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: Sep 29, 2021
To: "John Morgan" [redacted]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-21-1938

RE: Manuscript Number ONG-21-1938

Maternal Outcomes Following SARS-CoV-2 Infection in Vaccinated versus Unvaccinated Pregnant Patients

Dear Dr. Morgan:

Your manuscript has been reviewed by the Editorial Board and by special expert referees. The Editors are interested in potentially publishing your revised manuscript in a timely manner. In order to have this considered quickly, we need to have your revision documents submitted to us as soon as you are able. I am tentatively setting your due date to October 6, 2021, but please let me know if you need additional time.

The standard revision letter text follows.

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).

REVIEWER COMMENTS:

Reviewer #1: In this research letter, the authors compare the incidence of severe disease and other outcomes between women fully vaccinated and those unvaccinated. This research letter is well written, clear and concise. Only minor revisions are noted.

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Table 1. Demographics
- should the races be combined into categorical variables?

Table 2. Outcomes
- Both p-values and ORs should not both be necessary in Table 2. I would choose to keep ORs only to show the effect size.
- The authors do not report any adjustments for the differences in Table 1. This should either be explain or considered as adjusted ORs.
- The authors combine severe and critical illness, it would be helpful to see both pieces independently as well under the primary outcome

Reviewer #2: This paper is a retrospective cohort study (June 15th 2020-August 20th 2021) of maternal outcomes following SARS-CoV-2 infection in vaccinated and unvaccinated pregnant women. The authors demonstrated that vaccinated pregnant patients had a lower-odds of severe and critical COVID infections, and vaccinated patients did not require supplemental oxygen use or ICU admissions compared to unvaccinated pregnant patients. This study is very important, as it identified that although COVID-19 vaccines can be effective in pregnancy, the vaccination rate in pregnant women remain low. However, several critical issues need to be addressed by the authors:

General comments:
1. What was the timing of COVID vaccinations during pregnancy? - First trimester, second or third trimesters? Does timing of vaccination during pregnancy matter?

2. A recently published study on maternal and fetal outcomes in pregnant and postpartum identified that compared to

unvaccinated women, vaccinated women had sufficient prenatal care (Wainstock T, Yoles I, Sergienko R et al. Prenatal maternal COVOD-19 vaccination and pregnancy outcomes. Vaccine, 2021; 39 (41): 6037-6040). Did the authors see a similar trend in their data? Did unvaccinated women receive adequate prenatal care?

3. It would have been nice if the authors evaluated neonatal outcomes (not just stillbirth) and gestational age at delivery using their data, as fear of adverse neonatal outcomes (for example, fear of miscarriages and teratogenicity) has been the major reason why pregnant women are not getting vaccinated.

4. What was the mean/median time from first vaccination to delivery (in weeks)? How about the mean/median time between second vaccination to delivery? These data are important for 3 reasons: First, the timing of vaccination to development of maternal immunity matters; second, the effects of vaccination in every trimester of pregnancy can be studied if the data is available; and third, it is very important in the current discussions about the optimal timing of COVID-19 vaccines in pregnant women.

5. Were the authors powered to demonstrate statistically significant differences in the primary outcome? What of the secondary outcome? If not, the authors should discuss the possibility of insufficient power, and its implications as limitations of the study.

6. Were the authors sufficiently powered to test differences between women who received one versus two doses of the COVID vaccine?

Additional comments:

Lines 10-11: Is the delta variant surge really responsible for the decrease in effectiveness of the mRNA vaccine against SARS-CoV-2? What are the discussions surrounding decreased vaccine effectiveness/efficacy in pregnant women? Does the physiology of pregnancy play any role?

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Line 27: How is partially vaccinated defined? Did all women receive the Pfizer and Moderna vaccines? As the authors know, these two vaccines have the highest efficacy. If other vaccines were received, would be important to know.

Lines 31-32: What percentage of this population was partially vaccinated? How was vaccination status reported - objectively or subjectively? What methodical issues can result if patients subjectively reported their vaccination status? How might this affect the authors findings?

Line 38-39: Were there placental pathologic studies to confirm if these stillbirths were associated with COVID?

Lines 49-51: ACOG and SMFM have put out very strong statements supporting vaccination in pregnant women. Please site the ACOG guidelines, and what ACOG and SMFM are doing to encourage vaccination in pregnant women.

Table 2: My biggest issue is with the odds ratios stated in table 2, page 6. Are these univariable (crude or unadjusted) or multivariable (adjusted) odds ratios for vaccinated versus unvaccinated pregnant women? If they are multivariable odds ratios for vaccinated versus unvaccinated women, what confounders were adjusted for in the analyses? The way table 2 is presented is very confusing and difficult to understand and interpret.

STATISTICAL EDITOR COMMENTS:

The Statistical Editor makes the following points that need to be addressed:

Table 1: Suggest adding a footnote to this table stipulating the definition in this Table for "vaccinated". Need units for BMI.

Table 2: Again, suggest a footnote re: "vaccinated". For the comparisons involving event = 0 vs finite number of events in the other group, should just use Fisher's test, rather than including a OR that is dependent on a continuity correction to avoid division by zero. Should also note in Discussion that the number of adverse events for the NS secondary outcomes allowed insufficient stats power to generalize their NS findings.

line 48: Why was the association of vaccination status vs smoking and greater BMI not included? All were statistically significant in this series?

EDITOR COMMENTS:

1. Thank you for submitting your work to Obstetrics & Gynecology. Given the timeliness and public health importance of your study we are interested in disseminating your work as a rapid communication if you can adequately address the comments raised by the peer reviewers. As such, I would ask that you and your co-authors submit revisions and responses to the reviewers' comments within one week. Again, thank you for allowing us to evaluate this important work.

2. The Editors of Obstetrics & Gynecology have increased 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.

3. When you submit your revised manuscript, please make the following edits to ensure your submission contains the required information that was previously omitted for the initial double-blind peer review:
* Include your title page information in the main manuscript file. The title page should appear as the first page of the document. Add any previously omitted Acknowledgements (ie, meeting presentations, preprint DOIs, assistance from non-byline authors).
* Funding information (ie, grant numbers or industry support statements) should be disclosed on the title page and in the body text. For industry-sponsored studies, the Role of the Funding Source section should be included in the body text of the manuscript.
* Include clinical trial registration numbers, PROSPERO registration numbers, or URLs at the end of the abstract (if applicable).
* Name the IRB or Ethics Committee institution in the Methods section (if applicable).
* Add any information about the specific location of the study (ie, city, state, or country), if necessary for context.

4. Obstetrics & Gynecology uses an "electronic Copyright Transfer Agreement" (eCTA), which must be completed by all authors. When you uploaded your manuscript, each co-author received an email with the subject, "Please verify your authorship for a submission to Obstetrics & Gynecology." Please check with your coauthors to confirm that they received and completed this form, and that the disclosures listed in their eCTA are included on the manuscript's title page.

5. For studies that report on the topic of race or include it as a variable, authors must provide an explanation in the manuscript of who classified individuals' race, ethnicity, or both, the classifications used, and whether the options were defined by the investigator or the participant. In addition, the reasons that race/ethnicity were assessed in the study also should be described (eg, in the Methods section and/or in table footnotes). Race/ethnicity must have been collected in a formal or validated way. If it was not, it should be omitted. Authors must enumerate all missing data regarding race and ethnicity as in some cases, missing data may comprise a high enough proportion that it compromises statistical precision and bias of analyses by race.

Use "Black" and "White" (capitalized) when used to refer to racial categories. The nonspecific category of "Other" is a convenience grouping/label that should be avoided, unless it was a prespecified formal category in a database or research instrument. If you use "Other" in your study, please add detail to the manuscript to describe which patients were included in that category.

6. All studies should follow the principles set forth in the Helsinki Declaration of 1975, as revised in 2013, and manuscripts should be approved by the necessary authority before submission. Applicable original research studies should be reviewed by an institutional review board (IRB) or ethics committee. This review should be documented in your cover letter as well in the Methods section of the body text, with an explanation if the study was considered exempt. If your research is based on a publicly available data set approved by your IRB for exemption, please provide documentation of this in your cover letter by submitting the URL of the IRB website outlining the exempt data sets or a letter from a representative of the IRB. In addition, insert a sentence in the Methods section stating that the study was approved or exempt from approval. In all cases, the complete name of the IRB should be provided in the manuscript.

7. Please submit a completed STROBE checklist to accompany your submission.

8. 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 has adopted the use of the reVITALize definitions. Please access the obstetric data definitions at https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-obstetrics-data-definitions and the gynecology data definitions at https://www.acog.org/practice-management/health-it-and-clinical-

informatics/revitalize-gynecology-data-definitions. If use of the reVITALize definitions is problematic, please discuss this in your point-by-point response to this letter.

9. Because of space limitations, it is important that your revised manuscript adhere to the following length restrictions by manuscript type: Research Letters should not exceed 600 words and may include no more than two figures and/or tables (2 items total). Stated word limits include the title page, précis, abstract, text, tables, boxes, and figure legends, but exclude references.

10. Specific rules govern the use of acknowledgments in the journal. Please note 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 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).
* If your manuscript was uploaded to a preprint server prior to submitting your manuscript to Obstetrics & Gynecology, add the following statement to your title page: "Before submission to Obstetrics & Gynecology, this article was posted to a preprint server at: [URL]."

11. 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 that states 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."

12. 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.

13. 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.

14. In your submission, the preferred citation should be in terms of an effect size, such as odds ratio or relative risk or the mean difference of a variable between two groups, expressed with appropriate confidence intervals. When such syntax is used, the P value has only secondary importance and often can be omitted or noted as footnotes in a Table format. Putting the results in the form of an effect size makes the result of the statistical test more clinically relevant and gives better context than citing P values alone.

If appropriate, please include number needed to treat for benefits (NNTb) or harm (NNTh). When comparing two procedures, please express the outcome of the comparison in U.S. dollar amounts.

Please standardize the presentation of your data throughout the manuscript submission. For P values, do not exceed three decimal places (for example, "P = .001"). For percentages, do not exceed one decimal place (for example, 11.1%").

15. 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.

16. 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 references you are citing are still current and available. Check the Clinical Guidance page at https://www.acog.org/clinical (click on "Clinical Guidance" at the top). If the reference is still available on the site and isn't listed as "Withdrawn," it's still a current document.

If the reference you are citing has been updated and 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.

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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 as a Microsoft Word document. 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 7 days from the date of this letter. If we have not heard from you by Oct 06, 2021, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

Best,

Jason Wright, MD
Editor-in-Chief, Elect
Obstetrics & Gynecology

2020 IMPACT FACTOR: 7.661
2020 IMPACT FACTOR RANKING: 3rd out of 83 ob/gyn journals

To the reviewers of *Obstetrics & Gynecology:*

The authors are submitting a Research Letter Titled: "Maternal Outcomes Following SARS-CoV-2 Infection in Vaccinated versus Unvaccinated Pregnant Patients" for consideration for publication in *Obstetrics & Gynecology.* The Research Letter is not under consideration in any other journal, and will not be submitted elsewhere unless a final negative decision is made by the editors of *Obstetrics and Gynecology.*

The lead author affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained:

Signed by: _____

I, John A. Morgan, MD, have reviewed and edited the submission to omit any identifying information. I hereby submit this self-blinded manuscript for consideration in *Obstetrics & Gynecology.*

This study was approved by the Ochsner Clinic Foundation Institutional Review Board on 8/8/2021.

The authors feel the findings of the current research letter is timely, providing information regarding vaccine effectiveness in pregnancy during the delta variant wave of SARS-CoV-2 infections. We appreciate the consideration by *Obstetrics & Gynecology.*

Sincerely,

John A. Morgan, MD

Maternal-Fetal Medicine

Ochsner Clinic Foundation

The authors appreciate the reviewers comments and advice for the improvement of the research letter under review. See authors responses to comments below.

REVIEWER COMMENTS:

Reviewer #1: In this research letter, the authors compare the incidence of severe disease and other outcomes between women fully vaccinated and those unvaccinated. This research letter is well written, clear and concise. Only minor revisions are noted.

Line 31: Can the authors provide the partial vaccination rate as well in the opening line?

See partial vaccination rate in results section in discussion of secondary analysis. Also see improved explanation of each group in results section

Line 33: "Younger age, BMI...was" - was should be changed to were

Change was made

Table 1. Demographics
- should the races be combined into categorical variables?

-Reporting of race was separated into individual values (see table 1) and p value for the entirety of the race category was calculated according to this request. Race was reported as a single entity and no specific race was singled out in the text. The authors feel it is important to discuss racial differences in vaccine acceptance due to potential disparities, but understand this is a very sensitive subject at this time. If there is another way the reviewer would like race to be presented we are happy to modify.

Table 2. Outcomes
- Both p-values and ORs should not both be necessary in Table 2. I would choose to keep ORs only to show the effect size.

-P-values were deleted and only OR/aOR were reported in table 2.

- The authors do not report any adjustments for the differences in Table 1. This should either be explain or considered as adjusted ORs.

Adjusted OR were reported for statistically significant outcomes, see table 2 and footer

- The authors combine severe and critical illness, it would be helpful to see both pieces independently as well under the primary outcome

These two outcomes were added in table 2. Due to the low rate of critical infection, there was not a statistically significant difference with regards to critical COVID 19 infection, but a vaccinated status was associated with a statistically significant lower rate of severe COVID 19 infection.

Reviewer #2: This paper is a retrospective cohort study (June 15th 2020-August 20th 2021) of maternal outcomes following SARS-CoV-2 infection in vaccinated and unvaccinated pregnant women. The authors demonstrated that vaccinated pregnant patients had a lower-odds of severe and critical COVID infections, and vaccinated patients did not require supplemental oxygen use or ICU admissions compared to unvaccinated pregnant patients. This study is very important, as it identified that although COVID-19 vaccines can be effective in pregnancy, the vaccination rate in pregnant women remain low. However, several critical issues need to be addressed by the authors:

General comments:
1. What was the timing of COVID vaccinations during pregnancy? - First trimester, second or third trimesters? Does timing of vaccination during pregnancy matter?

-The authors appreciate this comment, and feel this is an important outcome to investigate. We plan to perform further analysis of this data base in the future which will look into variation of outcomes and vaccine effectiveness by trimester. For the purposes of this brief research letter, we included all patients who had been vaccinated (which included prior to pregnancy and during all trimesters of pregnancy) to investigate vaccine effect on maternal outcomes in the period of delta variant predominance regardless of vaccine timing during pregnancy.

2. A recently published study on maternal and fetal outcomes in pregnant and postpartum identified that compared to unvaccinated women, vaccinated women had sufficient prenatal care (Wainstock T, Yoles I, Sergienko R et al. Prenatal maternal COVOD-19 vaccination and pregnancy outcomes. Vaccine, 2021; 39 (41): 6037-6040). Did the authors see a similar trend in their data? Did unvaccinated women receive adequate prenatal care?

-The authors agree this is an interesting data point and serves as a potential confounder of general maternal outcomes. The method of data extraction was using EPIC EMR system to pull data, and our data analysis team is unable to obtain data regarding the adequacy of prenatal care. Due to the large study size, this would be a laborious chart review of over 10,000 patients. We would like to add this analysis to our full review of this data base.

3. It would have been nice if the authors evaluated neonatal outcomes (not just stillbirth) and gestational age at delivery using their data, as fear of adverse neonatal outcomes (for example, fear of miscarriages and teratogenicity) has been the major reason why pregnant women are not getting vaccinated.

-The authors appreciate this comment and once again plan a further analysis of this study database including more complete neonatal outcomes. The focus of this brief research letter is the reporting the association between maternal COVID 19 vaccination and maternal outcomes from COVID 19 infection.

-Due to the short study time frame and inclusion of active pregnancies, a small percentage of the pregnancies (1792 of 10092, 17.7%) included in the study have delivered. Of the pregnancies that have delivered, no difference in preterm delivery rate was noted (13% vs 14%, p=0.685). The authors are hesitant to report preterm delivery rate as it is an incomplete picture of the cohort and may be underpowered to show a difference in the preterm delivery rate. We plan to include preterm delivery rate in the final analysis of the study data base.

4. What was the mean/median time from first vaccination to delivery (in weeks)? How about the mean/median time between second vaccination to delivery? These data are important for 3 reasons: First, the timing of vaccination to development of maternal immunity matters; second, the effects of vaccination in every trimester of pregnancy can be studied if the data is available; and third, it is very important in the current discussions about the optimal timing of COVID-19 vaccines in pregnant women.

-The authors agree that this is an important distinction. However, due to the short study period and focus specifically on maternal outcomes during the delta variant surge, this data is not available on most patients as the majority of patients in the study population have active, ongoing pregnancies. We plan to do a more thorough analysis once delivery data is available on this entire cohort.

5. Were the authors powered to demonstrate statistically significant differences in the primary outcome? What of the secondary outcome? If not, the authors should discuss the possibility of insufficient power, and its implications as limitations of the study.

-A power analysis was not performed due to the retrospective nature of this study, finite study period, and intention to include all patients who were actively pregnant during the study period. Our study did find a statistically significant difference with regards to the primary outcome. We acknowledge that our study may be underpowered to find statistically significant differences with regards to the secondary outcomes, and that this is a limitation of our study.

6. Were the authors sufficiently powered to test differences between women who received one versus two doses of the COVID vaccine?

-The authors appreciate and agree with this comment, and we plan to further investigate this outcome in our future more comprehensive analysis of this database.

Additional comments:

Lines 10-11: Is the delta variant surge really responsible for the decrease in effectiveness of the mRNA vaccine against SARS-CoV-2? What are the discussions surrounding decreased vaccine effectiveness/efficacy in pregnant women? Does the physiology of pregnancy play any role?

-See references #3-5 with regards to studies investigating vaccine effectiveness during the delta variant surge. The primary outcome of this study was to investigate if the vaccine is associated with an decreased risk of severe or critical covid infection during pregnancy in the setting of the delta variant surge. One of our secondary outcomes includes covid infection of any severity. Our results show that vaccinated patients have a lower rate of severe or critical covid infection as well as lower rate of covid infection of any severity. To our knowledge this is the first study reporting specifically on covid 19 vaccine association with delta variant infection in a pregnant population. Our results support continued vaccine efficacy against delta variant infection in pregnancy.

Line 20: How were the patients paired? Do the authors mean the patients were matched by vaccination status (vaccinated versus unvaccinated) prior to analysis? If non-vaccinated pregnant women were matched to vaccinated pregnant women, what was the ratio of the match (e.g., 1:1, 2:1, etc.)? What is the implication of matching by vaccination status on logistic regression analyses?

-Our patients were not paired. All vaccinated patients, as defined, as well as all unvaccinated patients with an active pregnancy during the study period were included in the study.

Line 27: How is partially vaccinated defined? Did all women receive the Pfizer and Moderna vaccines? As the authors know, these two vaccines have the highest efficacy. If other vaccines were received, would be important to know.

-Vaccine type was added in table 1 as well as a more detailed explanation of partial versus full vaccination. A more thorough explanation of vaccination status was also added to the methods text.

Lines 31-32: What percentage of this population was partially vaccinated? How was vaccination status reported - objectively or subjectively? What methodical issues can result if patients subjectively reported their vaccination status? How might this affect the authors findings?

-Vaccine status was reported objectively via EPIC electronic medical record which is merged with LINKS, the Louisiana Immunization Network, in which vaccine type and date can only be entered by authorized health care professionals. This information was added to table 2 footer.

Line 38-39: Were there placental pathologic studies to confirm if these stillbirths were associated with COVID?
-Placental pathologic studies are available on stillbirth patients, however pathology did not specifically comment or test for COVID 19 virus or infection. Due to the retrospective nature of the study, we are unable to specifically test for this at this time. We acknowledge this as a limitation of reporting the stillbirth data.

Lines 49-51: ACOG and SMFM have put out very strong statements supporting vaccination in pregnant women. Please site the ACOG guidelines, and what ACOG and SMFM are doing to

encourage vaccination in pregnant women.

SMFM and ACOG guidelines have been added as references and comment in the conclusion "As nationwide efforts to improve vaccination acceptance continue" was cited with SMFM and ACOG guidelines. Due to 600 word limitation, the authors are unable to add a comment about ACOG and SMFM vaccination efforts.

Table 2: My biggest issue is with the odds ratios stated in table 2, page 6. Are these univariable (crude or unadjusted) or multivariable (adjusted) odds ratios for vaccinated versus unvaccinated pregnant women? If they are multivariable odds ratios for vaccinated versus unvaccinated women, what confounders were adjusted for in the analyses? The way table 2 is presented is very confusing and difficult to understand and interpret.

-Adjusted OR were reported in table 2, see explanation in footer.

STATISTICAL EDITOR COMMENTS:

The Statistical Editor makes the following points that need to be addressed:

Table 1: Suggest adding a footnote to this table stipulating the definition in this Table for "vaccinated". Need units for BMI.

These comments were addressed.

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See footer for table 2

line 48: Why was the association of vaccination status vs smoking and greater BMI not included? All were statistically significant in this series?

We have included this in our conclusion.