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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)\*

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

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<sup>\*</sup>The corresponding author has opted to make this information publicly available.

**Date:** Jul 12, 2019

To: "Vivienne L Souter"

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

Subject: Your Submission ONG-19-1067

RE: Manuscript Number ONG-19-1067

Midwife and Obstetrician Labor Practices and Birth Outcomes in Low-Risk Pregnancies Delivered in Hospital

Dear Dr. Souter:

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 Aug 02, 2019, we will assume you wish to withdraw the manuscript from further consideration.

#### **REVIEWER COMMENTS:**

Reviewer #1: The authors have done an observational study on the outcomes of labour when under midwifery or obstetrician care. They have also compared the various interventions done in labour between the two groups. The abstract is pretty concise and well summarised.

There is a dearth of midwifery care and this has been pointed out well by the authors.

The midwifery model of care as it exists in UK has considerable patient and provider benefits and is well acknowledged.

Strict inclusion criteria is usually followed in midwifery led birthing suites and the authors have rightly excluded the high risk group.

They have used a intention to treat analysis but would be interesting to see how many had to be moved to the obstetrician group due to various labour problems. Also the specific criteria used for change to obstetrician model should have been mentioned. This is very important as it helps in maintaining the quality standards and plan midwifery services. It also helps in counselling woman of these statistics so that they feel comfortable in choosing this model.

Th authors mention that (Lines 214-215)Mean time from admission to delivery was longer for multiparous women in the midwife group (7.0 hours versus 6.4 hours; p<0.001) but actually in Table 3, 7 hrs is for actually the obstetrician group.

There seems to be a significant racial disparity -predominantly only white seems to be using the midwifery care model. Need to address this and strategies to overcome this needs to be discussed.

Also interesting to note that in the obstetrician model, a big number of women have been admitted when cervix was only 3 cm dilated. This probably then may reflect the increasing interventions in that group.

Also use of AROM, Oxytocin, epidural and episiotomy is consistently higher in the obstetrician model in both nulli and multi, highlighting the importance of supportive care in labour.

As the authors pointed out, the reduction in CS rates in the midwifery model is very significant and should encourage more research as it has far reaching implications. A randomised controlled trial will address this issue better but the practical problem in doing it, increases the importance of studies like this.

However as the authors pointed out, it being an observational study-the con founders could alter the outcomes. Also the midwife delivery numbers are very small- compared to the total number and the racial disparity further affects the

generalisation of these findings.

Reviewer #2: The authors present their work in which they compare midwife and obstetrician labor practices and birth outcomes in low risk in-hospital deliveries. The following items should be addressed:

- 1. The title is a bit cumbersome, and doesn't quite capture the objective of the manuscript. Consider rewording, and include that the two types of providers are being compared.
- 2. Methods line 109-117 although the intent of the authors is to remove any confounding, by excluding so many patients, the generalizability of the study is also compromised. For example, marijuana use and nicotine use may be unnecessary as exclusion criteria. How were fetal anomalies defined, did this include minor anatomic differences such as urinary tract dilation, or isolated club foot or cleft lip which would be unlikely to impact route of delivery? Consider an additional analysis in which some of these exclusion criteria are included.
- 3. Methods line 160-173 this information would be more helpful to the reader earlier in the methods section, perhaps after the first paragraph.
- 4. The results state that the birth weight was higher in the midwifery group compared to the physician group and some of the conclusions rest on this difference, however the mean difference listed in the table is only 52 grams for nulliparous patients and 169 grams for multiparous patients, which is not clinically significant. Please clarify and de-emphasize in the text. The same is true for length of labor, which only differed by a fraction of an hour in the mean value for both the nulliparous and multiparous patients.

Reviewer #3: This is a retrospective cohort study comparing birth outcomes in Low risk pregnancies between obstetrician and Midwifery practices. Data is from a multi-center quality improvement collaborative.

- 1. There is a significant baseline differences between the two groups. Midwives had a higher proportion of white, multiparous women in their practice, how was this specifically addressed.
- 2. Line 218 "After adjustment for confounders". The specific confounders should be spelled out.

#### STATISTICAL EDITOR COMMENTS:

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

Table 4: For many of the maternal outcomes, the counts among the midwife cohorts were too few to allow for adjustment with 6 variables. Specifically, for the nulliparous comparisons: SMM, blood transfusions. Also, the counts and therefore the proportions of adverse events PPH, transfusion or SMM were so low that there was also limited power to generalize the NS findings, even if they had been adjustable. For the multiparous comparisons, the same issue with low counts vs adjustment for 6 variables is an issue re: OVD, CD, and all complications. The counts and frequencies are so few/low that power is limited to generalie the NS findings.

Table 5: Same issue with low counts and low power and inability to adjust for 6 variables. For the adjustment model, this applies outcomes among the nulliparous: shoulder dystocia, 5 min Apgar < 7, glucose instability and birth trauma. For the adjustment model among the multiparous, this applies to 5 min APgar < 7, glucose instability, resuscitation, NICU admission and birth trauma. Again, there is low power to generalize any NS findings.

Could attempt a matching algorithm to determine whether the differences were corroborated, but that would decrease power and may therefore still be a limitation.

#### **EDITOR COMMENTS:**

1. Thank you for your submission to Obstetrics & Gynecology. In addition to the comments from the reviewers above, you

are being sent a notated PDF that contains the Editor's specific comments. Please review and consider the comments in this file prior to submitting your revised manuscript. These comments should be included in your point-by-point response cover letter.

- \*\*\*The notated PDF is uploaded to this submission's record in Editorial Manager. If you cannot locate the file, contact Randi Zung and she will send it by email rzung@greenjournal.org.\*\*\*
- How were patients assigned to either midwife or obstetrician care in labor and delivery? Patient choice? Did it depend on antepartum care? Did it ever change during the course of labor?
- Please indicate that these dates are the inclusion dates. As written, it looks like you only looked at births on those 2 specific dates. You could say "from January 1, 2015 to September 30, 2018"
- what about length of labor?
- please provide a reason for this assertion.
- Could you write the inclusions/exclusions a bit more clearly. Perhaps state the inclusions first: If I've got it correct: We included only those as midwifery births if the woman she was admitted to labor and delivery and received her intrapartum care by a midwife. Likewise, a woman was assigned to the obstetrician group if she was admitted by and received her intrapartum care by an obstetrician. We excluded births for which the prenatal care was provided by a midwife but the admitting practitioner was an obstetrician. The delivering clinician could be from a different group as the admitting clinician.

If I have that correct, it seems that by including women whose intrapartum care was managed by one provider type but the delivery by another provider type, you are risking major sources of bias. This in part depends on how patients are assigned to different clinician types in labor, what the scope of practice is for the CNM's in your hospitals (can they do forceps or Vacuums?)? Do the clinicians cross cover for each other when there is a high volume of laboring women (For instance, if the Ob is busy in a CS, can a midwife do a delivery of a woman the OB was previously laboring?).

- >=45 years
- how was shoulder dystocia defined?
- please provide the Levels of Maternal Care here.
- statistically different but this does not seem to be clinically significant. "About 45%" for both seems like a good description.
- when you call out data in the text to highlight, please provide the basis for calling things different as you did in line 182. As well, we strongly want you to provide CI's, not just p values, and effect size (like OR, RR, etc) where appropriate.
- We do no allow authors to describe variables or outcomes in terms that imply a difference (such us of the terms "trend" or "tendency" or "marginally different") unless there is a statistical difference. Please edit here and throughout.
- Again, while these are statistically different, it would be more transparent to point out that these differences are unlikely to be clinically different enough to have an association with the outcomes of your study.
- these are neonatal care levels, correct? Please provide LoMaternal Care (LoMC)
- please provide the data, again emphasizing the statistical differences of note and if they are likely to represent clinical differences. For instance, your rates of episiotomies in multips is statistically different, but is 1.8 vs 1.1% really clinically relevant.

What I'm getting at here is to ask you to be careful about spin here. You have some important information to convey here about the differences between intrapartum care by midwives and obstetricians in this population. Don't risk people ignoring the important points because they think you are trying to make too much out of differences that are clinically quite irrelevant.

- interesting, given the greater cervical dilation, one would expect a shorter labor duration in these patients.
- please avoid causal language. This is an association.
- 2. The Editors of Obstetrics & Gynecology are seeking to increase transparency around its peer-review process, in line with efforts to do so in international biomedical peer review publishing. If your article is accepted, we will be posting this revision letter as supplemental digital content to the published article online. Additionally, unless you choose to opt out, we

will also be including your point-by-point response to the revision letter. If you opt out of including your response, only the revision letter will be posted. Please reply to this letter with one of two responses:

- A. OPT-IN: Yes, please publish my point-by-point response letter.
- B. OPT-OUT: No, please do not publish my point-by-point response letter.
- 3. As of December 17, 2018, Obstetrics & Gynecology has implemented an "electronic Copyright Transfer Agreement" (eCTA) and will no longer be collecting author agreement forms. When you are ready to revise your manuscript, you will be prompted in Editorial Manager (EM) to click on "Revise Submission." Doing so will launch the resubmission process, and you will be walked through the various questions that comprise the eCTA. Each of your coauthors will receive an email from the system requesting that they review and electronically sign the eCTA.

Any author agreement forms previously submitted will be superseded by the eCTA. During the resubmission process, you are welcome to remove these PDFs from EM. However, if you prefer, we can remove them for you after submission.

4. Our journal requires that all evidence-based research submissions be accompanied by a transparency declaration statement from the manuscript's lead author. The statement is as follows: "The lead author\* affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained." \*The manuscript's guarantor.

If you are the lead author, please include this statement in your cover letter. If the lead author is a different person, please ask him/her to submit the signed transparency declaration to you. This document may be uploaded with your submission in Editorial Manager.

5. Please submit a completed STROBE checklist with your submission.

Responsible reporting of research studies, which includes a complete, transparent, accurate and timely account of what was done and what was found during a research study, is an integral part of good research and publication practice and not an optional extra. Obstetrics & Gynecology supports initiatives aimed at improving the reporting of health research, and we ask authors to follow specific guidelines for reporting randomized controlled trials (ie, CONSORT), observational studies (ie, STROBE), meta-analyses and systematic reviews of randomized controlled trials (ie, PRISMA), harms in systematic reviews (ie, PRISMA for harms), studies of diagnostic accuracy (ie, STARD), meta-analyses and systematic reviews of observational studies (ie, MOOSE), economic evaluations of health interventions (ie, CHEERS), quality improvement in health care studies (ie, SQUIRE 2.0), and studies reporting results of Internet e-surveys (CHERRIES). Include the appropriate checklist for your manuscript type upon submission. Please write or insert the page numbers where each item appears in the margin of the checklist. Further information and links to the checklists are available at http://ong.editorialmanager.com.

- 6. 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 and gynecology data definitions at https://www.acog.org/About-ACOG/ACOG-Departments/Patient-Safety-and-Quality-Improvement/reVITALize. If use of the reVITALize definitions is problematic, please discuss this in your point-by-point response to this letter.
- 7. 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 22 typed, double-spaced pages (5,500 words). Stated page limits include all numbered pages in a manuscript (i.e., title page, précis, abstract, text, tables, boxes, figure legends, and print appendixes) but exclude references.
- 8. 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).
- 9. Provide a short title of no more than 45 characters, including spaces, for use as a running foot.
- 10. 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

6 8/12/2019, 2:39 PM

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 limits for different article types are as follows: Original Research articles, 300 words. Please provide a word count.

- 11. Only standard abbreviations and acronyms are allowed. A selected list is available online at http://edmgr.ovid.com/ong/accounts/abbreviations.pdf. Abbreviations and acronyms cannot be used in the title or précis. Abbreviations and acronyms must be spelled out the first time they are used in the abstract and again in the body of the manuscript.
- 12. The journal does not use the virgule symbol (/) in sentences with words. Please rephrase your text to avoid using "and/or," or similar constructions throughout the text. You may retain this symbol if you are using it to express data or a measurement.
- 13. Abstract-Results and Results: Please express outcome data as both absolute and relative effects since information presented this way is much more useful for clinicians. In both the Abstract and the Results section of the manuscript, please give actual numbers and percentages in addition to odds ratios (OR) or relative risk (RR). 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.
- 14. 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.
- 15. 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 via the Clinical Guidance & Publications page at https://www.acog.org/Clinical-Guidance-and-Publications/Search-Clinical-Guidance.
- 16. Figure 1: In the exclusion box where n=724, the values total 728. Are items not mutually exclusive, or should a value be updated?
- 17. 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 http://edmgr.ovid.com/acd/accounts/ifauth.htm.

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.

18. If you choose to revise your manuscript, please submit your revision via Editorial Manager for Obstetrics & Gynecology at http://ong.editorialmanager.com. It is essential that your cover letter list point-by-point the changes made in response to each criticism. Also, please save and submit your manuscript in a word processing format such as Microsoft Word.

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 Aug 02, 2019, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

Nancy C. Chescheir, MD Editor-in-Chief

2018 IMPACT FACTOR: 4.965

2018 IMPACT FACTOR RANKING: 7th out of 83 ob/gyn journals

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 Dr Chescheir,,

Thank for reviewing our manuscript: "Midwife and Obstetrician Labor Practices and Birth Outcomes in Low-Risk Pregnancies Delivered in Hospital" (Manuscript Number ONG-19-1067).

Our response to the reviews is below and we have made revisions to the manuscript based on the comments and recommendations of the reviewers.

We look forward to hearing from you.

Yours Sincerely

Vivienne Souter

# Manuscript Number ONG-19-1067 Midwife and Obstetrician Labor Practices and Birth Outcomes in Low-Risk Pregnancies Delivered in Hospital

# **Response to Reviews**

Our responses are highlighted in italics and the Reviewers' comments are in bold.

#### **REVIEWER COMMENTS:**

#### Reviewer #1:

1. The authors have done an observational study on the outcomes of labour when under midwifery or obstetrician care. They have also compared the various interventions done in labour between the two groups.

The abstract is pretty concise and well summarised.

There is a dearth of midwifery care and this has been pointed out well by the authors.

The midwifery model of care as it exists in UK has considerable patient and provider benefits and is well acknowledged.

Strict inclusion criteria is usually followed in midwifery led birthing suites and the authors have rightly excluded the high risk group.

They have used a intention to treat analysis but would be interesting to see how many had to be moved to the obstetrician group due to various labour problems.

We agree with the reviewer that the rate of transfer of care between midwives and obstetricians is important. However, this was not a focus of our study. Our primary goal was to determine whether midwives provided similar care with similar outcomes to obstetricians when faced with similarly low risk populations.

Additionally, while we have information on involvement of different practitioner types at four different phases of care up until and including birth, capturing all transfers of care from midwifery to obstetrician care is not possible using OB COAP data (e.g. transfer of care for a postpartum hemorrhage or obstetrician repair of a complex perineal laceration in a midwifery patient, are not captured).

The OB COAP database includes information on the practitioner type (midwife or obstetrician only in this study) at specified phases of care: prenatal care, at the time of admission, during labor, and at the birth. If a change in practitioner type is observed between these phases, it implies a transfer of care has occurred.

Of the 3816 midwifery patients in the final cohort (where the admitting and intrapartum practitioner type was a midwife), 8.5% (n=325) had an operative birth (vacuum, forceps

or cesarean birth). Additionally 2% (n=81) had a spontaneous vaginal birth with a non-midwifery practitioner type (68 with an obstetrician and 13 with another practitioner type). Therefore approximately 1 in 10 of women receiving midwifery care in the final cohort gave birth with an obstetrician.

We have added a line to Table 2 to indicate the proportion of pregnant women who were delivered by a practitioner type that was different from the admission and labor management practitioner type.

	Nulliparas (N=10,806)			Multiparas (N=12,294)		
	Obstetrician (N= 9,096) n (%)	Hospital midwife (N= 1,710) n (%)	P-value (chi-sq or ANOVA)	Obstetrician (N=10,188) n (%)	Hospital midwife (N= 2,106) n (%)	P-value (chi-sq or ANOVA)
Different practitioner type at delivery	35 (0.4)	290 (17.0)	<0.001	82 (0.8)	74 (3.5)	<0.001

The following sentence has been added to the Results Section Page 13 Line 596

"Seventeen percent of nulliparous women and 3.5% of multiparous women in the midwife group were delivered by an obstetrician or other non-midwife practitioner. For the obstetrician group, 99.6% of nulliparous women and 99.2% of women in the obstetrician group were delivered by an obstetrician."

2. Also the specific criteria used for change to obstetrician model should have been mentioned. This is very important as it helps in maintaining the quality standards and plan midwifery services. It also helps in counselling woman of these statistics so that they feel comfortable in choosing this model.

There are no national guidelines in the US on specific indications for intrapartum transfer from hospital midwives to obstetricians. These are decided at a local level. When and why women in the midwifery group were referred to obstetrician care in labor likely varied between participating hospitals and even between practitioners within hospitals.

3. Th authors mention that (Lines 214-215) Mean time from admission to delivery was longer for multiparous women in the midwife group (7.0 hours versus 6.4 hours; p<0.001) but actually in Table 3, 7 hrs is for actually the obstetrician group.

We have corrected this in the text:

Page 13 Line 592

"Median time from admission to delivery was longer for multiparous women in the obstetrician group (7.0 hours versus 6.4 hours; p<0.001) (Table 3)."

4. There seems to be a significant racial disparity -predominantly only white seems to be using the midwifery care model. Need to address this and strategies to overcome this needs to be discussed.

We have added the following to the text to address this:

Page 12 Line 466

"The distribution of race was different between the obstetrician and midwifery groups with fewer minority population women in the midwife group compared to the obstetrician group for both nulliparous (26.6% versus 40.0% p<0.001) and multiparous women (26.8% versus 35.5% p<0.001) (Table 2)."

# Page 17 Line 767

"Increasing availability of midwifery care, public education about the scope and benefits of midwifery care, and increasing racial and ethnic diversity of midwives may support access to midwifery care by a more diverse patient population."

5. Also interesting to note that in the obstetrician model, a big number of women have been admitted when cervix was only 3 cm dilated. This probably then may reflect the increasing interventions in that group.

We agree that earlier admission is associated with increased intervention (See Kauffman E, Souter VL, Katon JG, Sitcov K. Cervical Dilation on Admission in Term Spontaneous Labor and Maternal and Newborn Outcomes. Obstet Gynecol. 2016;127(3):481-488).

However, interestingly, when we performed a sensitivity analysis adding cervical dilation at admission to the models (within spontaneous labors only), this did not change the adjusted risk for cesarean birth by care provider type. We plan to evaluate this and other factors that may have contributed to mode of delivery in future studies.

6. Also use of AROM, Oxytocin, epidural and episiotomy is consistently higher in the obstetrician model in both nulli and multi, highlighting the importance of supportive care in labour.

As the authors pointed out, the reduction in CS rates in the midwifery model is very significant and should encourage more research as it has far reaching implications. A randomised controlled trial will address this issue better but the practical problem in doing it, increases the importance of studies like this.

However as the authors pointed out, it being an observational study-the confounders could alter the outcomes. Also the midwife delivery numbers are very small-compared to the total number and the racial disparity further affects the generalisation of these findings.

We agree with the reviewer. The number of women receiving midwifery care was limited by two things. First, most women receive care in pregnancy from obstetricians in the US and so inevitably the number of midwifery patients available for evaluation is much smaller than the number of pregnant women receiving care from obstetricians. Second, this was a comparison of care between practitioner type and we wanted to create a very low risk population for both the midwifery and obstetrician groups. Consequently, the number of women in both groups was reduced when we excluded risk factors.

The racial and ethnic diversity of the groups reflects the pregnant population in our geographical area and the type of care they receive (midwifery versus obstetrician). Greater racial diversity may have increased to the generalizability of the study results. However, having controlled for confounding by race/ethnicity, our findings represent associations with care provider type that are independent of race.

Page 16 Line 705 This sentence in the limitations section of the Discussion has been changed to read:

"Additionally the findings may not be generalizable to a broader and more diverse patient population.."

## Reviewer #2:

The authors present their work in which they compare midwife and obstetrician labor practices and birth outcomes in low risk in-hospital deliveries. The following items should be addressed:

1. The title is a bit cumbersome, and doesn't quite capture the objective of the manuscript. Consider rewording, and include that the two types of providers are being compared.

The title has been changed to: Comparison of Midwifery and Obstetrician Care in Low-Risk Hospital Births

2. Methods line 109-117 - although the intent of the authors is to remove any confounding, by excluding so many patients, the generalizability of the study is also compromised. For example, marijuana use and nicotine use may be unnecessary as exclusion criteria. How were fetal anomalies defined, did this include minor anatomic differences such as urinary tract dilation, or isolated club foot or cleft lip which would be unlikely to impact route of delivery? Consider an additional analysis in which some of these exclusion criteria are included.

We excluded fetal anomalies in the database irrespective of severity, including those that may have had no impact on the birth or newborn course and we agree that women disclosing marijuana and nicotine use could also have been included in the study. The rationale for this was to produce an extremely low risk population so that obstetrician

and midwifery care could be compared with minimal potential for bias due to population risk factors.

We plan to evaluate outcomes by provider type for a broader patient population in a later analysis.

3. Methods line 160-173 - this information would be more helpful to the reader earlier in the methods section, perhaps after the first paragraph.

We have moved this paragraph to Page 7 Line 115

4. The results state that the birth weight was higher in the midwifery group compared to the physician group and some of the conclusions rest on this difference, however the mean difference listed in the table is only 52 grams for nulliparous patients and 169 grams for multiparous patients, which is not clinically significant. Please clarify and de-emphasize in the text. The same is true for length of labor, which only differed by a fraction of an hour in the mean value for both the nulliparous and multiparous patients.

We have edited the Results section to highlight this point (see tracked changes).

*In the Comment section we have removed the following sentence:* 

"Midwifery care was associated with more births at >41 weeks and higher birth weights which may have been expected to increase the rate of cesarean birth.."

#### Reviewer #3:

This is a retrospective cohort study comparing birth outcomes in Low risk pregnancies between obstetrician and Midwifery practices. Data is from a multi-center quality improvement collaborative.

1. There is a significant baseline differences between the two groups. Midwives had a higher proportion of white, multiparous women in their practice, how was this specifically addressed.

All outcomes were stratified by parity (nulliparous versus multiparous) and models were adjusted for multiple confounding factors including maternal age and race. Please see our response to Reviewer 1 (Item 6.) above.

2. Line 218 "After adjustment for confounders". The specific confounders should be spelled out.

Page 13 Line 600

The confounders adjusted for in the model have been included in parenthesis in this sentence: "After adjustment for confounders (maternal age, BMI, height, race, induction of labor, and epidural, including hospital and practitioner as random effects)...,"

#### STATISTICAL EDITOR COMMENTS:

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

Table 4: For many of the maternal outcomes, the counts among the midwife cohorts were too few to allow for adjustment with 6 variables. Specifically, for the nulliparous comparisons: SMM, blood transfusions. Also, the counts and therefore the proportions of adverse events PPH, transfusion or SMM were so low that there was also limited power to generalize the NS findings, even if they had been adjustable. For the multiparous comparisons, the same issue with low counts vs adjustment for 6 variables is an issue re: OVD, CD, and all complications. The counts and frequencies are so few/low that power is limited to generalie the NS findings.

We agree that our study lacks power particularly for some of the rare outcomes such as blood transfusion, severe maternal morbidity, and cesarean birth in very low risk multiparous women.

The reviewer points out low counts for 2 outcomes among nulliparas and OVD, CD and all complications for the multiparous group. We agree that the low counts for the complications limits our findings' generalizability for these outcomes. However, using the sample sizes for the multiparous study group, we calculated >80% power to detect a 1% change in the frequency of the outcome where the prevalence in the unexposed (obstetrician) group is above 1.1%. Thus, we believe we do have sufficient power to detect differences in CD and OVD for the multiparous group.

We also agree with the reviewer that we have insufficient power for several of the complications and neonatal outcomes. We have modified Table 4 and Table 5 and removed the statistical models (crude RRs and adjusted RRs) for the outcomes where we lack power. We do report counts of neonatal outcomes and the frequency of those outcomes (with calculated 95% Cls) (updated Table 5) and report the only maternal outcome (3rd or 4th degree laceration) and the only neonatal outcome (shoulder dystocia) where we have statistical power to do so (updated Table 5).

Depending on the preference of the Editor, we are also willing to return to using the original tables with adjusted OR's and Cl's for all outcomes and to emphasize the lack of power for many of the outcomes in the Comment section.

Despite the low counts for some outcomes, we still felt it was important to report results for all neonatal and maternal outcomes of interest as there is relatively little data in the literature comparing midwife to obstetrician care, by parity, in the US context.

Table 5: Same issue with low counts and low power and inability to adjust for 6 variables. For the adjustment model, this applies outcomes among the nulliparous:

shoulder dystocia, 5 min Apgar < 7, glucose instability and birth trauma. For the adjustment model among the multiparous, this applies to 5 min APgar < 7, glucose instability, resuscitation, NICU admission and birth trauma. Again, there is low power to generalize any NS findings.

We have modified the sentence below to emphasize this in the limitations section of the Comment:

Page 15 Line 700: "The most important limitation of our study was the lack of power to evaluate uncommon outcomes (including severe maternal morbidity and most newborn outcomes) due to the relatively small population in the midwifery group and the need to adjust for multiple confounding factors. Larger studies would be needed to more fully evaluate midwifery care in the US."

See detailed comments above.

Could attempt a matching algorithm to determine whether the differences were corroborated, but that would decrease power and may therefore still be a limitation.

In sensitivity analyses, we also used an alternate approach to control for confounding via propensity score matching. Using this approach, control for confounding is addressed through matching of cases on key covariates. Thus, after propensity score matching, regression models are only adjusted for the treatment effect (provider type) which addresses the issue of model overfitting. Results for the propensity score approach are included in a separate document. (see supplemental Appendix 1) Overall, results using this approach were unchanged from the modified Poisson regression model in our manuscript.

Rather than traditional matching, in sensitivity analysis, we also controlled for confounding by a propensity based matching approach. Overall, there were no changes in the adjusted model conclusions using different modeling techniques. See attached details for the PS analyses.

#### **EDITOR COMMENTS:**

1. Thank you for your submission to Obstetrics & Gynecology. In addition to the comments from the reviewers above, you are being sent a notated PDF that contains the Editor's specific comments. Please review and consider the comments in this file prior to submitting your revised manuscript. These comments should be included in your point-by-point response cover letter.

\*\*\*The notated PDF is uploaded to this submission's record in Editorial Manager. If you cannot locate the file, contact Randi Zung and she will send it by email - rzung@greenjournal.org.\*\*\*

- How were patients assigned to either midwife or obstetrician care in labor and delivery? Patient choice? Did it depend on antepartum care? Did it ever change during the course of labor?

In general a patient's practitioner type in labor was consistent with the practitioner type for their prenatal care. Based on our experience of maternity care in our area, we assume patient choice was behind the prenatal practitioner type in most if not all cases, but we do not have the data needed to evaluate this.

We did observe a small number of women with a change in practitioner type between the prenatal phase of care and admission to labor and delivery (Figure 1): 2.3% (n=689) of 29,400 pregnancies without identifiable risk factors had their prenatal practitioner type specified as a midwife and the admitting practitioner as an obstetrician.

Additionally, 1.7% (n=491) of 29,400 pregnancies without identifiable risk factors had a change in practitioner type between admission and the intrapartum phase of care (Figure 1).

We don't have the data to ascertain why these changes in practitioner type occurred – it could have been patient choice, labor and delivery logistics, or identification of a risk factor or pregnancy complication. We excluded these patients from the final cohort because of concern that they may harbor risk factors / pregnancy complications that prompted transfer to obstetrician care.

We have provided more information on change in practitioner type between intrapartum care and birth, in our first response to Reviewer 1 (Item 1.): approximately 1 in 10 women who had admission/intrapartum managed attributed to a midwifery care, were ultimately delivered by an obstetrician. We have also added a new row to Table 2 to expand on this in the paper.

- Please indicate that these dates are the inclusion dates. As written, it looks like you only looked at births on those 2 specific dates. You could say "from January 1, 2015 to September 30, 2018"

Page 4 Line 42 We have changed this in the Abstract to:

"Retrospective cohort study of singleton births of 37+0-42+6 weeks' gestation at 11 hospitals between January 1, 2014 and December 31, 2018. ."

# - what about length of labor?

In the database, length of labor per se is not collected. We do have data on cervical dilation and length at the time of admission, and length of time from admission to delivery. Specifically, we cannot ascertain a length of labor that includes any labor prior to admission to the hospital.

Line 92 in the Study Data and Methods section

"It is likely that all midwives practicing at these hospital sites were credentialed as Certified Nurse Midwives (CNMs)."

- please provide a reason for this assertion.

We have changed this sentence about the type of midwives in the study to: Page 34 Line 111

"Although licensed midwives may be granted hospital privileges, we are not aware of any practicing in participating hospitals during the study period. Consequently the midwives in the study are likely all certified nurse midwives.".

## Line 102

Could you write the inclusions/exclusions a bit more clearly. Perhaps state the inclusions first: If I've got it correct: We included only those as midwifery births if the woman she was admitted to labor and delivery and received her intrapartum care by a midwife. Likewise, a woman was assigned to the obstetrician group if she was admitted by and received her intrapartum care by an obstetrician. We excluded births for which the prenatal care was provided by a midwife but the admitting practitioner was an obstetrican. The delivering clinician could be from a different group as the admitting clinician.

Page 8 Line 148 We have changed the inclusions and exclusions in the Study Data and Methods section to read:

"we included only those midwifery births where the woman was both admitted to labor and delivery and received her intrapartum care by a midwife. Likewise, a woman was assigned to the obstetrician group if she was admitted by and received her intrapartum care by an obstetrician. We excluded births for which the prenatal care was provided by a midwife but the admitting practitioner was an obstetrician."

# Line 102

If I have that correct, it seems that by including women whose intrapartum care was managed by one provider type but the delivery by another provider type, you are risking major sources of bias. This in part depends on how patients are assigned to different clinician types in labor, what the scope of practice is for the CNM's in your hospitals (can they do forceps or Vacuums?)?

We used an intent-to treat approach where the mode of delivery was assigned to the practitioner type associated with the patient's admission and intrapartum care. So, if a midwife admitted the patient and provided care in labor but an obstetrician performed a cesarean delivery, the cesarean delivery would be assigned to the midwife group. Since midwives do not perform cesareans births attributing outcomes to the delivering practitioner would have resulted in a 0% cesarean birth rate in the midwifery group.

Our understanding is that there were no midwives performing operative vaginal births (forceps/vacuum) in the hospitals in our study. There were 25 vacuum births that had midwives assigned as the practitioner type but we believe it is highly unlikely that the midwife actually performed the vacuum. Possible explanations for attribution of a midwife as the practitioner for a vacuum birth include errors in abstracting the clinical data or a situation where the obstetrician brought the head down to the perineum with the vacuum and then the midwife completed the delivery (something we have observed in our practice).

Whatever the practitioner type associated with performance of the actual delivery, the operative vaginal birth would have been attributed to the admission/intrapartum practitioner type. Since the primary outcomes of this study are delivery mode, not transfer of care at delivery, these cases do not impact our primary findings.

What we don't know is exactly when in labor the transfer of care from midwife to obstetrician occurred. So, intrapartum transfers of care may have been associated with a very short period of obstetrician care preceding for example an urgent cesarean or a longer period of obstetrician care. Please see our breakdown of intrapartum transfers in response to Reviewer 1 including the addition to Table 2.

#### Line 102

Do the clinicians cross cover for each other when there is a high volume of laboring women (For instance, if the Ob is busy in a CS, can a midwife do a delivery of a woman the OB was previously laboring?).

This does occur, however, it does not appear to be a common event in our cohort with only 0.3% (63/19284) of women in the obstetrician group ultimately having a spontaneous vaginal birth with a midwife. The exact circumstances of these births are unknown. Most (n=47,75%) were multiparas who we speculate may have had more rapid progress in labor resulting in delivery by a provider other than their own.

# Page 8 Line 159 >=45 years

This has been changed to ">=45 years"

#### **Line 147**

# how was shoulder dystocia defined?

No specific diagnostic criteria were required for shoulder dystocia. This outcome is based on whether a diagnosis of shoulder dystocia was recorded in the patient's medical record by the delivering clinician.

Page 10 Line 220 "shoulder dystocia" we have added ".... (based on recording of this

clinical diagnosis in the medical record rather than specified diagnostic criteria)...."

#### Line 163

- please provide the Levels of Maternal Care here.

We have changed to Levels of Maternal Care.

Page 7 Line 118 has been changed to:
".....hospital Level of Maternal Care...." and thereafter throughout the manusript

- statistically different but this does not seem to be clinically significant. "About 45%" for both seems like a good description.

Page 12 Line 465

We have changed this to read: "approximately 45% of women in both the midwife and in the obstetrician group were nulliparous"

- when you call out data in the text to highlight, please provide the basis for calling things different as you did in line 182. As well, we strongly want you to provide Cl's, not just p values, and effect size (like OR, RR, etc) where appropriate.

Changes have been made to the Results section to comply with this (see tracked changes in Results)

- We do no allow authors to describe variables or outcomes in terms that imply a difference (such us of the terms "trend" or "tendency" or "marginally different") unless there is a statistical difference. Please edit here and throughout.

Again, while these are statistically different, it would be more transparent to pointn out that these differences are unlikely to be clinically different enough to have an association with the outcomes of your study.

Changes have been made to the Results section to comply with this (see tracked changes in Results)

these are neonatal care levels, correct?
 Please provide LoMaternal Care (LoMC)

Yes they are in the original manuscript but we have now changed to hospital Levels of Maternal Care as noted above.

- please provide the data, again emphasizing the statistical differences of note and if they are likely to represent clinical differences. For instance, your rates of episiotomies in multips is statistically different, but is 1.8 vs 1.1% really clinically relevant.

This has been changed throughout the Results section

What I'm getting at here is to ask you to be careful about spin here. You have some important information to convey here about the differences between intrapartum care by midwives and obstetricians in this population.

Don't risk people ignoring the important points because they think you are trying to make too much out of differences that are clinically quite irrelevant.

We agree and we have changed the way we present the results accordingly.

- interesting. given the greater cervical dilation, one would expect a shorter labor duration in these patients.

We suspect there may be two things happening in the midwifery group - they appear to be coming into hospital with more advanced cervical dilation and they are also having less intervention / longer duration of labor before birth when they are in hospital. The midwife group probably does have comparable or longer duration of labor for both of these reasons.

- please avoid causal language. This is an association.

Page 15 Line 695

We have changed this to: "The reasons underlying the association between midwifery care and lower cesarean rates in our study are not clear."

- 2. The Editors of Obstetrics & Gynecology are seeking to increase transparency around its peer-review process, in line with efforts to do so in international biomedical peer review publishing. If your article is accepted, we will be posting this revision letter as supplemental digital content to the published article online. Additionally, unless you choose to opt out, we will also be including your point-by-point response to the revision letter. If you opt out of including your response, only the revision letter will be posted. Please reply to this letter with one of two responses:
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Yes, we would like to OPT-IN publish our point-by-point response letter.

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5. Please submit a completed STROBE checklist with your submission.

We have completed this

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6. 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 and gynecology data definitions at <a href="https://www.acog.org/About-ACOG/ACOG-Departments/Patient-Safety-and-Quality-Improvement/reVITALize">https://www.acog.org/About-ACOG/ACOG-Departments/Patient-Safety-and-Quality-Improvement/reVITALize</a>. If use of the reVITALize definitions is problematic,

please discuss this in your point-by-point response to this letter.

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- 9. Provide a short title of no more than 45 characters, including spaces, for use as a running foot.

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- 16. Figure 1: In the exclusion box where n=724, the values total 728. Are items not mutually exclusive, or should a value be updated?
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