

# OBSTETRICS & GYNECOLOGY



**NOTICE:** This document contains correspondence generated during peer review and subsequent revisions but before transmittal to production for composition and copyediting:

- Comments from the reviewers and editors (email to author requesting revisions)
- Response from the author (cover letter submitted with revised manuscript)\*
- Email correspondence between the editorial office and the authors\*

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

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

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

**Date:** Oct 19, 2018  
**To:** "Barbara Levy" [REDACTED]  
**From:** "The Green Journal" em@greenjournal.org  
**Subject:** Your Submission ONG-18-1801

RE: Manuscript Number ONG-18-1801

Facility Regulations: Patient Safety or Ideology?

Dear Dr. Levy:

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 09, 2018, we will assume you wish to withdraw the manuscript from further consideration.

#### REVIEWER COMMENTS:

##### REVIEWER #1:

In this manuscript, the authors present a current commentary on what constitutes a procedure that is given in context of laws ostensibly restrictive of abortion services. The "rules" regarding a Current Commentary are:

Current Commentary essays address issues, opinions, experiences, or perspectives of clinical relevance to the field of obstetrics and gynecology and obstetrician-gynecologists. Length should not exceed 12 manuscript pages (Table 1). The abstract should be a single paragraph that states what was done, what was found, and what the findings mean. Headings are not necessary in the body of the article.

The manuscript is appropriate and addresses a current issue facing OB/GYN practice. The abstract is a single paragraph although it features new material not expressly discussed in the manuscript (i.e. Supreme Court deliberations). Overall, as a document as it stands seems more like an ACOG Committee Opinion than a Current Commentary. There are frequent references to a systematic review that was done to inform the opinions featured in the manuscript but the manuscript is not that systematic review nor has that review been apparently published. This and other features of the manuscript contribute to a sense that the document is not well focused. I have the following specific comments/questions:

- 1) The role of government has been widely debated over the years. It is interesting to consider that matter in the particular context of abortion. Those opposing abortion would argue that the government has not only a role to protect the public but also the individual. Taking away from the "heat" of the abortion debate, the same government that condemns racism (a public concern) also protects the free speech and safety of a racist (an individual concern). Returning to abortion, among those opposing termination of an otherwise normal pregnancy, the pre-viable fetus is enough of a "person" to have rights that the government should protect (i.e. the location of the fetus relative to the uterus is not what defines personhood and persons are to be protected). I will avoid descending into the murk of when persons are persons (e.g. Romans only considered Romans persons hence their brutality to anyone else was completely normal) but suffice to say, if government regards the pre-viable fetus as a person, it is also its legitimate (and required) role to protect it.
- 2) Lines 26-39 are very "ACOG Committee Opinion looking" including the summary bullet points. Wouldn't it make sense to just call it that given the paper was apparently sponsored by them?
- 3) Who instigated the "Project?" If all these organizations pooled their efforts to determine was is a procedure then why not have this as some kind of consensus statement. Is a Current Commentary the right place for this manuscript?
- 4) Bullet on line 74 would benefit from an example. What is a matter of clinical practice or scope of practice does

become clearer later in the manuscript but a quick "e.g." might help smooth out some confusion.

5) Bullet on line 82 seems odd - wouldn't a procedure be a procedure irrespective of which kind of person does it? If the effort of the Project was to determine the essence of a procedure then I would think the medical specialty would be irrelevant.

6) Lines 93-103 don't seem much like a Current Commentary. This reads like a methods section but this manuscript isn't a "study" that requires that nor is it expected in an "opinion" piece to include how a committee sought to tackle a given question. This jumble only gets deeper in the next section that describes a systematic review that was already published in another journal. It seems a bit like a "book report" to spend so much time describing an already published manuscript. The systematic review's conclusions alone are what supports the opinions being forwarded in the manuscript.

Overall the gist of this manuscript is that an outpatient procedure should be objectively defined to render guidance of who, where and how they are performed. This alone is a useful goal across a variety of clinical settings besides just abortion. The authors rightly pursued this question because of how politics was impacting abortion access, leading to the conclusion that, "its politics, not public safety." Ironically, it could also be said that the matter of determining the features of an outpatient procedure is about "science, not politics." The admixture of sorting out the features of an outpatient procedure with politics, however, may have muddied the most pertinent message.

#### REVIEWER #2:

Overall, this is an excellent and much-needed clinical commentary about whether or not facility regulations regarding outpatient abortion are derived from patient safety considerations or politics/ideology. My concern is that, regardless of how coherent and authoritative this commentary is, it will fall on deaf ears.

That said, as this commentary utilized a well-defined process and methodology to come to its conclusions, what it concludes is that there is no evidence that outpatient abortion facilities should not be required to meet standards applicable to office-based facilities overall. The most important aspect of the study, however, is that (as stated in lines 182-184) "Participants found no evidence of any patient safety or quality of care problems related to the examined facility factors in offices or clinics that provide primary care and gynecology procedures." I would suggest adding that to the conclusions, as that makes it clear that the conclusions (which are couched somewhat broadly with regard to office-based procedures in general) relate to abortion specifically.

#### REVIEWER #3:

Great perspective from which to tackle a very important topic. This appears to be a systematic review of the effect of facility regulations, ie those that target abortion providers with the intent of restricting access to abortions, on patient safety. However, it was not very clear from reading the title and abstract what the objective or methods of this study were, and even after reading it I remain unclear about the soundness and rigor of the methods. Similarly, the way it is currently written, it is difficult to derive a clear conclusion about what these findings mean for the practice of obstetrics and gynecology. As this is an important and unique perspective from which to view the current political climate affecting our practice, I encourage the journal to consider this work for publication after the authors revise as follows:

1-- clarify the objectives in the title

2-- specifically delineate the objectives and methods in the abstract

3-- include a figure as well as text describing the methods

4-- strengthen the conclusion section with specific recommendations and a discussion of the implications for our practice

#### 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. 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>.

3. 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).

Please limit your Introduction to 250 words and your Discussion to 750 words.

4. 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).

5. 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."

6. 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 words. Please provide a word count.

7. 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.

8. 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.

9. 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](mailto: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>.

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

## Daniel Mosier

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**From:** Barbara Levy  
**Sent:** Wednesday, November 7, 2018 5:44 PM  
**To:** Daniel Mosier; [REDACTED]  
**Cc:** Denise Shields  
**Subject:** RE: Manuscript Revisions: ONG-18-1801R1  
**Attachments:** 18-1801R1 ms (11-5-18v1)LEVY.docx

Hi Daniel,

I have attached revisions. I do not agree with the running title since these are not guidelines for performing procedure but rather guidelines for the facilities. It could read: Guidelines for facilities performing outpatient procedures. I've answered the other queries.

Many thanks!

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**From:** Daniel Mosier  
**Sent:** Wednesday, November 7, 2018 4:07 PM  
**To:** [REDACTED] Barbara Levy  
**Cc:** Denise Shields  
**Subject:** Manuscript Revisions: ONG-18-1801R1

Dear Dr. Levy,

Thank you for submitting your revised manuscript. It has been reviewed by the editor, and there are a few issues that must be addressed before we can consider your manuscript further:

1. Please note the minor edits and deletions throughout. Please let us know if you disagree with any of these changes.
2. LINE 1: We have reversed the title and subtitle to emphasize what your paper is about.
3. LINE 11: Please add the city and state for this author.
4. LINE 25: If your paper is accepted, this information will be published with your article. Is this the correct email address to use?
5. LINE 48: Do you agree with the running title?
6. LINE 55: Do you agree with the rewording of the precis?

Please let me know if you have any questions. Your prompt response to these queries will be appreciated; please respond no later than COB on **Friday, November 9<sup>th</sup>**.

Sincerely,  
-Daniel Mosier

**Daniel Mosier**  
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**From:** [REDACTED]  
**To:** [Stephanie Casway](mailto:Stephanie.Casway)  
**Cc:** [REDACTED]  
**Subject:** Re: O&G Figure Revision: 18-1801  
**Date:** Tuesday, November 6, 2018 11:18:54 AM

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This looks great, Stephanie. Thank you.

Barbara Levy MD, FACOG  
[REDACTED]

On Nov 6, 2018, at 7:44 AM, Stephanie Casway <[SCasway@greenjournal.org](mailto:SCasway@greenjournal.org)> wrote:

Good Morning Dr. Levy,

Your figure has been edited, and a PDF of the figure is attached for your review. Please review the figure CAREFULLY for any mistakes.

PLEASE NOTE: Any changes to the figures must be made now. Changes made at later stages are expensive and time-consuming and may result in the delay of your article's publication.

To avoid a delay, I would be grateful to receive a reply no later than Thursday, 11/8. Thank you for your help.

Best wishes,

Stephanie Casway, MA  
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<18-1801 Fig 1 (11-6-18 v1).pdf>