

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)*

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obgyn@greenjournal.org.

Date: Jul 23, 2021
To: "Elizabeth Nethery" [REDACTED]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-21-1299

RE: Manuscript Number ONG-21-1299

Birth outcomes for planned home and licensed freestanding birth center births in Washington State

Dear Dr. Nethery:

Your manuscript has been reviewed by the Editorial Board and by special expert referees. Although it is judged not acceptable for publication in Obstetrics & Gynecology in its present form, we would be willing to give further consideration to a revised version.

If you wish to consider revising your manuscript, you will first need to study carefully the enclosed reports submitted by the referees and editors. Each point raised requires a response, by either revising your manuscript or making a clear and convincing argument as to why no revision is needed. To facilitate our review, we prefer that the cover letter include the comments made by the reviewers and the editor followed by your response. The revised manuscript should indicate the position of all changes made. We suggest that you use the "track changes" feature in your word processing software to do so (rather than strikethrough or underline formatting).

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

Your paper will be maintained in active status for 21 days from the date of this letter. If we have not heard from you by Aug 13, 2021, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1: In this large, retrospective cohort study of data collected for births occurring over 5 1/2 years from a single state, the authors present their data on maternal and perinatal birth outcomes in women delivering electively out of hospital either at home or in a state-licensed, freestanding birth center. They were unable to identify any difference in adverse pregnancy outcomes between those women choosing home birth compared with those electing delivery at a freestanding birth center. Indeed, the composite perinatal mortality rate was 0.57/1000 births which equals the ACOG reported expected with in hospital births. This is a remarkable achievement and the authors and others should be congratulated for these results which are in contrast to several other similar publications recently which suggested more concerning data for such models of Obstetrical care.

I would ask the authors to consider the following questions/points:

- 1) What is the percentage of women giving birth in the state of Washington whom are multiparous women?
- 2) The population of women in this report are not reflective of that of women giving birth in the United States. In the reported cohort, 86% are not obese, 84% are white, 79% are less than 35 years old and 64% are multiparous. Would the authors consider commenting on these potential confounding variables and how this may effect the exportability of this data?
- 3) Over 30% of nulliparous women required transport to a hospital as did an additional 4.4% of newborns. Is nulliparity a relative contraindication to delivery out of hospital?
- 4) Did any of the freestanding birth centers have physical proximity to a hospital?
- 5) Did the rate of transfer vary by geography, provider or distance to hospital?
- 6) How available was the option for an epidural and how was this controlled?

Reviewer #2: (Midwives' Association of Washington State, MAWS)

This is a retrospective analysis over 5.5 years 2015-2021 of maternal and perinatal outcomes of planned community births in an "integrated midwifery system of practice" in Washington State.

Data analysis comes from the MAWS data entry into Midwives Alliance of North America (MANA) Statistics data registry, a validated national birth registry. This data is uploaded into the the Obstetrical Care Outcomes Assessment Program (OB COAP) dataset semiannually. OB COAP is a clinician-led, continuous quality improvement collaborative based at the Foundation for Health Care Quality, a nonprofit organization in Seattle, Washington. Data keeping is a requirement for practicing midwives (mostly CPMS with some CNM's). Comparison is made between planned home births and planned free standing accredited birth centers.

1. Can you describe differences in practice between the two settings. Guidelines for intrapartum management for either setting? Is there any FHR monitoring at all in either setting. What resources does a free standing birth center have that a home setting would not have? Give the reader some foundation in practice
2. The 4 intrapartum and 2 neonatal deaths. What were the causes? are they potentially preventable?, Discussion should include what we know about term low risk intrapartum deaths and early neonatal deaths <7 days within a hospital and does a hospital confer protection? Infection?, acidosis?, meconium aspiration syndrome?
3. The guidelines for entry and exit into and out of community midwifery care are well defined, Are there guidelines for the management of prenatal care especially in an integrated community midwifery practice. Example do all women get GBS? an anatomy ultrasound? How would you know about polyhydramnios or oligohydramnios unless you had access to ultrasounds in the third trimester? If there are no guidelines is there is a dominant practice or a high degree of variability If you do not have this data it is important to state that the prenatal care received is unknown
4. lines 253-254 To our knowledge, this is the first study to report a comparison of planned home births to planned births in freestanding, state-licensed birth centers within the same US state.
Refrain from claiming to be the first unless you give the search criteria
5. What were the main reasons for the 30% intrapartum transfers of nulliparas or the 5% multipara: epidural? fetal concerns? protracted labor?infection? Were the neonatal complications part of this transfer group
6. Your comparison of out comes is to other "International settings" What is the definition of an International setting? developed countries please define

Reviewer #3: Based on available data, ACOG released Committee Opinion 697 "Planned Home Birth" which contains the following language: "Women inquiring about planned home birth should be informed of its risks and benefits based on recent evidence. Specifically, they should be informed that although planned home birth is associated with fewer maternal interventions than planned hospital birth, it also is associated with a more than twofold increased risk of perinatal death (1-2 in 1,000) and a threefold increased risk of neonatal seizures or serious neurologic dysfunction (0.4-0.6 in 1,000). These observations may reflect fewer obstetric risk factors among women planning home birth compared with those planning hospital birth. Although the American College of Obstetricians and Gynecologists (the College) believes that hospitals and accredited birth centers are the safest settings for birth, each woman has the right to make a medically informed decision about delivery." This Committee Opinion was reaffirmed in 2020.

This manuscript, "Birth outcomes for planned home and licensed freestanding birth centers in Washington State," presents data comparing the maternal and perinatal outcomes of pregnant people intending to deliver at home versus in freestanding birth centers in a Washington State cohort between 1/1/2015 and 6/30/2020. Data was collected from the Midwives Alliance of North America Statistics data registry where data was inputted for all consenting pregnant clients at the onset of prenatal care. Delivery and outcome data was abstracted from the medical records. Excluded from the analysis were pregnant people with conditions not within guidelines for community birth, such as non-cephalic presentation at onset of labor, pre-pregnancy diabetes, prior cesarean delivery, multifetal pregnancy, etc. An intent to treat analysis was used. Maternal outcomes studied included hospital admission, mode of delivery, epidural anesthesia, 3rd or 4th degree laceration and a composite of severe maternal morbidity and "physiologic birth." Perinatal outcomes included hospital admission, small- and large-for-gestational-age, NICU admission and a composite of severe perinatal mortality and morbidity, exclusive breastfeeding at discharge from midwifery care.

Of the 11,442 births planned as community births at the onset of labor, 93% were within guidelines and were included in the study. 6,265 planned birth center births (2,740 nulliparas and 3,525 multiparas) and 4,344 planned home births (1,091 nulliparas and 3525 multiparas). 86% gave birth in their planned location. The cesarean delivery rate was 4.7% overall, 11% for nulliparas and 1% for multiparas. The rate of perinatal death was 0.57 per 1000 births. There was no increased risk

of cesarean birth, operative birth NICU admission or other adverse delivery or postpartum outcomes in those who planned home birth compared to those who planned birth center birth. The perinatal mortality rate was comparable to countries where community birth and community midwifery are established parts of the health care system.

This study presents important data regarding the safety of planned home and birth center birth with guidelines in an integrated health care system using community midwives. This results can be used for future guidance from ACOG and for counseling pregnant people as they make their obstetric care choices.

Limitations of this study include that data was collected only from consenting patients. It is not clear how many patients did not consent to have data collected. 94% of Midwives' Association of Washington State members participated in data collection so some data was missed in this manner. The population that chose community birth was largely White, non-Hispanic. These results may not apply to a more diverse population.

STATISTICAL EDITOR COMMENTS:

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

Table 1: Need units for BMI. Need to statistically compare the two cohorts, since they were not randomly allocated. Since some in each group later delivered in hospital, should also include a Table compared the characteristics of the groups which actually delivered at home vs birth centers. Also, this sample is from 2015-2020, so were there some women with more than one birth in this series? If so, then would need to adjust for correlation of outcomes for each individual. This could be done by randomly choosing one delivery per mother, or by adjusting for intra-class correlation. Either way, the sample size is actually or effectively decreased and the inferences and CIs need to be updated.

Table 3: Re: hospital admission, why are the 1455 intrapartum transfers excluded? If data are presented as intent-to-treat (lines 145-148), then all outcomes in all 10640 should be reported, rather than separating out those transferred intrapartum. If needed, could report in supplemental material the analysis based on actual delivery site, but if ITT, then should be consistent.

Table 4: There is no adjustment for multiple hypothesis testing, many of the comparisons are underpowered (eg, late PP adm, operative Vag birth, cesarean multiparas, episiotomy etc), so the NS findings cannot be generalized. Without prospective estimation of power/sample size and a primary outcome, these cannot be generalized and should just be descriptive, rather than attempting to extrapolate these findings to all similar birth settings.

Table 5: Most of these studies have similar low counts of perinatal mortality events, so there is low power to discern a difference statistically. There is no statistical difference comparing this study with the others, but also there is insufficient stats power to have discerned a difference.

EDITOR COMMENTS:

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

- A. OPT-IN: Yes, please publish my point-by-point response letter.
- B. OPT-OUT: No, please do not publish my point-by-point response letter.

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

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. Your submission indicates that one or more of the authors is employed by a pharmaceutical company, device company, or other commercial entity. This must be included as a statement in the Financial Disclosure section on the title page.

- Audrey Levine, Smooth Transitions, Foundation for Health Care Quality

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

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 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.

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 5,500 words. Stated word limits include the title page, précis, abstract, text, tables, boxes, and figure legends, 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).

* 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]."

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 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.

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. Line 253: Your manuscript contains a priority claim. We discourage claims of first reports since they are often difficult to prove. How do you know this is the first report? If this is based on a systematic search of the literature, that search should be described in the text (search engine, search terms, date range of search, and languages encompassed by the search). If it is not based on a systematic search but only on your level of awareness, it is not a claim we permit.

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. Please review examples of our current reference style at <http://ong.editorialmanager.com> (click on the Home button in the Menu bar and then "Reference Formatting Instructions" document under "Files and Resources"). Include the digital object identifier (DOI) with any journal article references and an accessed date with website references. Unpublished data, in-press items, personal communications, letters to the editor, theses, package inserts, submissions, meeting presentations, and abstracts may be included in the text but not in the reference list.

In addition, the American College of Obstetricians and Gynecologists' (ACOG) documents are frequently updated. These documents may be withdrawn and replaced with newer, revised versions. If you cite ACOG documents in your manuscript, be sure the references you are citing are still current and available. Check the Clinical Guidance page at <https://www.acog.org/clinical> (click on "Clinical Guidance" at the top). If the reference is still available on the site and isn't listed as "Withdrawn," it's still a current document.

If the reference you are citing has been updated and replaced by a newer version, please ensure that the new version supports whatever statement you are making in your manuscript and then update your reference list accordingly (exceptions could include manuscripts that address items of historical interest). If the reference you are citing has been withdrawn with no clear replacement, please contact the editorial office for assistance (obgyn@greenjournal.org). In most cases, if an ACOG document has been withdrawn, it should not be referenced in your manuscript.

16. Figure 1: Are the items excluded in n=833 not mutually exclusive? Please upload as a figure file on Editorial Manager.

17. 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.

18. 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>.

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If you choose to revise your manuscript, please submit your revision through Editorial Manager at <http://ong.editorialmanager.com>. Your manuscript should be uploaded as a Microsoft Word document. Your revision's cover letter should include the following:

- * A confirmation that you have read the Instructions for Authors (<http://edmgr.ovid.com/ong/accounts/authors.pdf>), and
- * A point-by-point response to each of the received comments in this letter. Do not omit your responses to the Editorial Office or Editors' comments.

If you submit a revision, we will assume that it has been developed in consultation with your co-authors and that each author has given approval to the final form of the revision.

Again, your paper will be maintained in active status for 21 days from the date of this letter. If we have not heard from you by Aug 13, 2021, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

Dwight J. Rouse, MD, MSPH

Editor-in-Chief

2020 IMPACT FACTOR: 7.661

2020 IMPACT FACTOR RANKING: 3rd 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.

August 8, 2021

Dear Dr. Dwight Rouse,

We are grateful for the opportunity to submit a revised version of our manuscript “Birth outcomes in planned home and freestanding birth center births in Washington State” for consideration in *Obstetrics & Gynecology*.

We have included point-by-point responses to all comments made by the reviewers and editor as part of this cover letter (pages 2-17). Substantive text edits in the uploaded manuscript are indicated with Track Changes.

As noted previously, the manuscript is being submitted only to *Obstetrics & Gynecology*. This manuscript has not been published anywhere else and is not under consideration by any other publication. It will not be submitted elsewhere until a final decision is made by the Editors of *Obstetrics & Gynecology*.

The current study is based on data for the Midwives Association of Washington State obtained through the Obstetrics Clinical Outcomes Assessment Program. The data were considered to be exempt from human subjects’ IRB review by the Western Institutional Review Board (now Western Copernicus Group, <https://www.wcgirb.com/>). A letter documenting this is attached.

We have obtained written permission from all persons named in the acknowledgements.

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

Signed by: Elizabeth Nethery *The manuscript’s guarantor.

We look forward to hearing from you after review of the manuscript.

Yours Sincerely,

Elizabeth Nethery, MSc, MSM, PhD Candidate (Epidemiology)
University of British Columbia, School of Population and Public Health

Attached:
pages 2-20, responses to reviewers and editor
pages 21-22, IRB review exemption letter

Point-by-point responses to reviewers and editor:

Re: Manuscript Number ONG-21-1299

Birth outcomes for planned home and licensed freestanding birth center births in Washington State

REVIEWER COMMENTS:

Reviewer #1:

In this large, retrospective cohort study of data collected for births occurring over 5 1/2 years from a single state, the authors present their data on maternal and perinatal birth outcomes in women delivering electively out of hospital either at home or in a state-licensed, freestanding birth center. They were unable to identify any difference in adverse pregnancy outcomes between those women choosing home birth compared with those electing delivery at a freestanding birth center. Indeed, the composite perinatal mortality rate was 0.57/1000 births which equals the ACOG reported expected with in hospital births. This is a remarkable achievement and the authors and others should be congratulated for these results which are in contrast to several other similar publications recently which suggested more concerning data for such models of Obstetrical care.

I would ask the authors to consider the following questions/points:

1) What is the percentage of women giving birth in the state of Washington whom are multiparous women?

Using national vital statistics/birth certificate data (1), we obtained the total yearly births in Washington State. Based on 2016-2019, 69% of births in Washington State were to multiparas. 64% of our study cohort were multiparas.

Sources:

1. United States Department of Health and Human Services (US DHHS) Centers for Disease Control and Prevention (CDC). Natality public-use data 2016-2019. CDC Wonder Online Database. <http://wonder.cdc.gov/natality-expanded-current.html>. Published 2020. Accessed July 26, 2021.

2) The population of women in this report are not reflective of that of women giving birth in the United States. In the reported cohort, 86% are not obese, 84% are white, 79% are less than 35 years old and 64% are multiparous. Would the authors consider commenting on these potential confounding variables and how this may effect the exportability of this data?

We agree that the demographics and risk profile of this cohort are not representative of the wider birthing population (i.e. including planned hospital births) in the United States. However, a birthing population of planned community births is expected to have 'lower obstetrical risk' than the general population as individuals with multiple comorbidities are recommended to birth in hospital. The characteristics of our study population do not impact the internal validity of our findings with regards to the comparison of planned home to birth center births. Differences in the characteristics of the population by planned birth setting (home v birth center) were adjusted for in the multiple regression models.

Specifically, among all US planned home and birth center births, 86% were not obese, 81% were non-Hispanic and White, 77% were to mothers less than 35 years old and 77% were multiparous. (3,4) In a cohort of planned community births using the MANAStats data registry for all US states (2004-2009, 2012-2014), 88% identified as Non-Hispanic White (5). While our study cohort is overall low-risk and similar to the US-wide population of community births, this Washington State cohort did have a higher rate of Medicaid (29.4%), compared to the general US population with 17.9% of birth center births and 8.6% of home births associated with Medicaid coverage. (4)

In our interpretation of findings, we do not suggest that all birthing people in the United States consider a community birth. Some clinical characteristics/conditions would always lead to a recommendation to deliver in hospital; however, birthplace decisions are made by birthing people based on which risks are acceptable to them and their family (1). To facilitate this decision-making, all health care professionals must clearly outline their recommendations (without coercion) and clearly document circumstances when a pregnant person chooses a course of action which differs from their recommendations. Nevertheless, our study certainly did not find that nulliparity, non-White race, age >35 years or obesity, in absence of other comorbidities, were contraindications to planning a home or birth center birth based on magnitude of risk.

One purpose of our study was to describe findings from Washington state planned *community* births and to discuss those findings within the context of other published studies of *planned community* births from the entire US (mixed midwifery integration) and other high-income countries (which differ from the entire US in having more robust integration of community midwifery and planned home birth in the broader health system). With that in mind, our study cohort is, in fact, relatively similar to the current birthing population of *planned community births* in the US. The key difference is the level of midwifery integration in Washington State.

We have edited/added the Discussion section of the manuscript to address internal validity and generalizability of our study findings to the current US population of planned home and birth center births and to the broader US birthing population:

Lines 302-308:

“Demographics and obstetric characteristics of this cohort were similar to home and birth center births in other US states; however, results reported in this study may not be generalizable to states with different legislation, training, and integration of community midwives. While this cohort is not representative of the broader US birthing population (including planned hospital births), this reflects eligibility for community birth and does not limit the internal validity of the comparison between home and birth centers or the generalizability of our findings to a low-risk, more racially diverse cohort within a state with a similar level of midwifery integration.”

Sources:

1. Kotaska A. Informed consent and refusal in obstetrics: A practical ethical guide. *Birth*. 2017;44(3):195-199. doi:10.1111/birt.12281
2. Vedam S, Stoll K, MacDorman M, et al. Mapping integration of midwives across the United States: Impact on access, equity, and outcomes. *PLoS One*. 2018;13(2):1-20. doi:10.1371/journal.pone.0192523

3. United States Department of Health and Human Services (US DHHS) Centers for Disease Control and Prevention (CDC). Natality public-use data 2016-2019. CDC Wonder Online Database. <http://wonder.cdc.gov/natality-expanded-current.html>. Published 2020. Accessed July 26, 2021.
4. MacDorman MF, Declercq E. Trends and state variations in out-of-hospital births in the United States, 2004-2017. *Birth*. 2019;46(2):279-288. doi:10.1111/birt.12411
5. Cheyney M, Bovbjerg M, Everson C, Gordon W, Hannibal D, Vedam S. Outcomes of Care for 16,924 Planned Home Births in the United States: The Midwives Alliance of North America Statistics Project, 2004 to 2009. *J Midwifery Womens Health*. 2014;59(1):17-27. doi:10.1111/jmwh.12172

3) Over 30% of nulliparous women required transport to a hospital as did an additional 4.4% of newborns. Is nulliparity a relative contraindication to delivery out of hospital?

As the reviewer notes, over 30% of nulliparous birthing people transported to the hospital prior to birth. These transported nulliparas experienced a relatively low rate of cesarean birth (37%) and a low absolute risk of neonatal complications, likely reflecting the appropriate use of transfer protocols. Further, the overall risk of cesarean birth among all planned home or birth center births in nulliparas in our study is 11.4%. Thus, we do not conclude that nulliparity is a relative contraindication to delivery out of hospital. A non-urgent transfer to hospital is not an adverse outcome, per se, but an indication of a practice environment where community midwives are confident in transferring into hospital without fear of retribution.

In our clinical experience, the majority of transports to hospital for nulliparas are non-urgent transfers which occur in the clients' private vehicle (not an ambulance) because of a need for pain relief (epidural) or because of slow progress/labor dystocia in the 1st stage. Unfortunately, these data do not capture information on the circumstance or indication of transfers. To provide some context, a nationwide study of US community midwives (data from 2000) demonstrated a 25.1% transfer rate for nulliparas, but only 5.1% were noted as 'urgent transfers'. (1) Similarly, in a study from the UK (data from 2008-2010, with a similar 32% nulliparous transfer rate), 10% of transfers were noted as 'potentially urgent'. (2) In the same study, 78% of nulliparas were transferred for failure to progress, meconium staining (without fetal distress) or epidural. Guidelines for indications for transfer are similar in Washington State to the UK.

In a separate systematic review of home to hospital transfers from planned home births in "Western countries", transfer rates for nulliparous individuals ranged from 23.4 – 45.4% and from 5.8 – 12% for multiparas. (3) The review noted a higher transfer rate in settings/countries where home birth was an integrated and regulated part of the health care system and the most common reason for transfer was slow progress in labor, occurring in between 5.2-9.8% of all planned home births (we would estimate about 20-30% of all transfers).

We feel it is important for midwives, physicians, and birthing families planning a community birth to be informed about this transfer rate (30% among nulliparas). While we cannot speak for all community midwives, several of the authors are active midwives (current or retired) who offer home and birth center births. Our counseling on planned place of birth includes a detailed conversation on frequency of transfer to hospital (by parity) and a review of the common and uncommon reasons for transfer to hospital, including situations when we would recommend an urgent transfer.

In our study (Table 3), 1.8% of newborns required transfer to hospital within 6 hours after delivery. The 2.3% of newborns who were admitted to hospital between 6 hours and 6 weeks of life are typically newborns who experience a complication well after delivery and, in our experience, often due to neonatal concerns unrelated to midwifery care or community birth. Of note, the data registry reflects hospital admissions up to 6 weeks of life (or postpartum for the birthing person), but in Washington State, the scope of Licensed Midwives (LMs) includes care for newborns only up to 2 weeks of life. However, LMs do provide postpartum care for the birthing person, up to 6 weeks after delivery.

The rate of neonatal readmissions with NICU admission was 66/10605 (0.6%). For 83 cases of late neonatal hospital admissions, the only complication noted was “jaundice.” In most communities, infants requiring phototherapy will also require a hospital admission.

We have added some detail to the Discussion on nulliparous transfers and what is known from other settings. We have also added a Table to the supplemental materials reporting cohort characteristics by actual place of births (Appendix 3).

Lines 276-279:

“Detailed transfer data for this cohort were not available; however, others have reported slow labor progress as the most common indication for transfer in nulliparas⁴³⁻⁴⁵ and the rate of “potentially urgent” hospital transfers⁴⁵ was 0-5% of all births.”

Sources:

1. Johnson KC, Daviss B-A. Outcomes of planned home births with certified professional midwives: large prospective study in North America. *BMJ*. 2005;330(7505):1416. doi:10.1136/bmj.330.7505.1416
2. Rowe RE, Townend J, Brocklehurst P, et al. Duration and urgency of transfer in births planned at home and in freestanding midwifery units in England: secondary analysis of the birthplace national prospective cohort study. *BMC Pregnancy Childbirth*. 2013;13:224. doi:10.1186/1471-2393-13-224
3. Blix E, Kumle M, Kjærgaard H, Øian P, Lindgren HE. Transfer to hospital in planned home births: a systematic review. *BMC Pregnancy Childbirth*. 2014;14:179. doi:10.1186/1471-2393-14-179

4) Did any of the freestanding birth centers have physical proximity to a hospital?

None of these birth centers are owned or physically attached to a hospital; most are owned/operated by practicing midwives (or retired midwives) and function as independent small businesses. Thus, all are “freestanding” birth centers, licensed by the Washington State Department of Health as ‘childbirth centers.’ Further, all of the birth centers in our study period are within 15 minutes travel time to a hospital (in normal driving conditions); median distance to a hospital for all birth centers in the study is 2.2 miles (min-max 0.5-12 miles). Several birth centers in Washington State are located in smaller communities and serve rural people who might prefer a home birth but live in areas (e.g. island communities or very remote/rural areas) where a community midwife is unwilling/unable to attend them at home, because of distance from hospital or inadequate access to emergency services.

We have added a clarification about birth centers’ proximity to hospitals in the Methods section.

Lines 125-126:

“Median distance to a hospital for birth centers in the study was 2.2 miles (min-max: 0.5 - 12); none were physically ‘attached’ to or inside a hospital.”

5) Did the rate of transfer vary by geography, provider or distance to hospital?

While we agree it is important to examine variability in transfer rates, this is beyond the scope of this study. Given the relatively limited information in this dataset about both transfers and the lack of individual-level geographic data for mapping distance to hospital, we did not examine these issues in this analysis.

Rate of transfer did vary by provider and by rural status (rural v. non-rural residence); but this is highly confounded in this dataset by other differences in case-mix among rural and non-rural residence (e.g. parity, risk status, income, age, demographics).

Future research using this dataset could include a study designed to address questions related to transfers.

6) How available was the option for an epidural and how was this controlled?

Freestanding birth centers do not have either epidurals or anesthesia. These are also not available in the home setting.

After transfer to a hospital setting, patients would have had access to an epidural or any other pharmaceutical pain relief options offered at the hospital site. All hospitals who receive community intrapartum transfers have epidurals available. After an intrapartum transfer, 953/1455 (65%) of patients in our cohort were known to receive an epidural.

While there was a difference in the rate of epidural use by birth setting (Table 4), this is because of differences in parity by birth setting. Stratified by parity, the rate of epidural use among nulliparas was 21.6% (planned birth center) and 21.1% (planned home) and among multiparas was 2.2% (planned birth center) and 1.6% (planned home). There was no difference in the frequency of epidural use in hospital after a transfer from home compared to freestanding birth center after adjusting for parity and other confounders (Table 4). We did not adjust for epidural use in models for delivery outcomes as we did not hypothesize epidurals as a potential confounder for the effect of planned place of birth on neonatal or delivery outcomes.

Reviewer #2:

This is a retrospective analysis over 5.5 years 2015-2021 of maternal and perinatal outcomes of planned community births in an "integrated midwifery system of practice" in Washington State.

Data analysis comes from the MAWS data entry into Midwives Alliance of North America (MANA) Statistics data registry, a validated national birth registry. This data is uploaded into the the Obstetrical Care Outcomes Assessment Program (OB COAP) dataset semiannually. OB COAP is a clinician-led, continuous quality improvement collaborative based at the Foundation for Health Care Quality, a nonprofit organization in Seattle, Washington. Data keeping is a requirement for practicing midwives (mostly CPMS with some CNM's). Comparison is made between planned home births and planned free standing accredited birth centers.

1. Can you describe differences in practice between the two settings. Guidelines for intrapartum management for either setting? Is there any FHR monitoring at all in either setting. What resources

does a free standing birth center have that a home setting would not have? Give the reader some foundation in practice

As of August 2021, there are 24 active birth centers in Washington State, all licensed by the Washington Department of Health. (1) The providers who practice in these birth centers are primarily Licensed Midwives and a few Certified Nurse Midwives; many also attend home births. Regardless of their *location* of practice, these providers must adhere to the midwifery licensure rules of this state. For this study, all providers are also MAWS members who generally adhere to the guidelines of MAWS, regardless of where they attend births.

There is little difference in practice between attending births in a freestanding birth center versus in a home setting. Washington State freestanding birth centers often offer large birth tubs that most homes do not have. All medications, oxygen, resuscitation equipment, instruments, etc. are usually stored in fixed locations at the birth center; when midwives attend births in the home setting, they transport those items with them to the patient's home (often in large suitcases/bags or plastic totes).

In Washington State, the eligibility criteria for birth center birth differs somewhat from home birth, as legislation for Washington State Childbirth Centers (2) specifies a “low-risk” criteria that excludes known breeches, multifetal gestations, vaginal birth after cesarean and pregnancy beyond 42 weeks from birth center deliveries. In our study, we restricted our cohort to “low-risk” group (within MAWS Guidelines *and* meeting birth center eligibility criteria); results for all deliveries are reported in the supplemental material. The definition of our “low-risk” criteria and study cohort is noted in the manuscript (lines 143-145).

Intrapartum management by community-based midwives (LMs and CNMs) who attend planned home or birth center births follows national guidelines (3) (e.g. ACOG approaches to limit intervention during labor and birth) and international standards (3-5) for low-risk laboring people.

Fetal heart rate (FHR) monitoring in labor is the same in both settings (planned home or freestanding birth center). LMs use Intermittent Auscultation (IA) according to standard national protocols (6-7), generally using a hand-held Doppler. If continuous fetal monitoring is indicated, this necessitates a transfer to the hospital.

We have added a brief sentence to the Discussion describing home and birth center settings and antepartum, intrapartum and postpartum management.

Lines 268-271

“Antepartum, intrapartum and postpartum management by community midwives (LMs, CPMs and CNMs) is essentially the same in both settings and midwifery professionals follow national and international standards and guidelines for low-risk birthing people.⁴⁰⁻⁴²”

Sources:

1. Washington State Department of Health. Birthing / Childbirth Centers License Requirements. <https://www.doh.wa.gov/LicensesPermitsandCertificates/FacilitiesNewReneworUpdate/BirthingChildbirthCenters/LicenseRequirements>. Published 2021. Accessed August 3, 2021.
2. Washington State Legislature. Washington Administrative Code Chapter 246–329 (Childbirth Centers). <https://app.leg.wa.gov/wac/default.aspx?cite=246-329>.

3. ACOG Committee on Obstetric Practice. ACOG Committee Opinion No. 766: Approaches to Limit Intervention During Labor and Birth. *Obstet Gynecol.* 2019;133(2):e164-e173. doi:10.1097/AOG.0000000000003074
4. World Health Organization. Intrapartum Care for a Positive Childbirth Experience.; 2018. <http://apps.who.int/iris/bitstream/10665/260178/1/9789241550215-eng.pdf?ua=1%0Ahttp://www.who.int/reproductivehealth/publications/intrapartum-care-guidelines/en/>.
5. Oladapo OT, Tunçalp, Bonet M, et al. WHO model of intrapartum care for a positive childbirth experience: transforming care of women and babies for improved health and wellbeing. *BJOG An Int J Obstet Gynaecol.* 2018;125(8):918-922. doi:10.1111/1471-0528.15237
6. American College of Nurse-Midwives. Intermittent Auscultation for Intrapartum Fetal Heart Rate Surveillance. *J Midwifery Women's Heal.* 2015;13(5):626-632. doi:10.1111/jmwh.12372
7. Miller DA. *Intrapartum Fetal Heart Rate Monitoring: Overview.* (Berghella V, ed.) UpToDate. 2021. www.uptodate.com

2. The 4 intrapartum and 2 neonatal deaths. What were the causes? are they potentially preventable?, Discussion should include what we know about term low risk intrapartum deaths and early neonatal deaths <7 days within a hospital and does a hospital confer protection? Infection?, acidosis?, meconium aspiration syndrome?

We have limited access to case reviews for the fetal and neonatal deaths. As far as we are aware, neither meconium aspiration syndrome nor infection were contributory causes in any of the fetal or neonatal deaths. We cannot report clinical details, as cases could be individually identifiable.

MAWS' Quality Management Program Incident Reviews allow for a protected, confidential assessment of fetal or neonatal deaths and provides recommendations to midwives regarding follow-up actions (e.g. continuing education, repeating/updating training or revising/creating practice guidelines). This process also generates topics for continuing education for broader membership. All Washington State Licensed Midwives, Certified Professional Midwives and Certified Nurse-Midwives who attend births, have current certification in Neonatal Resuscitation as per national standards (American Academy of Pediatrics (AAP) Neonatal Resuscitation Program (NRP)).

Regarding term, low risk fetal or neonatal deaths, while there are birth certificate data available in the US, these are insufficient for studying causes and preventability of perinatal death in the USA in any birth setting (planned hospital and/or planned community births). Perinatal mortality audits (1) do not appear to be broadly implemented at either the state-level or nationally (in the US). It appears that for the US in particular, there is limited information on causes and preventability of perinatal death in any birth setting.

Sources:

1. Flenady V, Middleton P, Smith GC, et al. Stillbirths: The way forward in high-income countries. *Lancet.* 2011;377(9778):1703-1717. doi:10.1016/S0140-6736(11)60064-0

3. The guidelines for entry and exit into and out of community midwifery care are well defined, Are there guidelines for the management of prenatal care especially in an integrated community midwifery practice. Example do all women get GBS? an anatomy ultrasound? How would you know about polyhydramnios or oligohydramnios unless you had access to ultrasounds in the third trimester?

If there are no guidelines is there is a dominant practice or a high degree of variability If you do not have this data it is important to state that the prenatal care received is unknown

Licensed Midwives (LMs), Certified Professional Midwives and Certified Nurse-Midwives learn about appropriate prenatal management of low-risk patients in their educational programs. In order to become licensed in Washington State, applicants must first pass the national board exam from the North American Registry of Midwives as well as a Washington State-specific exam. All licensed midwives must maintain a set of policies, procedures and practice guidelines, as well as participate in regular peer review as a condition of licensure (1).

The standard of practice for LMs in Washington State includes offering the same standard laboratory tests and screens (routine bloodwork, genetic screening, gestational diabetes, fetal anatomy ultrasound, Group Beta strep) that are offered by hospital-based health professionals (i.e., Obstetricians, Family Practice Physicians or Certified Nurse Midwives). Licensed Midwives can order and interpret all of these laboratory tests/procedures. LMs can also order and interpret third trimester ultrasounds (e.g., for fluid, fetal growth, postdates monitoring). MAWS guidelines specify criteria for “*consultation* with a physician” or “*transfer* to a physician or other qualified hospital-based provider” during the antepartum period, as well as during the intrapartum or postpartum period (2).

Licensed midwives in Washington State can and do administer intrapartum antibiotic prophylaxis for GBS-positive patients in the home and freestanding birth center settings. LMs can administer vaccines offered during pregnancy, postpartum, and to neonates in the first 2 weeks, as well as antihemorrhagic medications, IV fluids, Rho (D) immune globulin and local anesthetics for perineal repair. The full legend of drugs and devices for Licensed Midwives is available in the Washington Administrative Code. (1) Legends of drugs and devices for community midwives in other states vary; as noted by Effland et al., “LMs in Washington have access to more medications, devices, and supplies relevant to the care of low-risk clients than do most community midwives practicing in other United States jurisdictions” (2)

Midwives refer to obstetricians, maternal-fetal medicine specialists, and other health care professionals when indicated based on the MAWS guidelines for discussion, consultation, collaboration and referral (3).

We have added to the Discussion describing home and birth center settings and antepartum, intrapartum and postpartum management.

Lines 268-271

“Antepartum, intrapartum and postpartum management by community midwives (LMs, CPMs and CNMs) is essentially the same in both settings and midwifery professionals follow national and international standards and guidelines for low-risk birthing people.”⁴⁰⁻⁴²

Sources:

1. Washington State Legislature. Washington Administrative Code Chapter 246-834 (Midwives). <https://app.leg.wa.gov/wac/default.aspx?cite=246-834>.
2. Effland KJ, Hays KE, Zell BA, Lawal TK, Koontz M. Medication access and midwifery integration: An example of community midwifery advocacy for access in Washington State , USA. *Birth*. 2020;(November):1-10. doi:10.1111/birt.12523

3. Midwives' Association of Washington State. Indications for Discussion, Consultation and Transfer of Care in a Home Birth or Birth Center Midwifery Practice. Seattle, USA; 2021. <https://www.washingtonmidwives.org/clinical-guidelines.html>.

4. lines 253-254 To our knowledge, this is the first study to report a comparison of planned home births to planned births in freestanding, state-licensed birth centers within the same US state. Refrain from claiming to be the first unless you give the search criteria

We have removed this claim.

5. What were the main reasons for the 30% intrapartum transfers of nulliparas or the 5% multipara: epidural? fetal concerns? protracted labor?infection? Were the neonatal complications part of this transfer group

As we noted in our responses to Reviewer 1, we have limited information in this dataset about reasons for transfer to hospital. While we agree that an assessment of transfers is of interest, a detailed examination of transfer cases is beyond the scope of this study.

MAWS' midwives recommend transfer according to the MAWS Guidelines (1) document which describe criteria for transfer. In our clinical experience, the majority of transports to hospital for nulliparas are non-urgent transfers which occur in the clients' private vehicle (not an ambulance) because of a need for pain relief (epidural) or because of slow progress/labor dystocia in the 1st stage. Unfortunately, these data do not capture information on the circumstance or indication of transfers. To provide some context, a nationwide study of US community midwives (data from 2000) demonstrated a 25.1% transfer rate for nulliparas, but only 5.1% were noted as 'urgent transfers'. (1) Similarly, in a study from the UK (data from 2008-2010, with a similar 32% nulliparous transfer rate), 10% of transfers were noted as 'potentially urgent'. (2) In the same study, 78% of nulliparas were transferred for failure to progress, meconium staining (without fetal distress) or epidural. Guidelines for indications for transfer are similar in Washington State to the UK.

In a separate systematic review of home to hospital transfers from planned home births in "Western countries", transfer rates for nulliparous individuals ranged from 23.4 – 45.4% and from 5.8 – 12% for multiparas. (3) The review noted a higher transfer rate in settings/countries where home birth was an integrated and regulated part of the health care system and the most common reason for transfer was slow progress in labor, occurring in between 5.2-9.8% of all planned home births (we would estimate about 20-30% of all transfers).

We feel it is important for midwives, physicians, and birthing families planning a community birth to be informed about this transfer rate (30% among nulliparas). While we cannot speak for all community midwives, several of the authors are active midwives (current or retired) who offer home and birth center births. Our counseling on planned place of birth includes a detailed conversation on frequency of transfer to hospital (by parity) and a review of the common and uncommon reasons for transfer to hospital, including situations when we would recommend an urgent transfer.

Severe neonatal complications in the post-delivery period were reported regardless of transfer status. Among the 44 cases with severe perinatal mortality or morbidity, 18/1455 were after an

intrapartum transfer, 14 were after a neonatal transfer (<6hrs) and 15 occurred with a late neonatal readmission.

We have added some detail to the Discussion on nulliparous transfers and what is known from other settings.

Lines 276-279:

“Detailed transfer data for this cohort were not available; however, others have reported slow labor progress as the most common indication for transfer in nulliparas⁴³⁻⁴⁵ and the rate of “potentially urgent” hospital transfers⁴⁵ was 0-5% of all births.”

Sources:

1. Johnson KC, Daviss B-A. Outcomes of planned home births with certified professional midwives: large prospective study in North America. *BMJ*. 2005;330(7505):1416. doi:10.1136/bmj.330.7505.1416
2. Rowe RE, Townend J, Brocklehurst P, et al. Duration and urgency of transfer in births planned at home and in freestanding midwifery units in England: secondary analysis of the birthplace national prospective cohort study. *BMC Pregnancy Childbirth*. 2013;13:224. doi:10.1186/1471-2393-13-224
3. Blix E, Kumle M, Kjærgaard H, Øian P, Lindgren HE. Transfer to hospital in planned home births: a systematic review. *BMC Pregnancy Childbirth*. 2014;14:179. doi:10.1186/1471-2393-14-179

6. Your comparison of outcomes is to other "International settings" What is the definition of an International setting? developed countries please define

We focused on countries where community midwifery is considered ‘well integrated’. These countries are often considered as models where midwifery care is widely available at both home and freestanding birth centers and where midwifery care is within the health system. By and large, these are high-income countries with established health care systems; specifically, we compared publications using births from Canada, the United Kingdom, the Netherlands and New Zealand.

We have added a clarification in the Discussion.

Line 249:

“The perinatal mortality rate in this cohort was comparable to other international settings, defined as high-income countries where community birth and community midwifery is an established part of the health care system.”

Reviewer #3:

Based on available data, ACOG released Committee Opinion 697 "Planned Home Birth" which contains the following language: "Women inquiring about planned home birth should be informed of its risks and benefits based on recent evidence. Specifically, they should be informed that although planned home birth is associated with fewer maternal interventions than planned hospital birth, it also is associated with a more than twofold increased risk of perinatal death (1-2 in 1,000) and a threefold increased risk of neonatal seizures or serious neurologic dysfunction (0.4-0.6 in 1,000). These observations may reflect fewer obstetric risk factors among women planning home birth compared with those planning hospital birth. Although the American College of Obstetricians and Gynecologists (the College) believes that hospitals and accredited birth centers are the safest settings for birth, each

woman has the right to make a medically informed decision about delivery." This Committee Opinion was reaffirmed in 2020.

This manuscript, "Birth outcomes for planned home and licensed freestanding birth centers in Washington State," presents data comparing the maternal and perinatal outcomes of pregnant people intending to deliver at home versus in freestanding birth centers in a Washington State cohort between 1/1/2015 and 6/30/2020. Data was collected from the Midwives Alliance of North America Statistics data registry where data was inputted for all consenting pregnant clients at the onset of prenatal care. Delivery and outcome data was abstracted from the medical records. Excluded from the analysis were pregnant people with conditions not within guidelines for community birth, such as non-cephalic presentation at onset of labor, pre-pregnancy diabetes, prior cesarean delivery, multifetal pregnancy, etc. An intent to treat analysis was used. Maternal outcomes studied included hospital admission, mode of delivery, epidural anesthesia, 3rd or 4th degree laceration and a composite of severe maternal morbidity and "physiologic birth." Perinatal outcomes included hospital admission, small- and large-for-gestational-age, NICU admission and a composite of severe perinatal mortality and morbidity, exclusive breastfeeding at discharge from midwifery care.

Of the 11,442 births planned as community births at the onset of labor, 93% were within guidelines and were included in the study. 6,265 planned birth center births (2,740 nulliparas and 3,525 multiparas) and 4,344 planned home births (1,091 nulliparas and 3,253 multiparas). 86% gave birth in their planned location. The cesarean delivery rate was 4.7% overall, 11% for nulliparas and 1% for multiparas. The rate of perinatal death was 0.57 per 1000 births. There was no increased risk of cesarean birth, operative birth NICU admission or other adverse delivery or postpartum outcomes in those who planned home birth compared to those who planned birth center birth. The perinatal mortality rate was comparable to countries where community birth and community midwifery are established parts of the health care system.

This study presents important data regarding the safety of planned home and birth center birth with guidelines in an integrated health care system using community midwives. This results can be used for future guidance from ACOG and for counseling pregnant people as they make their obstetric care choices.

Limitations of this study include that data was collected only from consenting patients. It is not clear how many patients did not consent to have data collected. 94% of Midwives' Association of Washington State members participated in data collection so some data was missed in this manner. The population that chose community birth was largely White, non-Hispanic. These results may not apply to a more diverse population.

Thank you for your comments.

We have added a note to the Methods section regarding the rate of patients consenting to inclusion in the data registry from previously published work.

Lines 116-117:

“Client consent for participation in this data registry was previously reported as >95%.”

We have also added some context for generalizability of our findings to the broader birthing population.

Lines 302-308:

“Demographics and obstetric characteristics of this cohort were similar to home and birth center births in other US states; however, results reported in this study may not be generalizable to states with different legislation, training, and integration of community midwives. While this cohort is not representative of the broader US birthing population (including planned hospital births), this reflects eligibility for community birth and does not limit the internal validity of the comparison between home and birth centers or the generalizability of our findings to a low-risk, more racially diverse cohort within a state with a similar level of midwifery integration.”

STATISTICAL EDITOR COMMENTS:

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

Table 1: Need units for BMI. Need to statistically compare the two cohorts, since they were not randomly allocated. Since some in each group later delivered in hospital, should also include a Table compared the characteristics of the groups which actually delivered at home vs birth centers. Also, this sample is from 2015-2020, so were there some women with more than one birth in this series? If so, then would need to adjust for correlation of outcomes for each individual. This could be done by randomly choosing one delivery per mother, or by adjusting for intra-class correlation. Either way, the sample size is actually or effectively decreased and the inferences and CIs need to be updated.

Thank you for these excellent points.

Units for BMI: *We have added units for BMI to Table 1.*

Regarding a statistical comparison of the two cohorts: Since we did not specify hypotheses regarding the statistical similarity or difference between the two cohorts, we did not conduct hypothesis testing for each of the characteristics presented in Table 1. This table is purely descriptive. As explained in the STROBE statement’s accompanying article (1) “Inferential measures such as standard errors and confidence intervals should not be used to describe the variability of characteristics, and significance tests should be avoided in descriptive tables....In cohort studies, it may be useful to document how an exposure relates to other characteristics and potential confounders. Authors could present this information in a table with columns for participants in two or more exposure categories, which permits to judge the differences in confounders between these categories.”

We followed the method suggested here by reporting the frequency of each confounder according to exposure group without the addition of inferential measures or hypothesis testing. Furthermore, as we determined which variables were potential confounders of the association between community birth setting (home vs. birth center) and birth outcomes on a priori grounds based on subject-matter expertise of the research team (per current methodological

recommendations) (2, 3), statistical comparison of exposure groups would not impact subsequent analyses (for example by determining which variables to adjust for in adjusted models) nor interpretation of findings.

Despite these methodological recommendations, if *Obstetrics & Gynecology* requires that p-values be included in Table 1 for publication, we would concede this point and add p-values, which we leave to editorial discretion.

Regarding a table comparing the characteristics of those who actually delivered at home v birth center: We have added this table (*Appendix 3*) comparing the characteristics of the two cohorts stratified by actual birth setting.

We also added the following text in the Results section referencing this table.

Lines 214-216:

“The group who delivered in hospital had higher rates of nulliparity, BMI ≥ 30 kg/m², ≥ 35 y age, and labor that started after 41w+4d weeks of gestational (Appendix 3).”

Regarding individuals with more than one birth in the series: We did not have an identifier for individual patient in the dataset which would allow us to address correlation of repeated birth outcomes at the individual level.

To address this, we recalculated all frequency distribution confidence intervals and inference confidence intervals using bootstrapping with replacement to account for non-independence of outcomes between successive births to the same person. (4) Of note, bootstrapping had only a very minor impact on confidence intervals as we were previously using a more conservative approach to estimate confidence intervals (Bayes’ posterior high density intervals) and no impact on overall inferences. This minimal change in CIs is common in perinatal studies before and after using robust variance estimates for successive births to the same person (including when this variance adjustment is based on individual patient identifiers).

We have added text describing the bootstrapping in the Methods section.

Lines 175-178:

“As our data set does not include patient-level identifiers, we bootstrapped 200 samples with replacement from the study population to estimate valid confidence intervals (CIs) around our estimates to account for non-independence between outcomes of successive births to the same person.³¹”

Sources:

1. Vandenbroucke JP, Von Elm E, Altman DG, Gøtzsche PC, Mulrow CD, Pocock SJ, et al. Strengthening the Reporting of Observational Studies in Epidemiology (STROBE): Explanation and Elaboration. *PLoS Medicine*. 2007;4(10):e297.
2. Hernan MA. Causal Knowledge as a Prerequisite for Confounding Evaluation: An Application to Birth Defects Epidemiology. *American Journal of Epidemiology*. 2002;155(2):176-84.
3. Vanderweele TJ. Principles of confounder selection. *European Journal of Epidemiology*. 2019;34(3):211-9.

4. Carpenter J, Bithell J. Bootstrap confidence intervals: When, which, what? A practical guide for medical statisticians. *Stat Med.* 2000;19(9):1141-1164. doi:10.1002/(SICI)1097-0258(20000515)19:9

Table 3: Re: hospital admission, why are the 1455 intrapartum transfers excluded? If data are presented as intent-to-treat (lines 145-148), then all outcomes in all 10640 should be reported, rather than separating out those transferred intrapartum. If needed, could report in supplemental material the analysis based on actual delivery site, but if ITT, then should be consistent.

We have adjusted reporting in Table 3 and 4 to be consistent as intent-to-treat.

Table 4: There is no adjustment for multiple hypothesis testing, many of the comparisons are underpowered (eg, late PP adm, operative Vag birth, cesarean multiparas, episiotomy etc), so the NS findings cannot be generalized. Without prospective estimation of power/sample size and a primary outcome, these cannot be generalized and should just be descriptive, rather than attempting to extrapolate these findings to all similar birth settings.

In this study, adjusting for multiple comparisons would increase the chance of a Type 2 error (false negative error; increasing the chance of falsely accepting the null hypothesis). Given that we hypothesized no difference by planned birth setting (given that midwifery management and equipment availability is the same in both settings), not adjusting for multiple comparisons is the more conservative statistical approach.

We have removed reporting of adjusted models for outcomes with limited power.

Sources:

1. Rothman KJ. No adjustments are needed for multiple comparisons. *Epidemiology.* 1990;1(1):43-46. doi:10.1097/00001648-199001000-00010

Table 5: Most of these studies have similar low counts of perinatal mortality events, so there is low power to discern a difference statistically. There is no statistical difference comparing this study with the others, but also there is insufficient stats power to have discerned a difference.

We agree. This is why we did not attempt to present a test of statistical difference comparing our study to these other studies. However, ACOGs clinical guidance on “Planned Home Birth” (1) is based on studies with low counts of perinatal mortality and similarly low statistical power. A recent meta-analysis (2) which we cite in the manuscript used many of these studies to assess the risk of perinatal mortality comparing planned home to planned hospital births. We present the results in Table 5 (with 95% confidence intervals) to allow the reader to review the findings of our study in context with previous findings. However, our intent was not to discern a difference, but to note that the perinatal mortality rate in our study is statistically congruent with that from other international settings (high income countries) with ‘well-integrated’ midwifery.

Sources:

1. Planned Home Birth. Committee Opinion No 697. American College of Obstetricians and Gynecologists. *Obstet Gynecol.* 2017;129:e117-22. doi:10.1097/AOG.0000000000002024
2. Hutton EK, Reitsma A, Simioni J, Brunton G, Kaufman K. Perinatal or neonatal mortality among women who intend at the onset of labour to give birth at home compared to women of low obstetrical risk who intend to give birth in hospital: A systematic review and meta-analyses. *EClinicalMedicine.* 2019;14:59-70. doi:10.1016/j.eclinm.2019.07.005

EDITOR COMMENTS:

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

A. OPT-IN: Yes, please publish my point-by-point response letter.

B. OPT-OUT: No, please do not publish my point-by-point response letter.

A. OPT-IN

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

All authors have completed the eCTA agreement.

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.

We have used the required categorizations and described the data collection of the race/ethnicity data in the manuscript. We do not have data to describe which patients were included in the "other race" category and have added detail to the manuscript regarding this.

Lines 140-141:

"We do not have detailed information for the "other race" group as this categorization was predefined by the data registry"

4. Your submission indicates that one or more of the authors is employed by a pharmaceutical company, device company, or other commercial entity. This must be included as a statement in the Financial Disclosure section on the title page.

Audrey Levine, Smooth Transitions, Foundation for Health Care Quality

Smooth Transitions is not a pharmaceutical company. Smooth Transitions is a quality improvement program, housed at the Foundation for Health Care Quality (a Seattle-based non-profit) that promotes collaboration between community midwives and hospitals.

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

We have complied with this requirement.

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 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.

We have used reVITALize definitions where applicable.

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 5,500 words. Stated word limits include the title page, précis, abstract, text, tables, boxes, and figure legends, but exclude references.

We meet this criteria. The manuscript is 5200 words including the title page, abstract, text, tables, and captions.

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).

* 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]."

We comply with all the above guidelines.

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

We edited our short title to comply with this requirement. *Line 31.*

Planned home and birth center births

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 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.

We have verified that the Abstract reflects the revised version of the manuscript.

In addition, the abstract length should follow journal guidelines. The word limit for Original Research articles is 300 words. Please provide a word count.

We have added a word count to abstract. The abstract is currently 292 words.

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.

We have reviewed the manuscript for this issue.

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.

We have made minor changes to the manuscript to remove any / in sentences.

13. Line 253: Your manuscript contains a priority claim. We discourage claims of first reports since they are often difficult to prove. How do you know this is the first report? If this is based on a systematic search of the literature, that search should be described in the text (search engine, search terms, date range of search, and languages encompassed by the search). If it is not based on a systematic search but only on your level of awareness, it is not a claim we permit.

We have removed this claim.

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.

We have reviewed the Table checklist and made small changes to the tables to conform to journal style.

15. 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.

We have reviewed the reference style and made minor changes to reference list.

In addition, the American College of Obstetricians and Gynecologists' (ACOG) documents are frequently updated. These documents may be withdrawn and replaced with newer, revised versions. If you cite ACOG documents in your manuscript, be sure the references you are citing are still current and available. Check the Clinical Guidance page at <https://www.acog.org/clinical> (click on "Clinical Guidance" at the top). If the reference is still available on the site and isn't listed as "Withdrawn," it's still a current document.

If the reference you are citing has been updated and replaced by a newer version, please ensure that the new version supports whatever statement you are making in your manuscript and then update your reference list accordingly (exceptions could include manuscripts that address items of historical interest). If the reference you are citing has been withdrawn with no clear replacement, please contact the editorial office for assistance (obgyn@greenjournal.org). In most cases, if an ACOG document has been withdrawn, it should not be referenced in your manuscript.

We have reviewed all ACOG documents to ensure they are current and available.

16. Figure 1: Are the items excluded in n=833 not mutually exclusive? Please upload as a figure file on Editorial Manager.

No – they are not mutually exclusive – a total of 833 cases are excluded; but there is overlap in individual complications/conditions noted in the list. Appendix 2 documents excluded conditions in detail – 38 cases had >1 complication.

We have added to the Results section Lines 197-198:

“Of the 833 excluded pregnancies, 38 had >1 complication.”

Figure 1 is now uploaded as a figure file.

17. 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.

We have updated the Appendix references to a separate reference list.

18. 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>.

We will pay for open access publishing.

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