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)*

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

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

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

Date: May 14, 2021
To: "Rachel Flink-Bochacki" [redacted]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-21-892

RE: Manuscript Number ONG-21-892

Abortion restrictions and conservative diagnostic guidelines impede patient-centered care in early pregnancy loss

Dear Dr. Flink-Bochacki:

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 Jun 04, 2021, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1:

Thank you for the opportunity to review your work.

As gynecologist who takes care of patients described in this piece, who is also an abortion provider, I very much relate to the points highlighted in this piece. I think most general ObGyns who care for women in this bread-and-butter area will also appreciate you speaking out on this topic. Literally last week I was educating a PA who was taking care of a women with EPF in ER on in immediate (MVA) vs. delayed (serial betas) management.

While measures restricting abortion are not new and have been bulldozing our country with few geographic exceptions, and while the Green has been highlighting this topic in heir recent advocacy driven publications on the topic, I think framing abortion restrictions in the setting of EPF is a new way of bringing attention to the topic and hopefully helping clinicians feel validated in their battles with state abortion restrictions and educating others (like the PA I work with) who have not thought about it this way because they got trapped in the "pro-natal" view highlighted all the major guidelines.

I do not have any major points I would like to ask about, but below are my suggestions in terms of style/flow/content:

1. Case 1. I assume this was difficult for CJC to navigate abortion restrictions as a patient, but from clinician standpoint, those why was her OBGYN not helping her navigate those options? I assumed she had commercial insurance. I am thinking if I was her OBGYN I would have at least helped her get to abortion clinic if that's something she was willing to do.

2. Lines 96-112 esp. helpful since we often wonder exactly where such conservative numbers came from

3. Discussion about serial betas in PUL vs. IPUV very helpful.

Reviewer #2: Thank you for an excellent and thought provoking piece on an area of frequent dissatisfaction, both for patients and providers. Strong examples of how strict radiographic guidelines can seem to overrule sound clinical judgement both out of potential legal fears and financial reasons. Additionally, many of the quotes and apparent value judgements included from radiology publications (lines 99-100, lines 107-109, lines 127-131) are eye-opening. As someone that uses these EPL guidelines daily and has only read the Doubilet consensus paper, reading these quotes allowed me to realize how little some radiologists may understand about what our patients are actually going through. I greatly appreciate the inclusion of legal restrictions and how this can impede care. While you allude to insurance likely not covering the cost of a procedure if labeled as an abortion due to strict criteria not being met, I would consider

highlighting who this is then most likely to disproportionately impact - while some may be able/willing to pay out-of-pocket for an "abortion," this is often financially untenable for individuals with fewer resources, disproportionately impacting our most vulnerable patients. Abortion providers (especially free-standing abortion clinics) also may feel held to a higher standard when confirming EPL, including feeling at higher risk of external scrutiny/audits than an generalist OBGYN in private/academic practice.
A few other thoughts:
- Line 61-62: I suspect most physicians would have felt this HCG decline was diagnostic for an abnormal/nonviable pregnancy and proceeded with evacuation at this time regardless of legal restrictions for abortion. Nonetheless, the idea of concerns re: legal restrictions clouding clinical judgement is seen.
- Line 168-169: Would recommend modifying this sentence. At a minimum, recommend adding the word "options" to read "...limiting patient access to pain management options depending on care setting." Patients in freestanding abortion clinics still have access to pain management (paracervical, NSAIDs, head packs, etc.). While I do not believe you are implying procedures are performed without any pain control whatsoever, the second part of this sentence could be easily misinterpreted. And while versed/fentanyl is the most commonly administered combination of meds for sedation in freestanding clinics, some freestanding clinics offer toradol, ketamine, or even propofol if a CRNA is present, potentially making a patient's sedation experience identical to an OR setting.
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EDITOR COMMENTS:

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

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

Obstetricians and Gynecologists or at any other organizational meeting, that presentation should be noted (include the exact dates and location of the meeting).
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9. Please review examples of our current reference style at http://ong.editorialmanager.com (click on the Home button in the Menu bar and then "Reference Formatting Instructions" document under "Files and Resources). Include the digital object identifier (DOI) with any journal article references and an accessed date with website references. Unpublished data, in-press items, personal communications, letters to the editor, theses, package inserts, submissions, meeting presentations, and abstracts may be included in the text but not in the reference list.

In addition, the American College of Obstetricians and Gynecologists' (ACOG) documents are frequently updated. These documents may be withdrawn and replaced with newer, revised versions. If you cite ACOG 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 (exceptions could include manuscripts that address items of historical interest). 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 an ACOG document has been withdrawn, it should not be referenced in your manuscript (exceptions could include manuscripts that address items of historical interest). All ACOG documents (eg, Committee Opinions and Practice Bulletins) may be found at the Clinical Guidance page at https://www.acog.org/clinical (click on "Clinical Guidance" at the top).

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

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

You will be receiving an Open Access Publication Charge letter from the Journal's Publisher, Wolters Kluwer, and instructions on how to submit any open access charges. The email will be from publicationservices@copyright.com with the subject line 'Please Submit Your Open Access Article Publication Charge(s)'. Please complete payment of the Open Access charges within 48 hours of receipt.

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If you choose to revise your manuscript, please submit your revision through Editorial Manager at http://ong.editorialmanager.com. Your manuscript should be uploaded in a word processing format such as Microsoft Word. Your revision's cover letter should include the following:
* A confirmation that you have read the Instructions for Authors (http://edmgr.ovid.com/ong/accounts/authors.pdf), and
* A point-by-point response to each of the received comments in this letter. Do not omit your responses to the Editorial Office or Editors' comments.

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

Again, your paper will be maintained in active status for 21 days from the date of this letter. If we have not heard from you by Jun 04, 2021, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

The Editors of Obstetrics & Gynecology

2019 IMPACT FACTOR: 5.524
2019 IMPACT FACTOR RANKING: 6th out of 82 ob/gyn journals

Dwight J. Rouse, MD, MSPH
Editor-in-Chief
Obstetrics & Gynecology

Dear Dr. Rouse,

We are pleased to resubmit our manuscript, now titled "The burden of abortion restrictions and conservative diagnostic guidelines on patient-centered care for early pregnancy loss" for consideration as a Current Commentary in *Obstetrics & Gynecology*. We have incorporated the suggestions of the reviewers and editors, which we feel have helped strengthen our manuscript.

This manuscript has only been submitted to *Obstetrics & Gynecology* and will not be submitted elsewhere unless a final negative decision is made by the Editors of *Obstetrics & Gynecology*. The authors declare no financial or other conflicts of interest. We confirm that we have read the Instructions for Authors and have adhered to all Journal guidelines. We have obtained written permission from C.J.G.'s obstetrician (case 1) and Dr. Flink-Bochacki's patient (case 2) to publish this account.

Thank you for your consideration.

Sincerely,

Colleen Judge-Golden, MD, PhD
University of Pittsburgh School of Medicine
Incoming PGY-1, Department of Obstetrics & Gynecology, Duke University Hospital

Rachel Flink-Bochacki, MD, MPH **(corresponding author)**
Department of Obstetrics & Gynecology
Albany Medical Center
[redacted]

Reviewer Comments and Responses

Reviewer #1:

Thank you for the opportunity to review your work.

As gynecologist who takes care of patients described in this piece, who is also an abortion provider, I very much relate to the points highlighted in this piece. I think most general ObGyns who care for women in this bread-and-butter area will also appreciate you speaking out on this topic. Literally last week I was educating a PA who was taking care of a women with EPF in ER on in immediate (MVA) vs. delayed (serial betas) management.

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1. Case 1. I assume this was difficult for CJC to navigate abortion restrictions as a patient, but from clinician standpoint, those why was her OBGYN not helping her navigate those options? I assumed she had commercial insurance. I am thinking if I was her OBGYN I would have at least helped her get to abortion clinic if that's something she was willing to do.

Thank you for raising this point. The author did consider seeking care at an abortion clinic, although ultimately judged this option to be untenable for a variety of reasons, as now described in the manuscript (lines 80-86). CJG did not discuss this option with her OBGYN, and the provider did not suggest it as a possibility, likely due to the strict (though artificial) physical separation of abortion care from generalist practice in this area.

It is the author's belief that her obstetrician would have helped facilitate this option had CJG inquired; thus, it is our preference not to highlight this as a deficit on the part of the clinician in this case.

2. Lines 96-112 esp. helpful since we often wonder exactly where such conservative numbers came from.

Thank you.

3. Discussion about serial betas in PUL vs. IPUV very helpful.

Thank you.

Reviewer #2:

Thank you for an excellent and thought provoking piece on an area of frequent dissatisfaction, both for patients and providers. Strong examples of how strict radiographic guidelines can seem to overrule sound clinical judgement both out of potential legal fears and financial reasons. Additionally, many of the quotes and apparent value judgements included from radiology publications (lines 99-100, lines 107-109, lines 127-131) are eye-opening. As someone that uses these EPL guidelines daily and has only read the Doubilet consensus paper, reading these quotes allowed me to realize how little some radiologists may understand about what our patients are actually going through.

I greatly appreciate the inclusion of legal restrictions and how this can impede care. While you allude to insurance likely not covering the cost of a procedure if labeled as an abortion due to strict criteria not being met, I would consider highlighting who this is then most likely to disproportionately impact - while some may be able/willing to pay out-of-pocket for an "abortion," this is often financially untenable for individuals with fewer resources, disproportionately impacting our most vulnerable patients.

Thank you for this suggestion. We have added a sentence highlighting that restrictions on insurance coverage of abortion make seeking EPL care labeled as an abortion financially inaccessible to many, with a disproportionate impact on low income women (lines 199-202).

Abortion providers (especially free-standing abortion clinics) also may feel held to a higher standard when confirming EPL, including feeling at higher risk of external scrutiny/audits than a generalist OBGYN in private/academic practice.

Thank you for raising this interesting point. We agree that abortion providers may also be more likely to adhere to strict criteria when diagnosing EPL versus labeling care as an induced abortion due to regulations and scrutiny in a hostile environment. We have added a sentence to this effect (lines 202-205).

A few other thoughts:
- Line 61-62: I suspect most physicians would have felt this HCG decline was diagnostic for an abnormal/nonviable pregnancy and proceeded with evacuation at this time regardless of legal restrictions for abortion. Nonetheless, the idea of concerns re: legal restrictions clouding clinical judgement is seen.

Thank you for this comment. We agree that the author's HCG plateau/decline should be sufficient diagnostic evidence of nonviable pregnancy. However, numerous physicians in a respected obstetric practice were not comfortable proceeding with uterine evacuation due to the fact that existing guidelines require radiologic criteria to be met and do not promote any other specific diagnostic criteria, such as hCG levels, that would allow a holistic approach to diagnosis. This overreliance on established objective criteria, which we feel is largely driven by regulatory differences and stigma associated with providing abortion, is what prompted this commentary. We have revised the text to expand the description of the

physician's interpretation of the HCG levels and further contextualize how abortion restrictions influenced clinical decision making in this case (lines 75-79).

- Line 168-169: Would recommend modifying this sentence. At a minimum, recommend adding the word "options" to read "...limiting patient access to pain management options depending on care setting." Patients in freestanding abortion clinics still have access to pain management (paracervical, NSAIDs, head packs, etc.). While I do not believe you are implying procedures are performed without any pain control whatsoever, the second part of this sentence could be easily misinterpreted. And while versed/fentanyl is the most commonly administered combination of meds for sedation in freestanding clinics, some freestanding clinics offer toradol, ketamine, or even propofol if a CRNA is present, potentially making a patient's sedation experience identical to an OR setting.

Thank you for this recommendation. We agree that the original wording could be misconstrued. We have added the word "options" as suggested by the reviewer, and also edited the sentence to clarify that "freestanding abortion clinics cannot <u>always</u> offer the same level of sedation or anesthesia as an operating room" (lines 207-209).

- Line 188-191: This is a bold and potentially alienating statement, especially given that your readers are likely part of the scientific community. There are certainly many individuals in the scientific community that do not hold pronatalist values or trivialize emotional suffering. Many physicians apply PUL HCGs to IPUV routinely as a way to expedite care. That said, the point about lack of data or drive to collect said data is valid.

We appreciate the reviewer's insight. While we intended for this statement to be bold and thus highlight the disparity between attention to preserving fetal potential versus that to alleviating women's emotional suffering, we agree the phrasing could be unnecessarily alienating, and so we have reworded it as such: "Still, to date there has been limited research into expediting diagnosis of IPUV and EPL, reflecting the inherent pronatalist values in the current diagnostic approach and a lack of attention and consideration for women's emotional suffering." (lines 229-231).

<u>Reviewer #3</u>:

This article provides a beautifully written comparison of two different experiences of an early pregnancy loss and demonstrates the interference of state-level restriction on abortion in clinical decision making about pregnancy care in general. The authors offer bold and evidence-based arguments for why these restrictions and an overly conservative approach to diagnosing early pregnancy loss do and will lead to harm for some patients. It is an important perspective to share and provides well crafted arguments that physicians and other pregnancy-care providers can use to push back against state- and institution-level policies that are overly restrictive. I strongly support the publication of this article.

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EDITOR COMMENTS:

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Thank you. Our manuscript uses reVITALize definitions.

4. 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 3,000 words. Stated word limits include the title page, précis, abstract, text, tables, boxes, and figure legends, but exclude references.

Our revised manuscript adheres to the length restriction for Current Commentaries. The total word count has been added to the title page.

5. Do not structure the title as a declarative statement or a question.

We have re-titled the piece to avoid a declarative statement. The new title is “The burden of abortion restrictions and conservative diagnostic guidelines on patient-centered care for early pregnancy loss.”

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

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* Any and all manuscript preparation assistance, including but not limited to topic development, data collection, analysis, writing, or editorial assistance, must be disclosed in the acknowledgments. Such acknowledgments must identify the entities that provided and paid for this assistance, whether directly or indirectly.
* All persons who contributed to the work reported in the manuscript, but not sufficiently to be authors, must be acknowledged. Written permission must be obtained from all individuals named in the acknowledgments, as readers may infer their endorsement of the data and conclusions. Please note that your response in the journal's electronic author form verifies that permission has been obtained from all named persons.
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Resources). Include the digital object identifier (DOI) with any journal article references and an accessed date with website references. Unpublished data, in-press items, personal communications, letters to the editor, theses, package inserts, submissions, meeting presentations, and abstracts may be included in the text but not in the reference list.

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