

OBSTETRICS & GYNECOLOGY



NOTICE: This document contains comments from the reviewers and editors generated during peer review of the initial manuscript submission and sent to the author via email.

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

Date: Nov 15, 2018
To: "Robert M Rossi" [REDACTED]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-18-1925

RE: Manuscript Number ONG-18-1925

Contemporary trends in periviable obstetric and neonatal practice patterns for live births between 22 0/7 – 23 6/7 weeks' gestation

Dear Dr. Rossi:

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 Dec 06, 2018, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

REVIEWER #1:

The authors present a manuscript describing trends in management of periviable births. The following items should be addressed:

1. Since the primary outcome relates to cesarean section, that should be indicated within the title.
2. The variables included in the maternal adverse outcome are quite rare and extreme. Why were other variables such as postpartum hemorrhage, infectious morbidities, extended hospital stay, or others not included?
3. Given that the definition of maternal morbidity in this study is based on rare and extreme conditions, the last sentence of the abstract conclusion should be revised.
4. The differences in cesarean rate described in the results section are, in many cases, statistically significant but of such a small absolute difference that it renders them clinically non-significant. This should be addressed in the discussion.

REVIEWER #2:

An interesting review of current trends in OB care for the periviable pregnancy. The authors correctly conclude that the increased trends of C-section for periviable deliveries cannot be directly related to the NICHD recommendations, but there can be an association. Trends in delivery in the United States tend to follow an increase in C-section delivery for a perceived benefit in neonatal outcomes, whether this benefit actually exists or not.

It is very interesting to demonstrate and increase in C-section deliveries for those pregnancies closer to the traditional 24 week 'cutoff' for neonatal viability, and also the associated increase in neonatal resuscitative efforts.

This study also shows that the survival rates are not substantially affected by the increase in C-section delivery, again showing in hard data that a C-section is in fact not protective in the delivery of the newborn.

This is an important study for these reasons, and also shows that overall neonatal survival has not been substantially impacted by the NICHD executive statement. The authors note that the rates of neonatal interventions did increase in the second time period, but this is more likely due to patient counseling and the interventions being offered, rather than a true

increase in neonatal survival.

REVIEWER #3:

General:

This is a population based cohort study of singleton births between 22W0d-23W6d comparing the difference of cesarean rate in a cohort prior to the publication of the joint executive summary on periviable birth to a cohort post publication. Secondary outcomes included maternal adverse outcomes, neonatal interventions and neonatal mortality.

Specific:

1. Line 180: Secondary outcomes included neonatal outcomes; however, the specific outcomes are not listed in the body of the text. Please clarify in the body of the text the outcomes evaluated.
2. Lines 181-182: Secondary outcomes also included adverse maternal outcomes. Why were only these outcomes included? Why were infectious morbidities (wound complications, endometritis, pelvic abscess, etc), thromboembolic events, or maternal mortality not included? This seems relevant as Epoch 2 had a larger cohort of obese and older women.
3. Lines 183-186: Is there a difference between what is reported in the 1989 and 2003 Standard Certificate of Live Birth data? If so, does this bias your data in any way?
4. Lines 187-189: These lines are confusing as in Figure 1 it appears women with multifetal gestations were completely excluded. However, the text makes it seem like an outcome was included. Please make this more clear that they were included in a secondary analysis only.
5. Lines 183-187 and Lines 194-197: These lines seem redundant.
6. Lines 205-207: Why was chronic hypertension used as a variable for adjusted model for cesarean risk and not other comorbidities such as diabetes mellitus, autoimmune disorders, renal disease, etc?
7. Lines 268-270 and 329-330: Please clarify that you did not observe higher rates of individual or composite maternal morbidity in the specific outcomes evaluated, as only four maternal adverse outcomes were evaluated.
8. Lines 311-312: As suboptimal dating leads to inaccurate gestational age assignment, can you stratify between the groups the number of pregnancies that were suboptimally dated?
9. Table 4: Please correct the risk for cesarean limited to 400-600 grams, as the numbers listed are for Epoch 1.
10. Figure 1: Please correct figure. Excluded data should be GA <22 or >24 weeks, instead of >23 weeks.
11. Figure 1: Why weren't known fetal anomalies excluded? How many neonates born in each Epoch had a fetal anomaly and how will this bias your neonatal outcome data?

STATISTICAL EDITOR'S COMMENTS:

1. lines 105-109: The proportions cited only refer to the composite rates, should not state that individual interventions were different without citing those specific measures. For example, lines 241-242, uterine rupture rates were higher in Epoch 1
2. lines 112-113: Higher rates of maternal morbidity were observed, but the difference was not statistically different. Should re-word.
3. Table 1: Multiple p-values appear to be NS that are marked as < .001: Medicaid, BMI classes Underwgt and overwgt. Also, the p-values for obese class 1 and 3 each are greater than < .001. Please verify all p-values in this Table.
4. Table 2: The counts and rates for individual components of adverse maternal outcomes are relatively small, so any NS findings cannot be generalized due to low power. As written, the reader may misinterpret the individual adverse outcomes as being a subset of the cesarean composite grouping. Suggest citing the cesarean in 1st row, then all in second, followed by the individual components. Or, could use a footnote to clarify that the individual components refer to all, not just the cesarean outcome group.
5. Table 3: Suggest additional measure of neonatal and infant death categories as median (range or IQR).
6. If the data exists, would be useful to add information re: morbidity among survivors at 1 year etc in the two Epochs.
7. Supp Table 1: Since several of the measures are conditional within a subset of the N cited at the top of the columns,

should note the denominators used for the various proportions cited. Could be in another Table or as footnote to present Table.

ASSOCIATE EDITOR'S COMMENTS:

Thank you for submitting your work to Obstetrics & Gynecology. We would be interested in a revision of your manuscript provided

- 1) You focus on absolute rate differences and eliminate the relative rate differences and percentages that you have presented;
- 2) Not use 22-24 weeks as a lumped outcome-if I am interpreting your data correctly, to the extent that the needle moved in any meaningful way it moved in the 23rd week;
- 3) You emphasize that the increased rate of intervention in the 23rd week was associated with minimal improvement in outcomes;
- 4) You declutter your tables which have too many rows and subgroups.

EDITORIAL OFFICE 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, 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.

2. 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. Variance is needed in the following sections:

a. Please cite or add variance to lines 322-325 (it is important...likely to receive other). This is from an AJP article by the same authors.

3. 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>.

4. 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.

5. Titles in Obstetrics & Gynecology are limited to 100 characters (including spaces). Do not structure the title as a declarative statement or a question. Introductory phrases such as "A study of..." or "Comprehensive investigations into..." or "A discussion of..." should be avoided in titles. Abbreviations, jargon, trade names, formulas, and obsolete terminology also should not be used in the title. Titles should include "A Randomized Controlled Trial," "A Meta-Analysis," or "A Systematic Review," as appropriate, in a subtitle. Otherwise, do not specify the type of manuscript in the title.

6. 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).

7. Provide a précis on the second page, for use in the Table of Contents. The précis is a single sentence of no more than 25 words, written in the present tense and stating the conclusion(s) of the report (ie, the bottom line). The précis should be similar to the abstract's conclusion. Do not use commercial names, abbreviations, or acronyms in the précis. Please avoid phrases like "This paper presents" or "This case presents."

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. We discourage claims of first reports since they are often difficult to prove. How do you know this is the first report? If this is based on a systematic search of the literature, that search should be described in the text (search engine, search terms, date range of search, and languages encompassed by the search). If on the other hand, it is not based on a systematic search but only on your level of awareness, it is not a claim we permit.

12. Our readers are clinicians and a detailed review of the literature is not necessary. Please shorten the Discussion and focus on how your results affect or change actual patient care. Do not repeat the Results in the Discussion section.

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

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

15. The Journal's Production Editor had the following comments on the figures in your manuscript:

"Figure 1: Please confirm or explain n values for the bottom half of the figure (14,799–7,734 does not equal 7,425; also the n values in n values in Epochs 1 and 2 minus those excluded for attempted trial of labor does not equal the sum of the n values in the final boxes). Additionally, the percentages in these final boxes do not total 100. Also, would you like to add a percentage for those excluded due to gestational age?

Figure 2: Is this figure available in the original file type (guessing Excel or PPT)? We would need to make some small edits, including removing the black background and moving the location of some of the values."

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

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

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

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

Figures should be no smaller than the journal column size of 3 1/4 inches. Art that is low resolution, digitized, adapted

from slides, or downloaded from the Internet may not reproduce. Refer to the journal printer's web site (<http://cjs.cadmus.com/da/index.asp>) for more direction on digital art preparation.

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 Dec 06, 2018, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

The Editors of Obstetrics & Gynecology

2017 IMPACT FACTOR: 4.982

2017 IMPACT FACTOR RANKING: 5th out of 82 ob/gyn journals

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