

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)*

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.

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

Date: 11/23/2022

To: "Andrea G. Edlow"

From: "The Green Journal" em@greenjournal.org

Subject: Your Submission ONG-22-1950

RE: Manuscript Number ONG-22-1950

COVID-19 mRNA vaccines in lactation: examining the evidence

Dear Dr. Edlow:

Thank you for sending us your work for consideration for publication in Obstetrics & Gynecology. Your manuscript has been reviewed by the Editorial Board and by special expert referees. The Editors would like to invite you to submit a revised version for further consideration.

If you wish to revise your manuscript, please read the following comments submitted by the reviewers and Editors. Each point raised requires a response, by either revising your manuscript or making a clear argument as to why no revision is needed in the cover letter.

To facilitate our review, we prefer that the cover letter you submit with your revised manuscript include each reviewer and Editor comment below, followed by your response. That is, a point-by-point response is required to each of the EDITOR COMMENTS (if applicable), REVIEWER COMMENTS, and STATISTICAL EDITOR COMMENTS (if applicable) below.

The revised manuscript should indicate the position of all changes made. Please use the "track changes" feature in your document (do not use strikethrough or underline formatting).

In order to have your submission considered for potential fast-track publication, we'd like to receive your revised manuscript by 12/01/2022. If you need an extension, please let the Editorial Office know.

EDITOR COMMENTS:

Please note the following:

* Help us reduce the number of queries we add to your manuscript after it is revised by reading the Revision Checklist at https://journals.lww.com/greenjournal/Documents/RevisionChecklist_Authors.pdf and making the applicable edits to your manuscript.

REVIEWER COMMENTS:

Reviewer #1: The authors present a well-researched, well-written, and timely article on COVID-19 vaccination and lactation (particularly given the media attention garnered by the recent JAMA Pediatrics article). My mostly minor comments follow:

- 1. The authors might consider cutting the first two sentences of the para starting on line 28. I feel these might unintentionally condone the idea of forgoing vaccination during pregnancy.
- 2. Along those lines, I would make sure framing up front is about vaccination during the postpartum/lactating period specifically (as there really is less of a focus on the impact of vaccination during pregnancy on lactation in the postpartum period).
- 3. The only thing really missing for me, is more of the "so what." I would love if the authors could expand upon the "okay, so here is what this means for patients," which is currently limited to just three sentences in the last para.
- 4. Table 1: Make sure these key points are all in the article itself. For instance, I don't recall the last point also being in the article.

1 of 2

- 5. Much of the manuscript is written in highly technical language. I would recommend trying to re-phrase some of this throughout for the lay/clinician/patient reader.
- 6. Please expand upon/clarify lines 25-27: "an individuals perceived risk of developing severe disease from COVID-19 may be lower now than previously in the pandemic." Do you mean an individual who was previously infected or all individuals? I might also consider saying "as of month year" instead of "now" as many readers will be reading this months from now when there could be another variant.
- 7. Would try to refrain from use of the word "women" and instead state "individuals" or "people" line 42. '

Reviewer #2: Thank you for the opportunity to review this manuscript entitled, "COVID-19 mRNA vaccines in lactation: examining the evidence." This narrative review is very well written, the overall message is "just right" and this would be of significant interest to the readership.

I have very minor edits that the Editing team may also address, but here it is just in case:

- -Line 9: The "CDC" should be spelled out the first time. The author(s) also says "and multiple professional organizations," but only provides references for the CDC and ACOG. Either remove that wording or add in more references to support "multiple."
- -Line 17: Perhaps clarify that that percentage of pregnant patients have been vaccinated as of xx date. It is provided in the references but easier to say it here so the reader does not have to look in the references to figure it out.
- -Line 44: Perhaps state, "To our knowledge..."
- -Line 47, remove period after "individuals"

Sincerely,
Torri D. Metz, MD, MS

Deputy Editor-Elect, Obstetrics

The Editors of Obstetrics & Gynecology

In compliance with data protection regulations, you may request that we remove your personal registration details at any time. (Use the following URL: https://www.editorialmanager.com/ong/login.asp?a=r). Please contact the publication office if you have any questions.

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HARVARD MEDICAL SCHOOL

Investigator

Vincent Center for Reproductive Biology 55 Fruit Street, Thier 9 Boston, MA 02114 Andrea G. Edlow, MD, MSc Assistant Professor of Obstetrics, Gynecology and Reproductive Biology

December 21, 2022

Dr. Torri D. Metz, Deputy Editor, Obstetrics-Elect *Obstetrics & Gynecology*

Dear Dr. Metz,

We are writing to submit our revision to the invited Narrative Review, "COVID-19 mRNA vaccines in lactation: examining the evidence" for consideration as an article in *Obstetrics & Gynecology*. Please find enclosed our responses to the Reviewers' comments.

Dr. Edlow has served as a consultant for Mirvie, Inc., and receives research funding from Merck Pharmaceuticals to study maternal vaccination in pregnancy; Dr. Shook has no disclosures. This manuscript was written specifically for *Obstetrics & Gynecology* and has not been previously published or submitted for consideration to any other journal. All authors have approved the manuscript for submission.

Thank you for your consideration. If you have any questions, please do not hesitate to contact us.

Sincerely,

Andrea G. Edlow, MD, MSc

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Lydia L. Shook, MD



REVIEWER COMMENTS:

additional clarity is needed.

Reviewer #1: The authors present a well-researched, well-written, and timely article on COVID-19 vaccination and lactation (particularly given the media attention garnered by the recent JAMA Pediatrics article). My mostly minor comments follow:

- 1. The authors might consider cutting the first two sentences of the para starting on line 28. I feel these might unintentionally condone the idea of forgoing vaccination during pregnancy.

 RESPONSE: We appreciate this perspective as we do not want to appear to condone forgoing vaccination. We have made the suggested change (Lines 22-27).
- 2. Along those lines, I would make sure framing up front is about vaccination during the postpartum/lactating period specifically (as there really is less of a focus on the impact of vaccination during pregnancy on lactation in the postpartum period).

 RESPONSE: We have shortened the introduction by making the changes suggested in this reviewer's first comment. We believe the stated purpose of the review as written in the third paragraph of the introduction sufficiently states the focus is on vaccination during lactation, but we defer to the Editor as to whether
- 3. The only thing really missing for me, is more of the "so what." I would love if the authors could expand upon the "okay, so here is what this means for patients," which is currently limited to just three sentences in the last para.

RESPONSE: We have added an additional concluding sentence about pursuing vaccination during pregnancy rather waiting until after delivery (Line 231-233).

4. Table 1: Make sure these key points are all in the article itself. For instance, I don't recall the last point also being in the article.

RESPONSE: We have added specificity regarding the bivalent vaccine (Line 14) and have confirmed that the points in the table are addressed in the article. We added the word "hospitalization" to Line 134 and rearranged the bullet points in the Table to better reflect the main article text.

- 5. Much of the manuscript is written in highly technical language. I would recommend trying to re-phrase some of this throughout for the lay/clinician/patient reader.
- RESPONSE: We have made changes to some of the technical language as suggested, with particular attention to the section on breastmilk immunity. We have also removed the abbreviation of breastmilk (BM) which we felt may have affected readability, but defer to the Editor for whether this abbreviation should be reconsidered. We have also simplified the language in the Table that we feel should improve readability/understanding of these key concepts.
- 6. Please expand upon/clarify lines 25-27: "an individuals perceived risk of developing severe disease from COVID-19 may be lower now than previously in the pandemic." Do you mean an individual who was previously infected or all individuals? I might also consider saying "as of month year" instead of "now" as many readers will be reading this months from now when there could be another variant. In response to RESPONSE: Reviewer's first comment, these lines have been removed.
- 7. Would try to refrain from use of the word "women" and instead state "individuals" or "people" line 42. 'RESPONSE: We appreciate this comment and have made the change.



Reviewer #2: Thank you for the opportunity to review this manuscript entitled, "COVID-19 mRNA vaccines in lactation: examining the evidence." This narrative review is very well written, the overall message is "just right" and this would be of significant interest to the readership.

I have very minor edits that the Editing team may also address, but here it is just in case:

-Line 9: The "CDC" should be spelled out the first time. The author(s) also says "and multiple professional organizations," but only provides references for the CDC and ACOG. Either remove that wording or add in more references to support "multiple."

RESPONSE: These changes have been made.

-Line 17: Perhaps clarify that that percentage of pregnant patients have been vaccinated as of xx date. It is provided in the references but easier to say it here so the reader does not have to look in the references to figure it out.

RESPONSE: We have made this change.

-Line 44: Perhaps state, "To our knowledge..." RESPONSE: We have made this change.

-Line 47, remove period after "individuals" RESPONSE: We have made this change.

