OBSTETRICS & GYNECOLOGY

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- 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: Jun 18, 2021
To: "Ariel Leigh Lanier" [redacted]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-21-961

RE: Manuscript Number ONG-21-961

A prospective comparison of neonatal outcomes after delivery in water vs. delivery on land

Dear Dr. Lanier:

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 Jul 09, 2021, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1: The authors are to be congratulated for reporting a large study on water births compared with land births in a low risk population that planned delivery in alternative birth centers(ABC) in a hospital system. This hospital system has a track record since 1995 and thus is one with significant experience.

1. Intro
The authors present the current state and highlight concerns with water birth and acknowledge the ACOG opinions.

2. Methods
It is unclear to me where these ABC's are located. Are these a separate area within Labor and Delivery, on a different hospital floor, or outside or the hospital? Please explain. I think this will give the reader a clearer picture of what is involved in the transfer process which becomes important in the urgent situation such as cord prolapse.
I think the choice of NICU admission as primary outcome was appropriate.

Editor: We would be interested in a substantially revised manuscript. Please simply describe the outcomes in the 3 groups with 95% confidence intervals for the outcomes. Please, since patients self-selected, don't make statistical comparisons between the groups.
Also, in wha way was this study conducted "prospectively"?

I understand that no a priori information on NICU admissions was available. This is surprising given the fact that the program was in place since 1995. I would have expected this outcome to have been collected as part of ongoing QA.
Among the categories of NICU admissions, I thought the one entitled "congenital/acquired" was artificial an would be better termed "other".

3. Results
The authors found no difference in NICU admissions between the groups.
The neonatal death was noteworthy. I think this highlights the importance of understanding where the ABC was located.
I would suggest a table detailing reasons for all transfers from water to land delivery rather than just the NICU admissions.

4. Discussion
The authors discuss prior journal reports on this topic. The Sidebottom paper was the only one listed. Were there others with larger sample sizes in prior reports. The authors may wish to highlights how their paper improves the knowledge base on this topic (eg largest series of water births).

Reviewer #2: Thank you for the opportunity to review the article for submission "A prospective comparison of neonatal outcomes after delivery in water vs. delivery on land". The authors performed a prospective observational study of "Water births" compared with "standard/land births" at four Alternative Birth Centers in their hospital system over a four year period 2015-2019. They categorized patients into three groups by site of labor (water/ land) and site of delivery (water/ land). They collected information on 2077 births (889 delivered in the water) and reviewed demographic data and delivery/birth outcome information. Some women chose to switch to land delivery and some were advised to switch to land delivery. They performed a binary logistic regression to evaluate NICU admission based on location of delivery. Location of delivery did not impact NICU admission while nulliparous status and increasing BMI did increase NICU admissions. The authors acknowledge their study was not designed as "intent to treat" and only involved low risk subjects in a non-hospital setting. There was an intrapartum fetal loss associated with cord prolapse.
The issue of water birth is popular in the lay media and pregnant women frequently inquire about the possibility of water birth. The readers of the Green journal should have updated information on this practice option to discuss the data with their patients. The current report includes 889 water births which would include it among the larger case series among research papers on this topic.
The current research report has some constraints that limit its generalizability. As mentioned by the authors the lack of randomization is the greatest weakness, though the overall low rate of neonatal problems after delivery is reassuring. The water births occurred in free standing birth centers suggesting a very low risk population, making it unclear if the results can be extrapolated to a broader population. The authors do not offer any insight on the management of the mother whose fetus was lost due to cord prolapse. Cord prolapse with poor outcome can occur in any setting; but thinking about the challenges of moving the mother out of the tub and emergent transfer caused me to reflect on ways to improve safety in birth center settings. There is a case series of 26,000 water births in the AABC database 2012-1017 Snapp C et al J Perinatal Neonatal Nurs 2020 1;16-26. I wondered if a portion of this cohort of births were included in that report. (That report did little evaluation or comparison and was primarily descriptive .)
If the report is accepted, I have some recommendations for major changes prior to publication.
1- Introduction- Given the limited amount of literature the average OB reads on this topic, I recommend a greatly expanded introduction. I suggest the authors review Vanderlann et al Midwifery 2018;59:27-38 for ideas on a more informative and data driven introduction to frame their question. Consider including the Cochrane review on this topic 2018, May 16 . I suggest adding a statement about the assignment of the term "land" birth. (I agree with its use rather than "standard " or "conventional" but I think it will help the reader get oriented to the research question.) If the supposition is that current ACOG guidance on water birth is not based on modern data, then provide the reader with relevant background data to supply them with the education to read the report .
2- Methods-
a. Was this data collected for this research question or collected as part of the AABC prospective database as described by Snapp et al?
b. I would like more details on the conduct of water birth at the AABC centers in the body of the paper. (I appreciated the information on disinfection). I am interested if the water temperature is monitored and if it is replaced as labor progresses. (such as if the parturient defecates). I recollect that some of the reports of early bad neonatal outcomes were related to delaying emerging of the neonate from the water to air. Is there a AABC standard for removal of the fetal head from the water?
c. Line 90 - I would suggest providing criteria for providers asking women to remove themselves from the tub. Does the AABC have guidelines for this ? Does including these patients in the land delivery bias that group as more complicated?
d. Line 102 - What does immediate access to emergency care specify? Call 911 and have ambulance transfer or stretcher transfer to an adjacent building ?
3- Results - I reviewed the tables but I didn't identify how many mothers/infants from each group required hospital transfer?
4- Discussion
I suggest that the authors think through their nomenclature and description of the water birth that their data supports. I think their data suggests that "Water birth conducted with AABC screening and management protocols by CNM or resident support " can be conducted with comparable neonatal outcomes. While I agree with the sentiments of the last paragraph, the role of the provider is to offer patients with the most complete information on which the patient may base their decisions. I suggest they qualify their statements with the information their data supports. This data should not be extrapolated to home birth situations or high-risk patients. Additionally, there is controversy in the literature on obstetric lacerations and tub birth so pelvic floor outcomes may differ. (Preston HL et al Int Urogynecol J 2019, 30:909-915) This morbidity might also be a consideration for the mother in the choice of water delivery. Neonatal outcome is not the only consideration.

Reviewer #3: This is a 5 year prospective observational study of women delivering at 4 different Alternative Birthing Centers (ABCs) in southwest Ohio in asingle system comparing neonatal outcomes (primary NICU admission) between those who labored/delivered in three different ways: Land/land, Land/water, Water/water

1. Objective: I would restate the Hypothesis and Objective including your primary outcome at the end of the Introduction/ should align with the Abstract

2. Materials and Methods: lines 117-118 Data was collected by observation, questionnaires, and post-partum phone calls." Can you please be more specific and define the process of each

3. Line 215-218 and line 172-173 Regarding the topic of race I refer you to Instructions for Authors 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
I would suggest eliminating lines 172-173 and please define how race was defined and recorded per Instruction for authors

4. Materials and Methods: Please provide more detail on delivery method in water/water. Example was baby removed from water immediately or did the baby float to top or did mother lift baby?
A short summary of ABC requirements (I would also keep the table in appendix 1) in Materials and Methods example Epidural yes or no. If an epidural was desired were they transferred to LAD down the Hallway

5 Appendix 2. There are 3 rows " Rule out sepsis due to maternal chorioamnionitis." Is this intentional?

STATISTICAL EDITOR COMMENTS:

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

Table 1: Need units for gestational and maternal ages, maternal BMI, length of education.

lines 118-120: The stats tests used to analyze quantitative and qualitative data (ANOVA and chi-square), when applied to three cohorts, evaluates the question as to whether the distribution of data among all 3 groups is explained by random error. The results do not allow for the conclusion that one of the three groups is the reason for the non-random distribution, nor that the p-value can be used to conclude a particular group can be ascribed that p-value. The wording on lines 139-141 implies that the p-values can be attributed to the water/water group, when the comparison was across all three groups. Only for the cesarean delivery comparison were the water/water and water/land groups directly compared.

Table 3 and lines 113-114: The Table should be re-done to cite first the primary, then the secondary outcomes and clearly separate the two. Another issue with the primary outcome is its low frequency and therefore limited power to generalize the NS conclusion. for the secondary outcomes listed (APGAR(5 min) < 7, Need for resuscitation, mortality), the frequencies are even rarer and the power even more limited. The other issue from Table 1 and from the study design itself, is that the groups were not randomly assigned and they were not equivalent in baseline characteristics.

Table 4: Again, low power to have discerned a difference in morbidity categories and therefore to generalize the conclusion of NS difference by category.

Fig 1: These are really secondary outcomes re: to NICU admission. Need to include a Table of unadjusted ORs, then adjusted ORs as separate columns with a footnote citing which variables were retained in the final model. It appears from the text (lines 157-161) that there were 7 variables included in the model vs a total of 61 instances of NICU admission and fewer than 61 for the various subsets of delivery. In that case, the model is over fitted to the data. The strong relationship of BMI and nulliparity to NICU admission reiterates the issues with unadjusted evaluation of NICU admission rates (Tables 1, 3).

EDITOR COMMENTS:

1. The Editors of Obstetrics & Gynecology are seeking to increase transparency around its peer-review process, in line with efforts to do so in international biomedical peer review publishing. If your article is accepted, we will be posting this revision letter as supplemental digital content to the published article online. Additionally, unless you choose to opt out, we will also be including your point-by-point response to the revision letter. 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. Obstetrics & Gynecology uses an "electronic Copyright Transfer Agreement" (eCTA). Please check with your coauthors to confirm that the disclosures listed in their eCTA forms are correctly disclosed on the manuscript's title page. Each of your coauthors received an email from the system, titled "Please verify your authorship for a submission to Obstetrics & Gynecology." Each author should complete the eCTA if they have no yet done so.

Samantha L. Wiegand (slewiegand@PremierHealth.com) still need to complete the form.

3. 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.

4. 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.

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

6. 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]."

7. 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 Original Research articles is 300 words. Please provide a word count.

8. ACOG is moving toward discontinuing the use of "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.

9. In your Abstract, manuscript Results sections, and tables, 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%").

10. 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.

11. 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).

12. 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: Please add tick marks along the x-axis.

13. 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.

14. 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 Jul 09, 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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time. (Use the following URL: https://www.editorialmanager.com/ong/login.asp?a=r). Please contact the publication office if you have any questions.

The Editors of Obstetrics & Gynecology

Re: Manuscript Number ONG-21-961

REVIEWER COMMENTS:

Reviewer #1: The authors are to be congratulated for reporting a large study on water births compared with land births in a low risk population that planned delivery in alternative birth centers(ABC) in a hospital system. This hospital system has a track record since 1995 and thus is one with significant experience.

1. Intro
The authors present the current state and highlight concerns with water birth and acknowledge the ACOG opinions.

2. Methods
It is unclear to me where these ABC's are located. Are these a separate area within Labor and Delivery, on a different hospital floor, or outside or the hospital? Please explain. I think this will give the reader a clearer picture of what is involved in the transfer process which becomes important in the urgent situation such as cord prolapse.

AUTHOR's RESPONSE: The ABCs are physically located in the hospital on the same floor as the traditional labor and delivery unit, with prompt access to obstetrical interventions or cesarean delivery achieved by transport via ambulation, wheelchair, or gurney. The manuscript has been updated with this statement (Lines 80, 111-114).

I think the choice of NICU admission as primary outcome was appropriate.

Editor: We would be interested in a substantially revised manuscript. Please simply describe the outcomes in the 3 groups with 95% confidence intervals for the outcomes. Please, since patients self-selected, don't make statistical comparisons between the groups.

AUTHOR's RESPONSE: All tables have been updated. The statistical comparisons have been removed and 95% confidence intervals added.

Also, in what way was this study conducted "prospectively"?

AUTHOR's RESPONSE: The parturients were enrolled in the study upon admission to the ABC. Written informed consent for the data collection was obtained upon admission by CITI trained nurses. Maternal demographics, delivery outcomes, and neonatal outcomes were obtained at the time of delivery by one of two MFMU research nurses (EK, or KF). Follow up phone calls were completed at approximately 6 months post-partum by the EK or KF.

I understand that no a priori information on NICU admissions was available. This is surprising given the fact that the program was in place since 1995. I would have expected this outcome to have been collected as part of ongoing QA.

AUTHOR's RESPONSE: NICU admissions from deliveries in the ABCs have been reviewed as part of the hospital system's quality review process, and as a requirement for CABC certification since their inception in 1995. We choose to not investigate the data retrospectively due to the lower quality of data.

Among the categories of NICU admissions, I thought the one entitled "congenital/acquired" was artificial and would be better termed "other".

AUTHOR's RESPONSE: This has been changed. The manuscript has been updated to reflect this (lines 138-143).

3. Results
The authors found no difference in NICU admissions between the groups.
The neonatal death was noteworthy. I think this highlights the importance of understanding where the ABC was located.
I would suggest a table detailing reasons for all transfers from water to land delivery rather than just the NICU admissions.

AUTHOR's RESPONSE: Thank you for the suggestion of including a table detailing all transfers from water to land delivery. As our primary outcome was NICU admissions, we did not prospectively collect this data. The requested data could be collected retrospectively by chart review but would be lower quality. This study was designed to assess whether delivery in water (water/water) affected the primary outcome. Women who initially labored in water then delivered on land (water/land) and had NICU admissions, would tend to bias the primary outcome towards the water/land group having higher NICU admissions. Women who initially labored in water then delivered on land (water/land) and did not have NICU admissions would tend to bias the water/water group to having a higher rate of NICU admissions, and the water/land group to have a lower rate. This results in a conservative conclusion that there was no difference (i.e. if there was bias it would tend to increase the rate in the water/water group and decrease the rate in the water/land group).

4. Discussion
The authors discuss prior journal reports on this topic. The Sidebottom paper was the only one listed. Were there others with larger sample sizes in prior reports. The authors may wish to highlights how their paper improves the knowledge base on this topic (eg largest series of water births).

AUTHOR's RESPONSE: It is our opinion the Sidebottom paper is a landmark paper on the topic of neonatal adverse outcomes with water birth. It was retrospective, but well controlled and most importantly contemporary. Prior reports have been smaller, retrospective or included women who did not deliver in water (hydrotherapy only). The meta-analysis by Vanderlaan et al summarizes the prior data well. We have updated our manuscript to state that our relatively large n is a strength of our paper. (lines 220-221)

Reviewer #2: Thank you for the opportunity to review the article for submission "A prospective comparison of neonatal outcomes after delivery in water vs. delivery on land". The authors performed a prospective observational study of "Water births" compared with "standard/land births" at four Alternative Birth Centers in their hospital system over a four year period 2015-2019. They categorized patients into three groups by site of labor (water/ land) and site of delivery (water/ land). They collected information on 2077 births (889 delivered in the water) and reviewed demographic data and delivery/birth outcome information. Some women chose to switch to land delivery and some were advised to switch to land delivery. They performed a binary logistic regression to evaluate NICU admission based on location of delivery. Location of delivery did not impact NICU admission while nulliparous status and increasing BMI did increase NICU admissions. The authors acknowledge their study
was not designed as "intent to treat" and only involved low risk subjects in a non-hospital setting. There was an intrapartum fetal loss associated with cord prolapse.
The issue of water birth is popular in the lay media and pregnant women frequently inquire about the possibility of water birth. The readers of the Green journal should have updated information on this practice option to discuss the data with their patients. The current report includes 889 water births which would include it among the larger case series among research papers on this topic.
The current research report has some constraints that limit its generalizability. As mentioned by the authors the lack of randomization is the greatest weakness, though the overall low rate of neonatal problems after delivery is reassuring. The water births occurred in free standing birth centers suggesting a very low risk population, making it unclear if the results can be extrapolated to a broader population. The authors do not offer any insight on the management of the mother whose fetus was lost due to cord prolapse. Cord prolapse with poor outcome can occur in any setting; but thinking about the challenges of moving the mother out of the tub and emergent transfer caused me to reflect on ways to improve safety in birth center settings. There is a case series of 26,000 water births in the AABC database 2012-1017 Snapp C et al J Perinatal Neonatal Nurs 2020 1;16-26. I wondered if a portion of this cohort of births were included in that report. (That report did little
evaluation or comparison and was primarily descriptive .)

AUTHOR's RESPONSE: Thank you for your thoughtful review. The ABCs are hospital based. Line 80 was updated to clarify this. These deliveries were not part of the AABC PDR database described by Snapp et al.

If the report is accepted, I have some recommendations for major changes prior to publication.

1- Introduction- Given the limited amount of literature the average OB reads on this topic, I recommend a greatly expanded introduction. I suggest the authors review Vanderlann et al Midwifery 2018;59:27-38 for ideas on a more informative and data driven introduction to frame their question. Consider including the Cochrane review on this topic 2018, May 16 . I suggest adding a statement about the assignment of the term "land" birth. (I agree with its use rather than "standard " or "conventional" but I think it will help the reader get oriented to the research question.) If the supposition is that current ACOG guidance on water birth is not based on modern data, then provide the reader with relevant background data to supply them with the education to read the report .

AUTHOR's RESPONSE: The introduction has been expanded to include Reviewer #1's recommendation to include the restrictions on conducting an RCT per Vanderlann and the conclusions from the Cochrane review that more data is needed. It is not clear to us what is being requested regarding the term "land" birth. We are attempting to follow the Instructions to the Authors by keeping the Introduction brief and less than 1 page.

2- Methods-

a. Was this data collected for this research question or collected as part of the AABC prospective database as described by Snapp et al?

AUTHOR's RESPONSE: This was a research protocol independent of the AABC PDR.

b. I would like more details on the conduct of water birth at the AABC centers in the body of the paper. (I appreciated the information on disinfection). I am interested if the water temperature is monitored and if it is replaced as labor progresses. (such as if the parturient defecates). I recollect that some of the reports of early bad neonatal outcomes were related to delaying emerging of the neonate from the water to air. Is there a AABC standard for removal of the fetal head from the water?

AUTHOR's RESPONSE: Appendix 1 has been updated and referenced in the methods section (lines 91-2, 99 and Appendix 1). The specific provisions for water temperature monitoring, water replacement, management of the newborn (there is no delay), and procedures for maternal defecation during labor, are in Appendix 1.

c. Line 90 - I would suggest providing criteria for providers asking women to remove themselves from the tub. Does the AABC have guidelines for this ? Does including these patients in the land delivery bias that group as more complicated?

AUTHOR's RESPONSE: The AABC does not have criteria for when a provider should ask a woman to remove herself from the tub (please see AABC Standards for Birth Centers, 2017 – can be found at: https://www.birthcenters.org/page/Standards.

The provisions for water birth (Appendix 1) are our hospital system's policy which provides guidelines. The specific guidelines listed in the Appendix are "non-reassuring" fetal status (General #6), signs of chorioamnionitis (General #7), and dystocia at the time of delivery (Second Stage #3). Other reasons to request a woman to leave the tub do not have specific guidelines and are usually based upon the care giver's clinic judgement and shared decision making with the woman. Examples of these would be an arrest of labor in either the first or second stage, or the provider recommends the woman receives another form of labor analgesia other than hydrotherapy.

d. Line 102 - What does immediate access to emergency care specify? Call 911 and have ambulance transfer or stretcher transfer to an adjacent building ?

AUTHOR's RESPONSE: The ABCs are physically located on the same floor as the traditional labor and delivery unit, with prompt access to obstetrical interventions or cesarean delivery achieved by transport via ambulation, wheelchair, or gurney. The manuscript has been updated with this statement (Lines 80, 111-114)

3- Results - I reviewed the tables but I didn't identify how many mothers/infants from each group required hospital transfer?

AUTHOR's RESPONSE: all deliveries occurred within the hospital. There were no hospital transfers. There were no women in the water/water group who were transferred to labor and delivery.

4- Discussion

I suggest that the authors think through their nomenclature and description of the water birth that their data supports. I think their data suggests that "Water birth conducted with AABC screening and management protocols by CNM or resident support " can be conducted with comparable neonatal outcomes. While I agree with the sentiments of the last paragraph, the role of the provider is to offer patients with the most complete information on which the patient may base their decisions. I suggest they qualify their statements with the information their data supports. This data should not be extrapolated to home birth situations or high-risk patients. Additionally, there is controversy in the literature on obstetric lacerations and tub birth so pelvic floor outcomes may differ. (Preston HL et al Int Urogynecol J 2019, 30:909-915) This morbidity might also be a consideration for the mother in the choice of water delivery. Neonatal outcome is not the only consideration.

AUTHOR's RESPONSE: We agree that our data should not be extrapolated to home birth situations or high-risk patients. Thank you for pointing out this important caution. The manuscript has been updated to reflect this (Lines 238-240). We agree there are benefits to water birth including the effect on the pelvic floor, but we did not study that as an outcome. We solely choose to report our percentage of perineal lacerations. This is an area which we may

look at in the future.

Reviewer #3: This is a 5 year prospective observational study of women delivering at 4 different Alternative Birthing Centers (ABCs) in southwest Ohio in asingle system comparing neonatal outcomes (primary NICU admission) between those who labored/delivered in three different ways: Land/land, Land/water, Water/water

1. Objective: I would restate the Hypothesis and Objective including your primary outcome at the end of the Introduction/ should align with the Abstract

AUTHOR's RESPONSE: The abstract and introduction have been changed to include the primary outcome (NICU admissions) in the objective statement in order to align.

2. Materials and Methods: lines 117-118 Data was collected by observation, questionnaires, and post-partum phone calls." Can you please be more specific and define the process of each

AUTHOR's RESPONSE: Maternal demographics, delivery outcomes, and neonatal outcomes were obtained at the time of delivery by one of two trained MFMU research nurses (EK, or KF). Neonatal outcomes were recorded at the time of neonatal discharge (Line 116). The written survey for pain assessment was given to the mother as close to deliver as possible (Lines 119-120). Follow up phone calls were completed at approximately 6 months post-partum by the EK or KF – the phone calls obtained additional data for future investigation and are not included in this report. The reference to post-partum phone calls was deleted.

3. Line 215-218 and line 172-173 Regarding the topic of race I refer you to Instructions for Authors 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
I would suggest eliminating lines 172-173 and please define how race was defined and recorded per Instruction for authors

AUTHOR's RESPONSE: Race is self-identified at the time of hospital registration. The options are Caucasian, Black or African American, Native Hawaiian, Other Pacific Islander, or Patient declined to answer/Unreported. In addition, patients have the option to identify their ethnicity as Hispanic or Latino. We assessed race in our study to identify existing disparities in the use of the ABC facilities. This is important as we found the use was not representative of the percentage of Blacks in our population, which is a limitation of our study and important to acknowledge. The manuscript has been updated to reflect this (lines 122-126). The requested lines (172-3) were eliminated.

4. Materials and Methods: Please provide more detail on delivery method in water/water. Example was baby removed from water immediately or did the baby float to top or did mother lift baby?
A short summary of ABC requirements (I would also keep the table in appendix 1) in Materials and Methods example Epidural yes or no. If an epidural was desired were they transferred to LAD down the Hallway

AUTHOR's RESPONSE: Please see response to Reviewer #2 inquiry 'c'. The addition of material to Appendix 1 addresses this inquiry. The manuscript has been updated to clarify that pharmacologic and neuraxial analgesia are not used (lines 92-93).

5 Appendix 2. There are 3 rows " Rule out sepsis due to maternal chorioamnionitis." Is this intentional?

AUTHOR's RESPONSE: Appendix 2 lists the individual diagnoses for each NICU admission. Each row represents one unique NICU admission. There were duplicated diagnoses, such as rule out sepsis. The Appendix has been updated to clarify this with the statement: "Each row represents one unique individual admission", added to the footer of each of the three tables.

STATISTICAL EDITOR COMMENTS:

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

Table 1: Need units for gestational and maternal ages, maternal BMI, length of education.

AUTHOR's RESPONSE: These were added.

lines 118-120: The stats tests used to analyze quantitative and qualitative data (ANOVA and chi-square), when applied to three cohorts, evaluates the question as to whether the distribution of data among all 3 groups is explained by random error. The results do not allow for the conclusion that one of the three groups is the reason for the non-random distribution, nor that the p-value can be used to conclude a particular group can be ascribed that p-value. The wording on lines 139-141 implies that the p-values can be attributed to the water/water group, when the comparison was across all three groups. Only for the cesarean delivery comparison were the water/water and water/land groups directly compared.

AUTHOR's RESPONSE: As requested by the Editors' comments (see responses to Reviewer #1, under Methods 2, above), the statistical comparisons were removed and 95% Confidence Intervals reported.

Table 3 and lines 113-114: The Table should be re-done to cite first the primary, then the

secondary outcomes and clearly separate the two. Another issue with the primary outcome is its low frequency and therefore limited power to generalize the NS conclusion. for the secondary outcomes listed (APGAR(5 min) < 7, Need for resuscitation, mortality), the frequencies are even rarer and the power even more limited. The other issue from Table 1 and from the study design itself, is that the groups were not randomly assigned and they were not equivalent in baseline characteristics.

AUTHOR's RESPONSE: The table has been reordered with the primary outcome (NICU admissions) on the first row. The statistical comparisons were removed and replaced with 95% confidence intervals.

Table 4: Again, low power to have discerned a difference in morbidity categories and therefore to generalize the conclusion of NS difference by category.

AUTHOR's RESPONSE: The statistical comparisons were removed and replaced with 95% confidence intervals.

Fig 1: These are really secondary outcomes re: to NICU admission. Need to include a Table of unadjusted ORs, then adjusted ORs as separate columns with a footnote citing which variables were retained in the final model. It appears from the text (lines 157-161) that there were 7 variables included in the model vs a total of 61 instances of NICU admission and fewer than 61 for the various subsets of delivery. In that case, the model is over fitted to the data. The strong relationship of BMI and nulliparity to NICU admission reiterates the issues with unadjusted evaluation of NICU admission rates (Tables 1, 3).

AUTHOR's RESPONSE: Figure 1 has been removed. The outcome from the LR is summarized in table 5. The final model only includes BMI and nulliparity.

EDITOR COMMENTS:

1. The Editors of Obstetrics & Gynecology are seeking to increase transparency around its peer-review process, in line with efforts to do so in international biomedical peer review publishing. If your article is accepted, we will be posting this revision letter as supplemental digital content to the published article online. Additionally, unless you choose to opt out, we will also be including your point-by-point response to the revision letter. 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.

AUTHOR's RESPONSE: OPT-IN: Yes, please publish my point-by-point response letter.

2. Obstetrics & Gynecology uses an "electronic Copyright Transfer Agreement" (eCTA). Please

check with your coauthors to confirm that the disclosures listed in their eCTA forms are correctly disclosed on the manuscript's title page. Each of your coauthors received an email from the system, titled "Please verify your authorship for a submission to Obstetrics & Gynecology." Each author should complete the eCTA if they have no yet done so.

Samantha L. Wiegand (slewiegand@PremierHealth.com) still need to complete the form.

AUTHOR's RESPONSE: Thank you for this notification. The email address provide for Dr Wiegand contains a typographical error. Her correct email address is slwiegand@premierhealth.com

Please note that two additional authors have been added to the manuscript. E. Kaye Snow and Rose A. Maxwell. We will update the authors with this resubmission, along with their email addresses so they may promptly confirm their disclosures.

3. 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.

AUTHOR's RESPONSE: Race is self-identified at the time of hospital registration. The options are Caucasian, Black or African American, Native Hawaiian, Other Pacific Islander, or Patient declined to answer/Unreported. In addition, patients have the option to identify their ethnicity as Hispanic or Latino. We assessed race in our study to identify existing disparities in the use of the ABC facilities. This is important as we found the use was not representative of the percentage of Blacks in our population, which is a limitation of our study and important to acknowledge. The manuscript has been updated to reflect this (lines 122-126). The requested lines (172-3) were eliminated.

4. 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://urldefense.com/v3/__https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-obstetrics-data-definitions__;!!On18fmf1aQ!nirq24gMBRhUobz1TwDRwZ2yPJQo6vjscRZap44gSH_Q2WXkJ-XIjE_MD4JMEMKlSVLJ$ and the gynecology data definitions at https://urldefense.com/v3/__https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-gynecology-data-definitions__;!!On18fmf1aQ!nirq24gMBRhUobz1TwDRwZ2yPJQo6vjscRZap44gSH_Q2WXkJ-XIjE_MD4JMEMjRQ-Dl$. If use of the reVITALize definitions is problematic, please discuss this in your point-by-point response to this letter.

AUTHOR's RESPONSE: Thank you for this direction. We believe our data definitions are consistent with reVITALize.

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

AUTHOR's RESPONSE: Word count is 3473.

6. 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]."

AUTHOR's RESPONSE: Added to title page: Presented in part as an ePoster Presentation at the Virtual Annual Clinical and Scientific Meeting of the American College of Obstetricians and Gynecologists. March 19, 2021.

7. 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 Original Research articles is 300 words. Please provide a word count.

AUTHOR's RESPONSE: Abstract word count is 296

8. ACOG is moving toward discontinuing the use of "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.

9. In your Abstract, manuscript Results sections, and tables, 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%").

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Figure 1: Please add tick marks along the x-axis.

AUTHOR's RESPONSE: Figure 1 has been removed

13. 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.

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