal outcomes. The results of the multi-center randomized trial (reference #4 in the manuscript), however, do not seem to support the contention that labor induction alters the rate of chorioamnionitis, as it was similar among those who were induced (13.3%) and those managed expectantly (14.1%; P=0.35), and postpartum length of stay was actually lower in the labor induction group.

9. Since clinically we speak in weeks and days and do not lump all comers into a week, a more continuous variable approach. Does risk change every day just a little.

Response: We appreciate the reviewer's reminder that clinically we discuss a pregnancy in terms (pun intended) of weeks and days. However, the management of pregnancy is often determined by pregnancies categorized in weeks (e.g., preterm premature rupture of membranes, administration of antenatal corticosteroid, early vs. late term, and determination of SGA or LGA). Thus we think it is a reasonable approach and congruent with the form of the available data.

Reviewer #2: This is a population-based cohort study using data from the U.S. vital statistics dataset (2011-2015), where births from low-risk nulliparous women who labored (and ultimately had a vaginal delivery or cesarean delivery) were compared based on the gestational age at delivery (39 to 41 weeks). This data was adjusted for maternal age, race/ethnicity, education, marital status, pre-pregnancy BMI, prenatal care, smoking, infant sex, and delivery year. Only births that were reported using updated 2003 revision of birth certificates were used. Composite maternal and neonatal morbidity were significantly higher with delivery at 40 and 41 weeks as compared to 39 weeks.

1. Novelty: Though there are other articles that attempt to answer questions like these, they are either randomized trials that are much smaller in size or other observational studies that use a slightly different cohort.

Response: We appreciate the reviewer's observation regarding the nuanced differences between our manuscript and other publications on similar topic.

2. Methodology:

i. From the methods section, it is unclear if patients that presented laboring with malpresentation (i.e. breech) were excluded. Given the potential risks with such a cohort, it may be worthwhile to exclude these.

Response: We appreciate the reviewer's request to clarify if women with malpresentation who were laboring were excluded. They were not, as this is one occurrence that can happen at any gestational age and their inclusion represents actual overall outcomes for a given gestational age. That said, in order to demonstrate that this inclusion did not alter the observed association, a sensitivity analysis was done in which non-vertex presentations were

excluded. In this sensitivity analysis, results were the same as in the primary analysis (Supplementary Tables 2 and 3).

ii. The methods section does not describe what dating criteria were used to assess for gestational age at time of delivery; as this is a large public dataset, I recognize this information may not be available. In my opinion, this should be cited as a limitation of this study.

Response: See Reviewer 1, points 1 and 9.

iii. Why do you believe that the composite neonatal morbidity was so much higher in this study than what was cited in the ARRIVE trial?

Response: We appreciate the reviewer's insightful inquiry about why the composite neonatal morbidity in our study (8.8 per 1,000 livebirths) differed from that in the ARRIVE trial (55.6 per 1,000 births) – although in actuality it was much lower than in the ARRIVE trial. Most importantly, the inclusion criteria between the studies were different. The most common adverse event for ARRIVE was "respiratory support" (which occurred in 40.6 per 1,000 deliveries) and the corresponding event in our analysis was mechanical ventilation (as that was what was coded) which had a rate of 3.2 per 1,000 births. And, the data available in birth certificate do not permit us to calculate the identical primary composite outcome of ARRIVE trial. For example, the following primary outcomes in ARRIVE are not available with the data in birth certificates: meconium aspiration syndrome, hypoxic ischemic encephalopathy, neonatal infection, birth trauma, intracranial or subgaleal hemorrhage or hypotension requiring vasopressor support.

In response to this inquiry, we have added the following lines in the revised manuscript (lines 229-234): "The composite neonatal morbidity in our study (8.8 per 1,000 livebirths) was lower than that in the ARRIVE trial[11] (55.6 per 1,000 births). Not only were the inclusion criteria between the studies different, but the composite neonatal morbidity in our study differed from that in ARRIVE as well. In our analysis, although we chose outcomes that were thought to be clinical important, we were unable to determine the frequency of some clinically-relevant morbidities given that the data are not available in the birth certificate."

iv. Given that maternal obesity is tied to various poor maternal outcomes, is it possible for the data to be further adjusted for class of obesity (class I, II, III)?

Response: We appreciate the reviewer's comment regarding the potential association of class I, II or III obesity with the adverse outcomes. To answer this question, we performed sensitivity analysis to further adjust for class of obesity (class I, II, III). The results of the sensitivity analysis were consistent with the original results: the adverse neonatal and maternal outcomes are higher at 40 and 41 weeks than at 39 weeks (Supplementary Table 4).

3. Significance: This study is interesting and helps to provide relevant data that clinicians can use when attempting to counsel low-risk patients on elective labor induction vs expectant management at term.

Response: We truly appreciate the reviewer's comment about our manuscript.

4. Presentation:

i. There were several grammatical errors noted throughout the text that should be corrected in order to minimize distractions to the reader. A few examples include:

Response: Our sincere apologies for the grammatical errors. We have reviewed the manuscript carefully and made the corrections as noted below.

a. On line 63, hysterectomy is misspelled.

b. On line 142, the section should be entitled "Discussion"

c. On line 155, the word "to" is seen twice in a row.

ii. The manuscript is an appropriate length to convey the information

Response: We truly appreciate the reviewer's comment about the appropriate length of the manuscript.

iii. In Table 2 (as well as the body of the text, I would use the term "uterine rupture" rather than "ruptured uterus."

Response: We have replaced the term "ruptured uterus" with "uterine rupture" throughout the manuscript and tables.

iv. In Figure 1, I would consider changing the title of the figure to something more descriptive than the term "flow chart" (i.e. Eligibility and study sample size).

Response: We have revised the Figure Legend and now it states:

Figure 1. Flow chart of live births in the U.S. (2011-2015): <u>Eligibility and sample size</u> (underlined the revised phrase).

v. Number and quality of references seems appropriate.

Response: We truly appreciate the reviewer's comment about the nature of references.

Reviewer #3: This manuscript addresses some areas of weakness in the ARRIVE trial in that the rarer outcomes were difficult to assess. By using birth certificate data over a 5 year period, this allowed for significant improvement in the evaluation of the rare outcomes (hysterectomy, seizures, death). While this data set is likely the only way to fully explore these data in a national setting, it does present some limitations that were well addressed in the discussion section, e.g.- limitations of data collected, variability in the states mandated information on the birth certificate, induction vs. expectant management and applicability to multiparous patients.

1. I found this manuscript to be timely, topical and supports the information presented in the ARRIVE trial so, in that way, it is not novel but complementary.

Response: We truly appreciate the reviewer's nuanced understanding of the manuscript: A supplement to the findings of ARRIVE, in spite some acknowledged shortcomings of the birth certificate data.

2. One area that is difficult to read is the section on page 9 line 122-124 where a double negative is unclear.

Response: We appreciate the reviewer's concerns with double negative in lines 122-124. We have revised the manuscript in the following manner (lines 169-171): "Women delivered at 39 weeks were more likely to be younger (< 35 years of age), of minority race, and have lower education, but they were less likely to be married, or overweight or obese."

3. I do question have some hesitation regarding some of the outcomes and the accuracy of the information that can be obtained from birth certificate data regarding in particular the number of hysterectomies and the rate of transfusion. The rate of overall transfusion was only listed at 0.22%, which is surprising given the hemorrhage risk has been quoted as between 5-15%. This likely is associated with under reporting on birth certificates, but there should be no significant difference between the groups that I could see. Additionally, it is surprising that the number of hysterectomies for this time frame is also 408, 0.01%), understanding that these are low risk nullips. Despite this, I do not see an easy alternative for evaluating these rare outcomes other than a country with a national birth registration database (eg- Netherlands, UK).

Response: We truly appreciate the thoughtful comments by the reviewer regarding the low rate of adverse among the uncomplicated nulliparous, and that these rates do not reflect the national rates.

In response to the reviewer's comments we have added the following (lines 263-266): "Third, our results may not be applicable to low risk parous women or to high-risk pregnancies. Thus, the rate of composite maternal and neonatal morbidity described here should not be generalized to the national rate of adverse outcomes."

Reviewer #4: Chen et al present the results of a large cohort study utilizing US national birth certificate data to determine the association of maternal and neonatal morbidity among healthy nulliparous women who deliver at 39, 40, and 41 weeks' gestation. The authors find increasing rates of cesarean delivery, composite maternal morbidity and composite neonatal morbidity with advancing gestation of delivery.

Furthermore, significant relationships were seen among many of the individual components that made up the composite outcome. The authors conclude that these findings, when used together with other recent studies, can help counseling patients regarding delivery timing and induction.

Response: We appreciate the succinct summary of our manuscript.

Questions and comments for the authors.

1. The data from this cohort are quite impression. The mode of delivery findings support the findings seen in the ARRIVE trial and due to the large number of subjects included, you were able to make conclusions regarding maternal and neonatal outcomes. Importantly, many of the outcomes demonstrate a dose-response of such with gestational age of delivery. I appreciate that you appropriately acknowledge the limitations of the 'induction' label in the revised birth certificate data. It is my understanding from reference 20 that the included study variables and outcomes are more valid in birth certificate data. Would it be helpful to the readers to report the "accuracy" in birth certificate data regarding the reported variables?

RESPONSE: We believe we have addressed the most important issue regarding validity (i.e., induction of labor). It would be quite lengthy (and beyond the scope of this manuscript) to detail the validity of the many variables and outcomes examined, but we have provided a reference that can convey that information for interested readers.

2. How were your covariates in your regression model chosen? Many of these variables differed on univariate analysis by gestational age of delivery. Were these chosen a priori or following univariate analysis.

Response: We choose these covariates a priori as they are known potential confounders. We then conducted univariate analysis to further examine the association.

3. What proportion of the population were coded as "unknown" for pre-pregnancy BMI, prenatal care, and smoking during pregnancy? It may be helpful to readers to report this rate such that they can get an idea on the potential impact of this.

Response: We appreciate the reviewer's inquiry about the proportion of the data that was unknown. The proportion of the population that was coded as "unknown" for pre-pregnancy BMI, prenatal care, and smoking during pregnancy has been presented in Table 1. There were

3.5% in pre-pregnancy BMI, 3.1% in prenatal care, and 3.9% in smoking during pregnancy. We have included this information the results section (lines 168-169 and Table 1).

STATISTICAL EDITOR COMMENTS:

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

Table 1: Need to enumerate all missing or unknown characteristics (eg, Maternal Race/Ethnicity)

Response: We appreciate the Statistical Editor's request to enumerate the unknown proportion among the demographics. For maternal characteristics, missing data were categorized and analyzed as "unknown" group and are presented in Table 1: maternal race/ethnicity (0.8%), maternal education (1.1%), prenatal care (3.1%), smoking during pregnancy (3.9%), pre-pregnancy BMI (3.5%). We have included this information in the revised manuscript (lines 168-169 and Table 1).

Table 2: There were some missing data for the maternal morbidities listed. Should enumerate all missing data. (especially important if missing data were more clustered in 41 wk cohort) The samples are larger and the counts of adverse events are also. However, there were 10 covariates used as adjustors, so for some of the aRRs, the model is likely over fitted (eg, 41 wk ruptured uterus (n = 46) or 41 wk unplanned hysterectomy (n = 87)). In the first case, it is NS anyway, but in the second case, should be cited as limitation to generalizing from these data.

Response: We appreciate the Statistical Editor's request about clarification of missing data with maternal morbidities. For maternal morbidities, missing data were 0.11% (n=3,595) for all individual morbidities and 0.11% (n=3,595) for composite maternal morbidity. There was no meaningful difference (standardized difference <0.1) in missing data between 39, 40, 41 gestational weeks. We have included this information in the revised manuscript (lines 188-190).

	GA			
Morbidity	**39**	**40**	**41**	**Total**
Composite maternal morbidity	**0.10**	**0.11**	**0.13**	**0.11**
Maternal transfusion	**0.10**	**0.11**	**0.13**	**0.11**
Ruptured uterus	**0.10**	**0.11**	**0.13**	**0.11**
Unplanned hysterectomy	**0.10**	**0.11**	**0.13**	**0.11**
Admission to ICU	**0.10**	**0.11**	**0.13**	**0.11**

Our multivariable regression models included data from 39-41 weeks; GA was used as the exposure variable, and the numbers of our maternal morbidity outcomes ranged from 408 to

9,103. Therefore, model over-fit was less of a concern. Since our aim was to compare outcome between GA weeks, we did not perform a subgroup analysis only within a specific GA (for example, 41 wk), as reviewer commented.

Table 3: Again, some data were missing for neonatal morbidities and those should all be enumerated. (especially important if missing data were more clustered in 41 wk cohort).

Response: For neonatal morbidities, missing data ranged 0% - 0.27% (n=8,901) for individual morbidity, and 0.35% (n=11,418) for composite neonatal morbidity. There was no meaningful difference (standardized difference <0.1) in missing data between 39, 40, 41 gestational weeks. We have included this information in the revised manuscript (lines 178-181).

	GA			
Morbidity	**39**	**40**	**41**	**Total**
Composite neonatal morbidity	**0.32**	**0.36**	**0.36**	**0.35**
Assisted ventilation > 6 hours	**0.07**	**0.08**	**0.10**	**0.08**
Neonatal seizure	**0.07**	**0.08**	**0.10**	**0.08**
Apgar score < 5 at 5 minutes	**0.25**	**0.29**	**0.27**	**0.27**
Neonatal Death	**0.00**	**0.00**	**0.00**	**0.00**

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: We appreciate the Editor's request to keep the objective in the abstract succinct. We have deleted the background in the objective and begin with the "To use a large national database to compare composite maternal or neonatal morbidity among low-risk full-term women (lines 34-36)."

- Mention the composite outcomes in your methods.

Response: We appreciate the Editor's request to mention the composite maternal and neonatal outcomes in the abstract. We have done so in lines 41-45.

-Also mention as requested by one reviewer how "weeks' are defined.

Response: We appreciate the Editor's request to describe what the gestational age by week entails. We added a sentence in the abstract (lines 40-41): (as reported in completed weeks; e.g., 39 weeks include 39+0 – 39+6 weeks).

- If you are going to report outcomes at 40 and 41 weeks separately, then please give us the % in each gestational age group and don't lump 40-41 weeks. If you are "lumping" them in your analysis, then indicate that in methods.

Response: We appreciate the Editor's request to clarify the results in the abstract about the proportion of deliveries at various gestational ages. In the revised manuscript, we added (lines 50-51): "Of 19.8 million live births during the study interval, 3.3 million met inclusion criteria: 43.5% delivered at 39 weeks, 41.4% at 40 weeks, and 15.1% at 41 weeks."

- While you do show an apparent "dose response" for the composite outcome, please temper your conclusions based on the small effect sizes. (Please note that effect sizes (RR, OR) within the zone of potential bias should be noted as weak. Those effect sizes in the zone of potential interest should be emphasized. (Ref: False alarms and pseudo-epidemics. The limitations of observational epidemiology. Grimes DA, Schulz KF. Ob Gyn 2012;120:920-7)

Response: We appreciate the Editor's suggestion that we temper the conclusion in that the increase in composite neonatal and maternal morbidity is modest. We have revised the last sentence of the abstract by adding two key words (underlined here but not in the revised manuscript) (lines 61-63): Among low-risk nulliparous women, the rate of composite neonatal and maternal morbidity increases, albeit modestly, from 39 through 41 weeks' gestation.

- Do you have primary and secondary outcomes? IF so, please state.

Response: We appreciate the Editor's suggestion that we identify primary and secondary outcomes. Throughout the manuscript, we note that the primary outcome was composite neonatal morbidity and the secondary outcome was the composite maternal morbidity (Lines 41-45, 83-85, 114-120). Additionally, to emphasize the primary outcome we have revised the manuscript to mention composite neonatal morbidity before describing maternal adverse outcome. Lastly, we have rearranged tables so as to have the primary outcome before the secondary outcome.

- perfectly stated. Thanks.

Response: We appreciate the Editor's compliment!

- again, please state what you mean be weeks. (39 wk 0 - 39 wk 6 days?) etc.

Response: See Reviewer 1, points 1.

- Did you consider looking at fetal deaths?

Response: We appreciate the Editor's suggestion on why we did not include stillbirth in the outcome. We used the Period Linked Birth-Infant Death Data Files that only include live births, which provide the data for our primary and secondary outcomes of neonatal and maternal morbidity variables. The Fetal Death Data Sets provided by CDC do not include data for our primary and secondary outcomes.

- Any transfusion? Why did you pick these morbidities? Why not use the CDC definition?

Response: We appreciate the Editor's request for clarification about the minimum number of units of transfusion to qualify as a maternal morbidity. For our analysis, maternal blood transfusion from birth certificate data did qualify as a maternal morbidity. There are several reasons why we selected this variable as a secondary outcome.

First, the birth certificate does not provide the number of units transfused. Secondly, randomized trials accept transfusion of any units as an adverse outcome. The ARRIVE trial and the TXA trial (https://clinicaltrials.gov/ct2/show/NCT03364491) for prevention of postpartum hemorrhage during cesarean delivery, for example, accept transfusion of any blood product as an outcome. Third, while transfusion of four units or more has been used as one of the components of severe maternal morbidity that is not the focus of our study. Fourth, although CDC also defines "severe maternal morbidity" using ICD-9 and DRG codes, they are only feasible in hospital discharge data or claims data. Our study used Period Linked Birth-Infant Death Data Files that were based on birth certificate data which link to infant death data. Fifth, we did a sensitivity analysis and even when transfusion is removed from the composite maternal morbidity, the pattern of increasing rate of adverse outcomes persist for women who deliver at 40 and 41 weeks (lines 196-197 and Supplementary Table 1).

- 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: We appreciate the Editor's suggestion. In the revised manuscript, we have provided raw numbers, percentage, RR and 95% CI in the results section where applicable.

- This would be more clearly written by just giving the rates at the different gestational ages first and then if you want to add the."18% higher" comparisons, do that. For instance, "The overall rate of composite maternal morbidity in the three gestational age categories were 2.76/1,000 live births (39 weeks), 2,82/1000 live births (40 weeks) and 3.67/1,000 live births (41 weeks).

Response: As previously suggested by the Editor, we have used the raw numbers where applicable in conjunction with the sentence structure provided above. Thus, in the revised

manuscript (lines 186-188): "At 39 weeks, the overall rate was 2.39/1,000 live births (3,423/1,433,863); at 40 weeks, 2.82/1000 live births (3,852/1,365,967); and at 41 weeks, 3.67/1,000 live births (1,828/497,474)."

- Same structure as above for maternal composite outcomes

Response: As previously suggested by the Editor, we have used the raw numbers where applicable in conjunction with the sentence structure provided above. Thus, in the revised manuscript (lines 176-178): "At 39 weeks, the composite neonatal morbidity was 7.52/1,000 live births (10,754/1,430,610); at 40 weeks, 9.11/1000 live births (12,413/1,362,557) and; at 41 weeks, 11.63/1,000 live births (5,772/496,314).

- When delivery occured after 39 weeks, the rate of ...pleasE put this in context. Similar to ARRIVE data? Cesarean rate is not one of your stated outcomes--while its important data, it shouldn't be your leading statement in your results or your discussion. these should be organized with primary outcome then secondary outcomes presented in that order.

Response: The Editor makes an excellent point that the first paragraph of discussion section should focus on the primary and secondary outcomes and not on the cesarean rate, which is not the primary focus. We also need to acknowledge that though the rate of complications increase significantly between 39 to 41 weeks, the absolute risks are low.

In response to this suggestion, we have added the following in the first paragraph of the revised manuscript (lines 220-225): "Both overall composite neonatal and maternal morbidity, as well as most individual components of the composite outcomes, are significantly higher at 40 and 41 weeks than at 39 weeks. As expected among low-risk women, the absolute rate of adverse outcomes were low (less than 1%). The sensitivity analysis is supportive of the association of increasing neonatal and maternal morbidity with advancing gestational age from 39 to 41 weeks in low-risk nulliparous women."

- why didn't you include all of these or did you consider admit to NICU and intubation x 6 hours or more to be surrogates for meconium aspiration? Or were these not part of the birth certificate data?

Response: The Editor has a good question regarding the reasons for the selecting the components of the composite and if they were surrogate for meconium aspiration. In our study, the components of the composite were derived from biological plausibility of complications with continued pregnancy and the morbidity outcomes that were available from birth certificate data.

- Important to reiterate here that the differences are quite small--yes, present but not large absolute differences.

Response: The Editor has an excellent point that though the differences are significant, the absolute differences are small. We have emphasized this in the following sentences of the revised manuscript:

1. **In the conclusion of the abstract, we note (lines 61-63): "Among low-risk nulliparous women, the rate of composite neonatal and maternal morbidity increases, albeit modestly, from 39 through 41 weeks' gestation."**
2. **In the first paragraph of the discussion, we note (lines 222-224): ". As expected among low-risk women, the absolute rate of adverse outcomes were low (less than 1%). …"**
3. **In the last paragraph of the discussion section, we wrote (lines 271-273): "In conclusion, among low-risk nulliparous women who delivered from 39 through 41 weeks, the risks of neonatal and maternal morbidity, while uncommon, increases as gestational age advances."**

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. 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. 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 https://urldefense.proofpoint.com/v2/url?u=http-3A__links.lww.com_AOG_A515&d=DwIGaQ&c=6vgNTiRn9_pqCD9hKx9JgXN1VapJQ8JVoF8oWH1AgfQ&r=VJpPTo49T-0x_4_RRjEU3b5lnUBHGdeCz2XaTZN6HUE&m=8nP3Al3G5AJ42ac_JzARFQa2tXqA2YlXJuaySLXJjgM&s=3fBqg6LgHa1pvI6JDijtiWD9EG2cQOZ05vsBjjTgT6w&e=, and the gynecology data definitions are available at https://urldefense.proofpoint.com/v2/url?u=http-3A__links.lww.com_AOG_A935&d=DwIGaQ&c=6vgNTiRn9_pqCD9hKx9JgXN1VapJQ8JVoF8oWH1AgfQ&r=VJpPTo49T-0x_4_RRjEU3b5lnUBHGdeCz2XaTZN6HUE&m=8nP3Al3G5AJ42ac_JzARFQa2tXqA2YlXJuaySLXJjgM&s=LPlE1AxJxHNlBfMXUeFpHrAK6m0EkycNGvInUop-qUw&e=.

5. 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.

6. Please note your potential 2019 SMFM presentation on the title page of the revised manuscript. If it is accepted, please let the Editorial Office know as soon as possible.

7. 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).

8. 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.

9. Only standard abbreviations and acronyms are allowed. A selected list is available online at https://urldefense.proofpoint.com/v2/url?u=http-3A__edmgr.ovid.com_ong_accounts_abbreviations.pdf&d=DwIGaQ&c=6vgNTiRn9_pqCD9hKx9JgXN1VapJQ8JVoF8oWH1AgfQ&r=VJpPTo49T-0x_4_RRjEU3b5lnUBHGdeCz2XaTZN6HUE&m=8nP3Al3G5AJ42ac_JzARFQa2tXqA2YlXJuaySLXJjgM&s=PDSHCfSl9x9yV9I9mJDEFCWicEPzNT7Laimvh8uzRFU&e=. 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.

10. 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.

11. Please review the journal's Table Checklist to make sure that your tables conform to journal style. The Table Checklist is available online here: https://urldefense.proofpoint.com/v2/url?u=http-3A__edmgr.ovid.com_ong_accounts_table-5Fchecklist.pdf&d=DwIGaQ&c=6vgNTiRn9_pqCD9hKx9JgXN1VapJQ8JVoF8oWH1AgfQ&r=VJpPTo49T-0x_4_RRjEU3b5lnUBHGdeCz2XaTZN6HUE&m=8nP3Al3G5AJ42ac_JzARFQa2tXqA2YlXJuaySLXJjgM&s=1ErIQTdXWtGq3JrNu0BhDOZEtm6GvqcmQrgk0Xx5q5U&e=.

12. 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 https://urldefense.proofpoint.com/v2/url?u=http-3A__www.acog.org_Resources-2DAnd-

2DPublications&d=DwIGaQ&c=6vgNTiRn9_pqCD9hKx9JgXN1VapJQ8JVoF8oWH1AgfQ&r=VJpPTo49T-0x_4_RRjEU3b5lnUBHGdeCz2XaTZN6HUE&m=8nP3Al3G5AJ42ac_JzARFQa2tXqA2YlXJuaySLXJjgM&s=hvBewt9OwyjLv2QJRjXw7Qc6SMO-fWzk_oXQyJYfKHc&e=.

13. If you choose to revise your manuscript, please submit your revision via Editorial Manager for Obstetrics & Gynecology at https://urldefense.proofpoint.com/v2/url?u=http-3A__ong.editorialmanager.com&d=DwIGaQ&c=6vgNTiRn9_pqCD9hKx9JgXN1VapJQ8JVoF8oWH1AgfQ&r=VJpPTo49T-0x_4_RRjEU3b5lnUBHGdeCz2XaTZN6HUE&m=8nP3Al3G5AJ42ac_JzARFQa2tXqA2YlXJuaySLXJjgM&s=bqo_nboWkM8w8HRYYpyZV-8jquJUXF57NWyG4Mzy6c0&e=. 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 Nov 02, 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

In response to the EU General Data Protection Regulation (GDPR), you have the right to request that your personal information be removed from the database. If you would like your personal information to be removed from the database, please contact the publication office.

In compliance with data protection regulations, please contact the publication office if you would like to have your personal information removed from the database.

References:

1. Rossi RM, DeFranco EA. Maternal Complications Associated With Periviable Birth. Obstet Gynecol. 2018;132:107-114.
2. Shamshirsaz AA, Fox KA, Erfani H, et al. Outcomes of Planned Compared With Urgent Deliveries Using a Multidisciplinary Team Approach for Morbidly Adherent Placenta. Obstet Gynecol. 2018;131:234-241.
3. Dotters-Katz SK, Panzer A, et al Maternal Morbidity After Previable Prelabor Rupture of Membranes. Obstet Gynecol. 2017;129:101-106.
4. Clark-Ganheart CA, Reddy UM, Kominiarek MA, et al. Pregnancy Outcomes Among Obese Women and Their Offspring by Attempted Mode of Delivery. Obstet Gynecol. 2015;126:987-93.
5. Eller AG, Bennett MA, Sharshiner M, et al. Maternal morbidity in cases of placenta accreta managed by a multidisciplinary care team compared with standard obstetric care. Obstet Gynecol. 2011;117:331-7.
6. Grobman WA, Rice MM, Reddy UM, Tita ATN, Silver RM, Mallett G, et al; Eunice Kennedy Shriver National Institute of Child Health and Human Development Maternal–Fetal Medicine Units Network. Labor Induction versus Expectant Management in Low-Risk Nulliparous Women. N Engl J Med 2018;379:513-523.

Randi Zung

From: Chen, Han-Yang [redacted]
Sent: Thursday, November 15, 2018 12:40 PM
To: Randi Zung
Cc: Chauhan, Suneet P
Subject: RE: Your Revised Manuscript 18-1726R1
Attachments: 18-1726R1 ms (11-15-18v2) (author edit).docx

Hi, Randi

I have reviewed the manuscript and made edits (see attached).
Please see my responses below.

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

We accepted all the edits. We also made some minor edits (see track changes).

2. If your paper is accepted, we won't publish it until our March issue, which posts online on 2/7. The SMFM meeting starts 1/11, and our February issue publishes on 1/10. The publication date of your article must be after the meeting has ended.

The SMFM will be on Feb 11-16, 2019. So we can post it online after 16, and publish it in March Issue.

3. Tables (and elsewhere): Please express this p-value and all the p-values in your paper to no more than three decimal places

We have made the changes of p-values.

4. Tables: Explain the reason for using boldface data in a footnote at the end of the table.

We have added in footnote: "Statistically significant results are highlighted in bold" from table 2 to table 7.

Thank you
Han-Yang

Han-Yang Chen, PhD
Assistant Professor

UTHealth The University of Texas
McGovern Medical School

Department of Obstetrics, Gynecology & Reproductive Sciences
[redacted]

From: Randi Zung [mailto:RZung@greenjournal.org]
Sent: Thursday, November 15, 2018 8:09 AM
To: [redacted]
Subject: Your Revised Manuscript 18-1726R1

Dear Dr. Chen:

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. If your paper is accepted, we won't publish it until our March issue, which posts online on 2/7. The SMFM meeting starts 1/11, and our February issue publishes on 1/10. The publication date of your article must be after the meeting has ended.

3. Tables (and elsewhere): Please express this p-value and all the p-values in your paper to no more than three decimal places

4. Tables: Explain the reason for using boldface data in a footnote at the end of the table.

To facilitate the review process, we would appreciate receiving a response within 24 hours.

Best,
Randi Zung

_ _
Randi Zung (Ms.)
Editorial Administrator | *Obstetrics & Gynecology*
The 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

From: [redacted]
To: Stephanie Casway
Subject: RE: O&G Figure Revision: 18-1726
Date: Wednesday, November 14, 2018 10:28:42 AM
Attachments: image003.png

Hi, Stephanie

The revised figure looks fine. I have some minor correction for the figure legend (see yellow highlight).

Figure 1. Flow chart of live births in the U.S. (2011–2015): Eligibility and sample size. *Items not mutually exclusive.

As we've stated in the cover letter, please note that the abstract of this paper was accepted for a poster presentation at 2019 SMFM (February 11 - 16, 2019) .

Thank you
Han-Yang

Han-Yang Chen, PhD
Assistant Professor

UTHealth | McGovern Medical School
The University of Texas Health Science Center at Houston

[redacted]

From: Stephanie Casway [mailto:SCasway@greenjournal.org]
Sent: Wednesday, November 14, 2018 7:51 AM
To: [redacted] Chen, Han-Yang [redacted]
Subject: O&G Figure Revision: 18-1726

Good Morning Dr. Chen,

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. In addition, please see our query below.

AQ1: Note that we made some edits to the text surrounding the revision of birth certificates. If this is not correct, just let us know.

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 Friday, 11/16. 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