OBSTETRICS & GYNECOLOGY

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

Date: Nov 01, 2018
To: "Caroline Carter Marrs" [redacted]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-18-1863

RE: Manuscript Number ONG-18-1863

Elective induction at 39 weeks: what is next?

Dear Dr. Marrs:

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 22, 2018, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1: Overall, I found this to be a somewhat sloppy analysis of the literature around IOL vs expectant management with poor attention to detail and multiple instances of inaccurate conclusions. There is a stark absence in the introduction and review of literature about the risks of induction of labor, not just in terms of cesarean delivery, but in terms of effects on labor itself, on maternal health, on breastfeeding, maternal-infant bonding, and on the experience of birth for women. Induction of labor is not a neutral tool, but rather an intervention that we must take seriously in terms of all of the risks/benefits attributable to it. I would have liked to see a more thoughtful approach to this topic given its import. No context is provided on our push to reduce primary cesarean deliveries or why there may be any controversy to the research question posed by the ARRIVE trial to begin with, which I would expected.

It is pretty clear that these authors are biased towards elective induction - I wonder of this piece would be more compelling if they simply stated that from the start? The setup is meant to feel as if they are neutral, but the language they use does not reflect this.

Line by line critiques:

line 43 - awkward phrase "not only is this not true but rather"

line 59 - this sentence should end with a period, not a question mark

line 63 - keep language consistent, i.e. "non-medically indicated" as in the previous line

line 78 - how does preeclampsia relate to a higher risk of c-section in and of itself? please provide citations

line 87 - awkward gerund "Prolonging the pregnancy may lead to developing a number of complications" - perhaps "the development of a number of complications"

This is fairly strong phrasing and would recommend softening -

Expectant management often leads to spontaneous labor, and can result in induction or cesarean delivery due to the development of complications such as preeclampsia or nonreassuring fetal status.

line 99 - please provide citations to the evidence that neonatal risk nadirs around 39 weeks or that maternal/neonatal risk increase after 39 weeks - this is not mentioned earlier.

line 101 - language such as "prolonging the pregnancy" feels unnecessarily harsh and inaccurate. a pregnancy is not "prolonged" if a woman is 39+5 or even 40+1 weeks. would recommend using different phrasing.

line 115 - This is a mischaracterization with regards to the primary outcome of the study, which was a composite neonatal outcome of death/morbidity. The results did not favor induction over expectant management with regard to this outcome.

line 126 - this conclusion requires far more explanation - who are these selected women per the ARRIVE trial? of note, women in the ARRIVE trial self-selected into the trial, and the vast majority of those offered did not opt in. Does this have any implications for these "selected women?"

line 130 - would recommend using proper medical terminology for all medical conditions including SLE instead of "lupus"

line 131 - the final sentence in this paragraph is confusing. Sure, women with medical conditions would be induced anyway - but isn't the point here that the vast majority of women would not be?

line 135 - why is it important to note that maternal age, BMI, or bishop score were exclusions?

line 172 - this section is not substantial enough to warrant its own subheading

line 185 - this statement is completely unsubstantiated. Additional costs of IOL include the externalities of having a bed occupied on a busy L&D, which forces other procedures to be delayed, ties up nursing resources, and potentially forces hard choices with expediting other deliveries. This is alluded to in the following paragraph, but would edit the statement made in this line.

line 194 - this recommendation seems like it's coming from left field - a system that utilizes the list of women currently planning to deliver at the hospital to look for opportunities for elective induction? like a transplant list?

line 209 - are we really suggesting that keeping a family in OB triage for days is a reasonable experience?

line 245 - it is tacky and arrogant to state "a more accurate conclusion" on behalf of ACNM. i'm sure they carefully selected their words and felt that their conclusions were accurate. furthermore, earlier it was stated that the propensity for a woman to self-select into a trial like this was akin to her propensity to consent to an elective induction. now the authors state that the propensity for a woman to self-select into a trial like this is akin to her propensity to participate in a randomized controlled trial. which is it? this argument seems to be adapted as convenient for these authors.

line 254 - this conclusion is inaccurate - the trial did not show that elective induction is not harmful. we don't know about the harms because that wasn't the intention of the trial.

Reviewer #2: Marrs et al provide us with a current commentary of elective induction at 39 weeks. The commentary largely revolves around the ARRIVE trial but incorporates a brief historical perspective and literature review. Finally the authors touch on important aspects of patient counseling, policy implications, cost effectiveness, defining failed induction of labor, and consideration for novel approaches to increase the feasibility of 39 week elective inductions by outpatient cervical ripening.

1. Lines (see below) - I generally do not comment on grammatical issues but given this is a commentary without new information to constructively review and the number of issues that ultimately were distracting to digest this submission I feel it necessary to list. If accepted, the manuscript will be copyedited but here are examples that made it difficult to read
   - Line 26 - Long sentence, consider making two separate sentences
   - Line 28 - says "group" > would consider "groups"
   - Line 30 - would consider saying the prior research has been "inconsistent" instead of "confusing"
   - Line 38 - I would favor the use of the term "belief" over "wisdom" - also in line 152
   - Line 48 - the term "weeks" is included in every range except "late term (41 0/7 - 41 6/7)" - be consistent
   - Line 52 - citation can "(3)" can be moved to the end of the sentence
   - Line 55 - GA has not been previously defined - and is not listed when similarly used in lines 47-49 - remove here or add in the other locations for consistency
   - Line 65 - would remove GA given multiple other places where it is not listed (Line 63, 67, etc)
   - Line 109 - "health" nulliparous - I would favor saying "low-risk" to be consistent with the manuscript or change to "healthy"
   - Line 119 - "neonates induction group" would say "neonates in the induction group" or something similar
   - Line 122 - "versus" change to "vs." to be consistent with rest of paragraph
   - Line 187 - "deliver" should be "delivery"

2. Line #76 - on first read this paragraph and the next paragraph starting on line 81 sound the same because the readers mind goes to the comparison initially of spontaneous labor versus induction. On re-read it's clear the first paragraph is focused on indicated inductions. I would consider re-wording the first sentence of this paragraph - maybe something like "First, some studies include both elective and indicated induction of labor".. so the point of this paragraph is understood by the more casual reader

3. Line 115-123 - When describing the results you describe the relative risk reduction (absolute percentages; relative risk; confidence interval). I would prefer it say "Cesarean deliveries were reduced (absolute percentages; relative risk; confidence interval)" to be less redundant though listing the relative risk reduction as currently listed may be easier for the casual reader who is less familiar with statistics to digest. Additionally listing relative differences is common place in the literature but in my opinion gives a perceived artificial inflation of the results compared to absolute difference - for instance if you do not specify relative versus absolute reduction, this sentence could also read "Cesarean deliveries were reduced by 3.6% (...)" if you were to base it on the absolute difference.

4. Line 131 & 167 - if the study is internally valid, why are the findings of the trial only applicable to this population. I hear this mentioned a lot in journal clubs, especially for new practice changing studies (late preterm steroids, etc) but we have to ask ourselves why are the results not generalizable to a larger population, certainly arguments can be made for why the results are not generalizable to certain populations who did not strictly meet inclusion criteria but judgement can be used to decide if the results of this study can be generalized to a broader population (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3369519/)

5. Line158 - regarding lower risk of "preeclampsia" I believe the ARRIVE trial grouped hypertensive disorders of pregnancy (gestational hypertension or preeclampsia). I would be consistent with the way it was presented and state lower risk of hypertensive disorders of pregnancy because it is unclear what drove the difference (i.e. it could have been the majority had gestational hypertension that drove the difference) unless a supplemental appendix I have not reviewed provides further data to support a lower risk specifically of preeclampsia

Reviewer #3: Marrs and colleagues provide a review of elective induction and discuss the recently published ARRIVE trial.
Comments for the authors:

1. It would be useful to quantitate the magnitude of adverse outcomes for early term deliveries/inductions compared to full term deliveries.

2. Would be helpful to briefly describe protocol compliance in the paragraph describing the ARRIVE data.

3. Line 159 cervix should be pleural.

4. Lines 230 organizations should be pleural.

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 authors who were personally involved with the planning, conduct and reporting or funding of the ARRIVE trial or who work at hospitals where the study was done should state this as a potential conflict of interest. You may not be an impartial proponent of research you were involved in. The readers have a right to know this potential source of bias.

- ACOG has made this recommendation for many years, not based on "recent" evidence.

- you use "recent' frequently in this manuscript. Could you be more specific?

- First time you've mentioned it in the manuscript. It needs a reference here and some more explanation.

- please support this statement with a reference.

- when?

- healthy

- Did any have failed inductions and were sent home so didn't deliver in this period? Did all of their inductions occur such that they were all actually delivered by 39 weeks 4 days? Or were the women allocated to elective induction actually begin their inductions from 39 0-4/7 weeks but maybe deliver by 39 5 or 6/7 weeks?

- We do no allow authors to describe variables or outcomes in terms that imply a difference (such us of the terms “trend” or “tendency” or “marginally different”) unless there is a statistical difference. Please edit here and throughout. While you end the sentence by noting no statistical difference you have to read to get there. Please consider: The rate of the primary neonatal composite outcome of perinatal death or severe morbidity was no different between groups (4.3% versus 5.4%.....)

- Please clearly state the CS rates in both groups. Really important to include the fact that there is a residual CS risk.

- Induction with a favorable cervix doesn't require cervical ripening. Please edit

- One of the conversations I have not heard about this point (longer LOS in L&D but overall shorter LOS in hospital) is that L&D beds are the scarce resource typically. From a hospital perspective, administrators and clinicians need to look at both types of beds. Will more L&D beds and fewer post partum beds be needed? How feasible is that? The discussion of impact has to include individuals with the full perspective. Same is true for insurers. THey don't just see L&D beds. {this is just my thought as an OB--not necessarily as an editor--doesn't require you to respond to this comment}

- and who meet criteria for considering elective induction at 39 weeks

- I believe "Unit" is plural. Line 227--should that be minimal? Would you consider "These should be considered minimal thresholds"....

- Rather than seemingly dismiss the ACNM's concerns, perhaps something like the importance of shared decision making and autonomy are reasons to share this information with their patients, even though a large number of women, for what ever reasons, chose not to participate in the ARRIVE trial. It maybe that a large number of women who choose midwifery care over obstetrical care will likewise decline induction at 39 weeks and that fits with the inclusion criteria--willingness to be induced being one of them.

- You have somewhat selectively chosen to only include SMFM and ACOG here. It seems a more balanced summary statement here would include the importance of the woman's informed choice to support her autonomy and if a patient chooses this option, then SMFM and ACOG's statements support that approach.

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. 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:

Please add a citation to lines 120-123 (the primary neonatal…for an interim analysis) since this is a quote.

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: Current Commentary articles should not exceed 12 typed, double-spaced pages (3,000 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).

6. Title: Please rephrase the title so that it avoids posing a question.

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.

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. Provide a short title of no more than 45 characters, including spaces, for use as a running foot.

9. 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."

10. 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: Current Commentary articles, 250 word. Please provide a word count.

11. 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.

12. 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.

13. 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.

14. 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 22, 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

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