

# 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](mailto:obgyn@greenjournal.org).

**Date:** Jun 25, 2021  
**To:** "Julia Ellen Burd" [REDACTED]  
**From:** "The Green Journal" em@greenjournal.org  
**Subject:** Your Submission ONG-21-1139

RE: Manuscript Number ONG-21-1139

Cessation of oxygen supplementation for category II fetal heart rate tracings in labor: A quality improvement study

Dear Dr. Burd:

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).

Please be sure to address the Editor comments (see "EDITOR COMMENTS" below) in your point-by-point response.

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 Jul 16, 2021, we will assume you wish to withdraw the manuscript from further consideration.

#### REVIEWER COMMENTS:

Reviewer #1: Abstract:  
Succinct and clear

#### Introduction:

The authors present this as a quality improvement effort, but perhaps they really mean that this is a study showing equivalency or a non-inferiority type study between a traditional standard of care and current knowledge. Perhaps by changing the standards they aren't really improving quality as much as not lessening quality by removing one aspect of care. The authors should consider the use of the language "quality improvement" as it applies to this paper.

#### Methods:

Why did the authors choose to include covid patients? Was this to try to increase the number of patients on oxygen? Rules for special cause variation needs more of an explanation. Why did the authors use this metric? Is this the standard metric for quality improvement studies?

#### Results:

Were umbilical cord gases collected?  
Why do the authors think they had such a high rate of ICN admissions (20%)?

#### Discussion:

Line 230- How long after maternal oxygenation do the animal studies report free oxygen radicals? Minutes? Hours?  
Line 239- The lowered umbilical artery pH associated in prior studies with maternal oxygen administration could also be explained by the underlying events/reasons why a mother is administered oxygen and not just the oxygen itself. I recommend adding this as a point.

#### Tables:

Table 3:  
I recommend removing 1 minute Apgar score as 1 minute Apgar score is not a current metric of neonatal health and does not predict neonatal outcome.

#### Figures:

Figure 2 doesn't seem to be discussed in the paper.  
Also, the figure legend for this figure needs more explanation. What are the 3 groups? What do the abbreviations mean?

Reviewer #2: This QI study examining abandoning the use of supplemental oxygen for patient in labor adds to the expansive list of ways COVID-19 has shown true the proverb "necessity is the mother of invention." The authors demonstrate that education during sign-out rounds and removal of non-breather oxygen masks all but eliminated the use of supplemental oxygen in labor without any negative maternal or neonatal consequences. Use of oxygen, like NPO status before surgery, represents an ingrained practice with little scientific evidence to support it. The practice is common, even though it adds cost to healthcare and is uncomfortable for patients. It took the emergency of COVID-19 to force change and the authors nicely point out that, with the proper buy-in, the change was neither difficult nor harmful.

Line 64 - The rationale for not administering supplemental oxygen without a proven clinical benefit is clear. However, it seems a bit disingenuous to set aside the theoretical benefits (e.g. improve fetal pulse oximetry in the fetus) because there is not a proven benefit, while at the same time maintaining just as theoretical harms (e.g. creation of oxygen free radicals in the fetus) as potential reasons to avoid supplemental oxygen in labor, particularly since the RCTs show no difference in maternal and neonatal outcomes with or without oxygen supplementation.

Line 72 - If the lack of difference held for only patients with category 2 tracings, for whom did it not hold?

Reviewer #3: This is a quality improvement study on the cessation of oxygen supplementation for category II fetal heart rate tracings in labor. The primary outcome was change in percentage of patients receiving oxygen supplementation.

#### Introduction

1. I am curious if there is any evidence that oxygen supplementation may be harmful to the developing brain, and I recommend consideration of adding this to the discussion.
2. Line 81-83 - what was the main driver behind your change in practice? As I read further in the paper, it sounds like this practice was implemented due to COVID-19 and the recommendation to avoid oxygen administration in this setting. Generally for quality improvement projects, it is best to determine the drivers affecting your outcome of interest so that changes you make are tailored to impact these drivers and effect the desired change.

#### Methods

1. Why was this practice change implemented? Was it because of COVID? Lack of evidence of the effectiveness of oxygen supplementation for category II FHR tracings? Evidence of potential harm of oxygen supplementation?
2. You have a nice description of the interventions used when implementing this policy

#### Results

1. In Figure 2, for your p-chart on the rate of oxygen administration in labor, the time of the intervention should be marked on the chart

#### Discussion

1. I agree, the retrospective nature of this study is a limitation, as we cannot tell if there was a true change in practice. Perhaps compliance was related more to the COVID-19 pandemic, and fears of spreading COVID with oxygen administration. I wonder if the change in practice has been sustained now that the COVID-19 vaccine is more widely available.
2. I also agree that the sample size is likely too small to assess the secondary outcomes of interest.

#### STATISTICAL EDITOR COMMENTS:

Table 2: Need to include units for BMI, GA at delivery.

Tables 2, 3 and line 158: For comparing small counts (ie,  $\leq 5$ ), should use Fisher's test., not Chi-square. The p-values for comparing "abn US doppler", "neonatal death" will become higher values, the p-values for the primary outcome and "COVID" will not materially change. For Table 3, the footnote should be changed, since there were no instances of mean  $\pm$  SD in that Table.

General: Cannot generalize the NS conclusions re: the NS comparisons of delivery or neonatal outcomes, since they were not evaluated for power/sample size. That is especially an issue for the outcomes with smaller proportions, it would have required a much larger sample size to discern differences for those.

Fig 2: Should include a Table enumerating the values associated with each of the blue squares indicated at 1/1/20, 2/1/20, 3/1/20, 3/20/20, 4/1/20, 5/1/20, 6/1/20 and 7/1/20> I presume that these were mean values for a time period, but need to clarify in a Table format what each of the numerators and denominators were. and their resulting percentage.

#### EDITOR COMMENTS:

1. The Editors of Obstetrics & Gynecology have increased transparency around the 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.

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 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.

3. Because of space limitations, it is important that your revised manuscript adhere to the following length restrictions by manuscript type: Clinical Practice and Quality articles should not exceed 5,500 words. Stated word limits include the title page, précis, abstract, text, tables, boxes, and figure legends, but exclude references.

4. 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]."

5. 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 limit for Clinical Practice and Quality is 300 words. Please provide a word count.

6. ACOG avoids using "provider." Please replace "provider" throughout your paper with either a specific term that defines the group to which are referring (for example, "physicians," "nurses," etc.), or use "health care professional" if a specific term is not applicable.

7. 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](http://edmgr.ovid.com/ong/accounts/table_checklist.pdf).

8. 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](mailto:obgyn@greenjournal.org)). In most cases, if an ACOG document has been withdrawn, it should not be referenced in your manuscript.

9. When you submit your revision, art saved in a digital format should accompany it. If your figure was created in Microsoft Word, Microsoft Excel, or Microsoft PowerPoint formats, please submit your original source file. Image files should not be copied and pasted into Microsoft Word or Microsoft PowerPoint.

Figure 1: Are items excluded not mutually exclusive?

Figure 2: Please cite the figure within the manuscript. Is this available at a higher resolution?

10. Each supplemental file in your manuscript should be named an "Appendix," numbered, and ordered in the way they are first cited in the text. Do not order and number supplemental tables, figures, and text separately. References cited in appendixes should be added to a separate References list in the appendixes file.

11. 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>.

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.

If you choose open access, you will receive 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](mailto: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 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 21 days from the date of this letter. If we have not heard from you by Jul 16, 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

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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.

Dear Editors,

Thank you for giving us the opportunity to enhance our manuscript entitled “Cessation of oxygen supplementation for category II fetal heart rate tracings in labor: A quality improvement study”

Below we have listed questions raised by the *Obstetrics & Gynecology* reviewers (Point A), followed by our response (Point B), as well as the position in the paper where changes were made (Point C) and the changes that were made (Point D). We submitted the revised manuscript using the “track changes” feature; pages and numbers refer to “track changes” copy. We also submitted a clean non-edited copy of the revised manuscript as well as a blinded clean copy of the revised manuscript per the updated *Obstetrics & Gynecology* guidelines.

Warm regards,

Julia Burd (for all authors)

#### REVIEWER COMMENTS:

Reviewer #1:

Point #1:

- a) Abstract: Succinct and clear
- b) Thank you for your positive review.
- c) –
- d) –

Point #2

- a) The authors present this as a quality improvement effort, but perhaps they really mean that this is a study showing equivalency or a non-inferiority type study between a traditional standard of care and current knowledge. Perhaps by changing the standards they aren't really improving quality as much as not lessening quality by removing one aspect of care. The authors should consider the use of the language "quality improvement" as it applies to this paper.
- b) We appreciate the reviewer's feedback. We sought to complete this project within the framework of quality improvement and clinical implementation, looking at rate of adherence as the primary outcome. We felt that it was important to also study effects of this implementation to assess the effects of this initiative at our institution. We hoped that by presenting this paper in a quality improvement format, we could offer other institutions strategies on how to implement these changes at their institutions. As noted, this study is not appropriately powered to be a non-inferiority study.
- c) –
- d) –

- a) Point #3  
Methods: Why did the authors choose to include covid patients? Was this to try to increase the number of patients on oxygen?
- b) We chose to not exclude COVID patients as the majority of COVID positive patients are asymptomatic positives and we did not want to exclude a large population. Notably, patients who were given oxygen for maternal desaturations, including COVID+ patients given oxygen for this reason, were excluded from the study. We did perform analysis of all secondary outcomes excluding COVID+ patients and noted no difference in outcomes (Page 10, lines 201-203). We added language to clarify reason for inclusion of COVID+ patients.
- c) Page 7, lines 129-132
- d) Notably, due to the prospective design of this study, COVID-19 positive patients, diagnosed either prior to admission or on universal nasopharyngeal swab on admission to labor and delivery, were not excluded if they need not require supplemental oxygen due to concern for introducing bias by exclusion of a potentially large number of patients.

#### Point #4

- a) Rules for special cause variation needs more of an explanation. Why did the authors use this metric? Is this the standard metric for quality improvement studies
- b) The SQUIRE 2.0 guidelines state that researchers should use “quantitative methods used to draw inferences from the data and methods for understanding variation within the data, including the effects of time as a variable.”<sup>1</sup> We have chosen the rules of special cause variation<sup>2</sup> as a standard to fulfill these requirements as have other quality-improvement publications.<sup>3</sup> We have expanded on the rules of special cause variation as requested.
- c) Page 8 Lines 157-164
- d) “The primary outcome was analyzed by control charts and significance was determined by rules for special cause variation, according to Provost and Murray in the Healthcare Data Guide, and was selected a priori. Special cause variation are rules that identify unexpected variations in quality improvement data that result from unusual occurrences. These rules are as follows: 1. A single point outside the control limits (either above the upper control limit or below the lower control limit); 2. At least 6 consecutive points all increasing or all decreasing; 3. Eight or more consecutive points all on the same side of the center line (all above the line or all below the line); 4. Two out of three points in the outer third of the chart; 5. At least 15 consecutive points in the inner third of the chart.<sup>17</sup>”

#### Point #5

- a) Results: Were umbilical cord gases collected?
- b) At our institution, umbilical cord gases are collected only at the providers discretion (ie, for babies with low Apgar scores). As data is inconsistently available, this information was not collected.
- c) –
- d) –



Point #6

- a) Why do the authors think they had such a high rate of ICN admissions (20%)?
- b) This specific cohort is those who were attempting a vaginal delivery, increasing the risk of chorioamnionitis and therefore an ICN admission as our institution admits all babies delivered in the setting of chorioamnionitis to the ICN. Additionally, as we do not have a pediatrics unit at the hospital, any baby who cannot “room in” with the mother is admitted to the ICN. We have added the high ICN admission rate as a limitation within our discussion section.
- c) Page 11, Lines 221-223
- d) Additionally, compliance and outcomes were only studied at one academic institution with a high ICN admission rate and measures were observed retrospectively with dependence on nursing documentation of oxygen supplementation.

Point #7

- a) Discussion: Line 230- How long after maternal oxygenation do the animal studies report free oxygen radicals? Minutes? Hours?
- b) We have added this information to the manuscript.
- c) Page 12, lines 249-251
- d) “Animal studies have shown that maternal oxygen administration results in elevated makers of free radical activity in the fetus after a period of fetal asphyxia with less than one hour of oxygen supplementation.”

Point #8

- a) Line 239- The lowered umbilical artery pH associated in prior studies with maternal oxygen administration could also be explained by the underlying events/reasons why a mother is administered oxygen and not just the oxygen itself. I recommend adding this as a point.
- b) The cited studies are randomized controlled trials of oxygen given prophylactically in the second stage of labor. We added language to clarify this.
- c) Page 13, lines 260-263
- d) “Our secondary outcomes concur with these findings. However, individual studies using prophylactic oxygen administration included in these analyses suggest the potential for lowered umbilical artery pH<sup>4</sup> and increased need for delivery room resuscitation<sup>5</sup> associated with maternal oxygen administration.”

Point #9

- a) Table 3: I recommend removing 1 minute Apgar score as 1 minute Apgar score is not a current metric of neonatal health and does not predict neonatal outcome.
- b) We chose to include this information both for information on neonates directly after delivery (ie, is the neonate more depressed without oxygen) as well as to maintain consistency with outcomes reported in RCTs. We respectfully request to keep the 1-minute Apgar score data available for other readers.



- c) –
- d) --

Point #10

- a) Figure 2 doesn't seem to be discussed in the paper. Also, the figure legend for this figure needs more explanation. What are the 3 groups? What do the abbreviations mean?
- b) Thank you for this point. A reference to Figure 2 has been added to the text and a legend has been added to figure 2.
- c) Page 9, Line 190, Figure 2
- d) "Figure 2," Legend is embedded within Figure 2

Reviewer #2:

Point #1

- a) This QI study examining abandoning the use of supplemental oxygen for patient in labor adds to the expansive list of ways COVID-19 has shown true the proverb "necessity is the mother of invention." The authors demonstrate that education during sign-out rounds and removal of non-breather oxygen masks all but eliminated the use of supplemental oxygen in labor without any negative maternal or neonatal consequences. Use of oxygen, like NPO status before surgery, represents an ingrained practice with little scientific evidence to support it. The practice is common, even though it adds cost to healthcare and is uncomfortable for patients. It took the emergency of COVID-19 to force change and the authors nicely point out that, with the proper buy-in, the change was neither difficult nor harmful.
- b) Thank you for your evaluation of this study.
- c) –
- d) –

Point #2

- a) Line 64 - The rationale for not administering supplemental oxygen without a proven clinical benefit is clear. However, it seems a bit disingenuous to set aside the theoretical benefits (e.g. improve fetal pulse oximetry in the fetus) because there is not a proven benefit, while at the same time maintaining just as theoretical harms (e.g. creation of oxygen free radicals in the fetus) as potential reasons to avoid supplemental oxygen in labor, particularly since the RCTs show no difference in maternal and neonatal outcomes with or without oxygen supplementation.
- b) Thank you for your comment. We agree that there are theoretical benefits and risks to giving oxygen. Based on the best available evidence and in concordance with NICE guidelines and policies in countries like The Netherlands, we have found that the lack of actual noted benefit is enough to change practice at our institution. We note other

potential harms of oxygen supplementation, including birth trauma (Page 13, lines 263-265).

- c) –
- d) --

Point #3

- a) Line 72 - If the lack of difference held for only patients with category 2 tracings, for whom did it not hold?
- b) The lack of difference was present for all groups. The line has been updated for clarity.
- c) Page 4, line 71-72
- d) This lack of difference was maintained in subgroup analyses of patients given oxygen prophylactically in the 2<sup>nd</sup> stage and for those with Category II FHT.

Reviewer #3:

Point #1

- a) This is a quality improvement study on the cessation of oxygen supplementation for category II fetal heart rate tracings in labor. The primary outcome was change in percentage of patients receiving oxygen supplementation.
- b) Thank you for your review of this study.
- c) –
- d) --

Point #2

- a) Introduction 1. I am curious if there is any evidence that oxygen supplementation may be harmful to the developing brain, and I recommend consideration of adding this to the discussion.
- b) We have added information related to this topic to the discussion section per your recommendation.
- c) Page 12, lines 251-253
- d) “It is also remarkable that resuscitation newborns with room air as opposed to 100% oxygen leads to decreased neonatal mortality with no change in neurodevelopmental impairment or hypoxic ischemic encephalopathy in meta-analysis.<sup>6</sup>”

Point #3

- a) Line 81-83 - what was the main driver behind your change in practice? As I read further in the paper, it sounds like this practice was implemented due to COVID-19 and the recommendation to avoid oxygen administration in this setting. Generally, for quality improvement projects, it is best to determine the drivers affecting your outcome of interest so that changes you make are tailored to impact these drivers and effect the desired change.

- b) We had been discussing as a department stopping oxygen supplementation based on the available data. The COVID-19 pandemic accelerated that discussion and put the practice into action. We include in the discussion section.
- c) Page 11, line 217-220
- d) “The guideline was rapidly implemented as part of the bundle for staff and patient safety in the unique setting of the start of the COVID-19 pandemic. Given this presented data, this practice has continued at our institution with excellent compliance in provider experience even as vaccination becomes more widely available.”

Point #4

- a) Methods 1. Why was this practice change implemented? Was it because of COVID? Lack of evidence of the effectiveness of oxygen supplementation for category II FHR tracings? Evidence of potential harm of oxygen supplementation?
- b) Please see Reviewer #3, Point #3
- c) –
- d) –

Point #5

- a) Methods: You have a nice description of the interventions used when implementing this policy
- b) We appreciate your comments.
- c) –
- d) –

Point #6

- a) Results 1. In Figure 2, for your p-chart on the rate of oxygen administration in labor, the time of the intervention should be marked on the chart
- b) Thank you for this suggestion. We have added this annotation.
- c) Figure 2
- d) Red circle added within Figure 2 for “New Protocol”

Point #7

- a) Discussion 1. I agree, the retrospective nature of this study is a limitation, as we cannot tell if there was a true change in practice. Perhaps compliance was related more to the COVID-19 pandemic, and fears of spreading COVID with oxygen administration. I wonder if the change in practice has been sustained now that the COVID-19 vaccine is more widely available.
- b) We have added language to address this question.
- c) Page 11, line 219-220
- d) Given this presented data, this practice has continued at our institution with excellent compliance in provider experience even as vaccination becomes more widely available.

Point #8

- a) I also agree that the sample size is likely too small to assess the secondary outcomes of interest.
- b) We agree with this comment and have thus not included secondary outcomes in the conclusions.
- c) –
- d) --

STATISTICAL EDITOR COMMENTS:

Point #1

- a) Table 2: Need to include units for BMI, GA at delivery.
- b) Thank you for this recommendation.
- c) Page 18, Table 2
- d) Admission BMI (kg/m<sup>2</sup>), Avg GA at delivery (weeks)

Point #2

- a. Tables 2, 3 and line 158: For comparing small counts (ie,  $\leq 5$ ), should use Fisher's test., not Chi-square. The p-values for comparing "abn US doppler", "neonatal death" will become higher values, the p-values for the primary outcome and "COVID" will not materially change.
- b. Thank you for this recommendation.
- c. Page 9, line 173-174 (Methods). Tables 2 and 3
- d. "If there were fewer than 5 events in each group, Fisher's exact test was used to evaluate categorical data."  
Fisher's exact test was applied for abnormal US dopplers and neonatal death with the changed p-value included in tables 2 and 3. There was no change in p-value for COVID and primary outcome with Fisher's exact test.

Point #3

- a) For Table 3, the footnote should be changed, since there were no instances of mean  $\pm$  SD in that Table.
- b) Thank you for this recommendation.
- c) Page 19, line 373
- d) Data are presented as: number of events / total number of deliveries, (percentage) and p-value

#### Point #4

- a) General: Cannot generalize the NS conclusions re: the NS comparisons of delivery or neonatal outcomes, since they were not evaluated for power/sample size. That is especially an issue for the outcomes with smaller proportions, it would have required a much larger sample size to discern differences for those.
- b) We agree and have included this more explicitly in the discussion section.
- c) Page 11 line 226-227
- d) This study is also not adequately powered to be able to state definitively that the delivery and neonatal outcomes included are non-significant.

#### Point #5

- a) Fig 2: Should include a Table enumerating the values associated with each of the blue squares indicated at 1/1/20, 2/1/20, 3/1/20, 3/20/20, 4/1/20, 5/1/20, 6/1/20 and 7/1/20> I presume that these were mean values for a time period, but need to clarify in a Table format what each of the numerators and denominators were. and their resulting percentage.
- b) We have included this table in Figure 2
- c) Figure 2
- d) Please see included table with figure

#### EDITOR COMMENTS:

#### Point #1

- a) The Editors of Obstetrics & Gynecology have increased transparency around the 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:
- b) **OPT-IN: Yes, please publish my point-by-point response letter.**

#### Point #2

- a) 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.

- b) We agree with these definitions.

#### Point #3

- a) Because of space limitations, it is important that your revised manuscript adhere to the following length restrictions by manuscript type: Clinical Practice and Quality articles should not exceed 5,500 words. Stated word limits include the title page, précis, abstract, text, tables, boxes, and figure legends, but exclude references.
- b) Our word count is less than this limit.

#### Point #4.

- a) 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]."

- b) No financial support was received for this study.

All assistance is acknowledged authorship.

This data was presented at the SMFM 41<sup>st</sup> Annual Pregnancy Meeting and this is noted on the title page.

This manuscript has not been previously uploaded.

#### Point #5

- a) 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 limit for Clinical Practice and Quality is 300 words. Please provide a word count.

- b) The abstract is consistent with these guidelines and is 286 words in length.

#### Point #6

- a) ACOG avoids using "provider." Please replace "provider" throughout your paper with either a specific term that defines the group to which are referring (for example, "physicians," "nurses," etc.), or use "health care professional" if a specific term is not applicable.
- b) We removed the reference to "provider."
- c) Page 21, line 401
- d) Historically, many health care professionals have used supplemental oxygen to resolve Category II FHT.

#### Point #7

- a) 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](http://edmgr.ovid.com/ong/accounts/table_checklist.pdf).
- b) These style recommendations were reviewed, and table style was updated accordingly.

#### Point #8

- a) 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

- b) In response:
  - a. We include a DOI with article references and an accessed date with website references.
  - b. We reference practice bulletin 116, last updated in 2010.
  - c. References are up to date.

Point #9

- a) When you submit your revision, art saved in a digital format should accompany it. If your figure was created in Microsoft Word, Microsoft Excel, or Microsoft PowerPoint formats, please submit your original source file. Image files should not be copied and pasted into Microsoft Word or Microsoft PowerPoint.

Question #1: Figure 1: Are items excluded not mutually exclusive?

- b) Figure 1: items are not mutually exclusive. We have included this in the figure legend.
- c) Page 20, line 381
- d) Note: Some patients met multiple exclusion criteria

Question #2 Figure 2: Please cite the figure within the manuscript. Is this available at a higher resolution?

- a) Figure 2 has been saved and uploaded at a higher resolution.

Point #10

- A) Each supplemental file in your manuscript should be named an "Appendix," numbered, and ordered in the way they are first cited in the text. Do not order and number supplemental tables, figures, and text separately. References cited in appendixes should be added to a separate References list in the appendixes file.
- B) Supplement has been renamed as appendix

Point #11

- a) 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>.

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.

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- b) We do not plan to submit this article for open access

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