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- Comments from the reviewers and editors (email to author requesting revisions)
- Response from the author (cover letter submitted with revised manuscript)*

**The corresponding author has opted to make this information publicly available.*

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Questions about these materials may be directed to the *Obstetrics & Gynecology* editorial office: obgyn@greenjournal.org.

Date: 01/10/2025
To: "Annika Hikade" [redacted]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-24-2070

01/10/2025

RE: ONG-24-2070: Trial of labor and vaginal birth after cesarean (VBAC): trends before and after the removal of race and ethnicity from the VBAC calculator

Dear Dr. Hikade:

Thank you for sending us your work for consideration for publication in Obstetrics & Gynecology. Your manuscript has been reviewed by the Editorial Board and by special expert referees. The Editors would like to invite you to submit a revised version for further consideration.

If you wish to revise your manuscript, please read the following comments submitted by the reviewers and Editors. Each point raised requires a response, by either revising your manuscript or making a clear argument as to why no revision is needed in the cover letter.

To facilitate our review, we prefer that the cover letter you submit with your revised manuscript include each reviewer and Editor comment below, followed by your response. That is, a point-by-point response is required to each of the EDITOR COMMENTS (if applicable), REVIEWER COMMENTS, and STATISTICAL EDITOR COMMENTS (if applicable) below. The revised manuscript should indicate the position of all changes made. Please use the "track changes" feature in your document (do not use strikethrough or underline formatting). Upload the tracked-changes version when you submit your revised manuscript.

Your submission will be maintained in active status for 21 days from the date of this letter. If we have not heard from you by 01/31/2025, we will assume you wish to withdraw the manuscript from further consideration.

EDITOR COMMENTS:

Please note the following:

* Help us reduce the number of queries we add to your manuscript after it is revised by reading the Revision Checklist at https://journals.lww.com/greenjournal/Documents/RevisionChecklist_Authors.pdf and making the applicable edits to your manuscript.

* As of January 2024, only certain article types will appear in the print version of the journal. All accepted articles will continue to publish online. All articles will be indexed in PubMed as an official article of Obstetrics & Gynecology. Additional information is available in the Instructions for Authors (https://journals.lww.com/greenjournal/Pages/InformationforAuthors.aspx#II).

* Please upload your multi-part figure as an individual high res figure file (jpeg or png) in Editorial Manager.

EDITOR'S COMMENTS:

The VBAC calculator has been validated in cases of two prior cesarean sections--consider citing this paper because it would address one of the Reviewer's critiques above.

REVIEWER COMMENTS:

Reviewer #1:

Overall: This study examines whether the rates of pursuing a trial of labor after cesarean (TOLAC) and vaginal birth after cesarean (VBAC) changed following removal of one component from a popular counseling tool, an online calculator used to predict the likelihood of TOLAC success. The authors use data from U.S. Natality files from 2019-22 (the VBAC calculator was changed in 6/2021). The authors calculate overall TOLAC attempt rates and VBAC success rates as well as break these outcomes down by racial group (non - Hispanic White, non - Hispanic Black, Hispanic, and non - Hispanic Asian). They find that neither the TOLAC rate nor the VBAC rate really changed after the calculator was modified.

They find that patients from non - Hispanic White racial and ethnic backgrounds are less likely to have a successful VBAC, even when attempting TOLAC at higher rates.
Strengths of the study include a timely and succinct result regarding the effect of the TOLAC calculator on population - level rates of TOLAC and VBAC. I also appreciate the authors highlighting the residual racial and ethnic disparities (although this finding isn't new). Weaknesses of the paper include an inability to see whether there were changes on a smaller scale (ie, in some states or locales) and lack of ability to verify whether patients and practitioners were even using the calculator. The authors are unable to truly ascertain whether patients were eligible for a TOLAC, although, as they point out, this was unlikely to affect different groups differentially.

Specific comments are as follows:
1. Line 59: September 1 is not 8 weeks after June 1. Please fix this.

2. I realize space is an issue but can you give information about how race and ethnicity are ascertained in Natality files?

Reviewer #2:

This is an international time series analysis of US natality data files from 2019 - 2022 following removal of the race and ethnicity fields from the MFMU VBAC calculator, with replacement by the field chronic hypertension requiring treatment.

Included were live singleton cephalic term deliveries with up to 2 prior cesareans. The authors compared demographic characteristics and TOLAC and VBAC rates for the overall population and by specific racial and ethnicity groups using a single unit interrupted time series analysis. The authors found that there were no immediate or longer term changes in rates of TOLAC, or in overall rate successful VBAC. However differences in the rates of successful VBAC across specific racial and ethnic groups persisted both before and after the change.

The manuscript addresses a significant issue and uses national data to evaluate trends, which is of interest but perhaps not exactly novel, as there are other analyses of VBAC with and without race and ethnicity in national registries. The limitations of the analysis are explained in the Appendix. These include the assumption that all patients with one or two prior cesareans are eligible for TOLAC, without additional data.

Reviewer #3:

The objective of this research letter was to describe TOLAC and VBAC rates before and after updates to the VBAC calculator were made. Overall, the manuscript was well written and uses some novel statistical methods. However, the selection of the study population (i.e. analysis included patients with 1-2 prior cesareans, but the calculator was based on data with patients that had 1 prior cesarean) and inconsistent reporting of the denominators is questionable.

Lines 36-37: Suggest rewording the description of the updated calculator. The updated model was based on re-running the model selection algorithm that did not consider race and ethnicity. The race-ethnicity factor was not simply "replaced" with another variable.

Lines 41-65: Please specify the statistical software used and level of statistical significance used for this analysis. Additionally, please provide a description of the test of comparisons that were done for Table 1.

Lines 43-44: Please include a citation for the U.S. natality files and when these were accessed for this analysis.

Lines 43-45: Authors provide an explanation with their STROBE checklist detailing how they retrieved their study population. Some elements of these details should be included in the text. For example, the calculator was developed using data from those that had 1 prior cesarean delivery. However, this analysis includes patients with 1-2 prior cesarean deliveries. The authors should explain why patients with 2 cesarean deliveries were included, or if they considered running their analysis with only those that had 1 cesarean delivery.

Liens 52-55, Table 1: There are several different denominators and it's not clear which is correct. The text has n=1568452; the sum of the denominators (first row) of Table 1 are n=1405663 (=938148 + 467515); for some of the variables in Table

1, the sum of the counts is n=1047478. The authors should check and make sure this is consistent in the text and tables. If there are missing data, then those should be noted appropriately in the tables.

Lines 62-63: Offset values for Poisson models typically specify the time period. Please clarify what is meant by "offset for the number of live births".

Lines 64-65: The average reader may not understand this terminology. Please include a brief explanation and interpretation of what "level" and "slope" means for this analysis.

Lines 69-71: Highly suggest including confidence intervals for the overall average TOLAC and VBAC rates.

Lines 71-72: Please see previous comment. Statistical test for comparisons should be specified.

Lines 72-73: Highly suggest including confidence intervals for the successful VBAC percentage.

Table 1: Please see previous comment. Unclear why the sum of the counts and the denominators do not match. What does "Live birth order" mean here?

Appendix 1: Suggest including confidence intervals around the VBAC percentages.

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Sincerely,
The Editors of Obstetrics & Gynecology

In compliance with data protection regulations, you may request that we remove your personal registration details at any time. (Use the following URL: https://www.editorialmanager.com/ong/login.asp?a=r). Please contact the publication office if you have any questions.

Dear Editors:

Thank you for your consideration of our Research Letter entitled *Trial of labor and vaginal birth after cesarean (VBAC): trends before and after the removal of race and ethnicity from the VBAC calculator.* We are grateful to the reviewers for their thoughtful comments and to the editors for the opportunity to submit a revised and improved manuscript.

See below for a point-by-point response to the comments. Attached is the marked and revised manuscript. We hope that you find our responses and revisions satisfactory.

Sincerely,

Annika Hikade, MD

EDITOR'S COMMENTS: The VBAC calculator has been validated in cases of two prior cesarean sections--consider citing this paper because it would address one of the Reviewer's critiques above.

RESPONSE: Thank you for pointing this out. We have added more background on the VBAC calculator's derivation and subsequent validation in patients with two prior cesarean sections.

TEXT: (Lines 33-36) *The Maternal-Fetal Medicine Units Network's VBAC calculator is a clinical tool that predicts the likelihood of VBAC. It was derived from a cohort of people with singleton, vertex, term gestations and one prior cesarean who underwent trial of labor after cesarean (TOLAC), and was subsequently validated in those with two prior cesareans.*[2,3]

2. Grobman WA, Lai Y, Landon MB, et al. Development of a nomogram for prediction of vaginal birth after cesarean delivery. Obstet Gynecol. 2007;109(4):806-812. doi:10.1097/01.AOG.0000259312.36053.02
3. Metz TD, Allshouse AA, Faucett AM, Grobman WA. Validation of a vaginal birth after cesarean delivery prediction model in women with two prior cesarean deliveries. Obstet Gynecol. 2015;125(4):948-952. doi:10.1097/AOG.0000000000000744

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TOLAC attempt rates and VBAC success rates as well as break these outcomes down by racial group (non - Hispanic White, non - Hispanic Black, Hispanic, and non - Hispanic Asian). They find that neither the TOLAC rate nor the VBAC rate really changed after the calculator was modified.

They find that patients from non - Hispanic White racial and ethnic backgrounds are less likely to have a successful VBAC, even when attempting TOLAC at higher rates. Strengths of the study include a timely and succinct result regarding the effect of the TOLAC calculator on population - level rates of TOLAC and VBAC. I also appreciate the authors highlighting the residual racial and ethnic disparities (although this finding isn't new). Weaknesses of the paper include an inability to see whether there were changes on a smaller scale (ie, in some states or locales) and lack of ability to verify whether patients and practitioners were even using the calculator. The authors are unable to truly ascertain whether patients were eligible for a TOLAC, although, as they point out, this was unlikely to affect different groups differentially.

Specific comments are as follows:

(1) REVIEWER COMMENT: Line 59: September 1 is not 8 weeks after June 1. Please fix this.

(1) RESPONSE: Thank you for pointing out this discrepancy. We have refined our rationale for why we selected September 1 as the interruption point. We wanted to exclude pregnancies already in the third trimester at the time of the VBAC calculator revision on June 1.

TEXT: (Lines 61-64) *We selected an interruption point (Sep 1, 2021) 13 weeks after the calculator revision (Jun 1, 2021) to exclude pregnancies already in the third trimester at the time of the revisions, which were unlikely to have been influenced by the change.*

(2) REVIEWER COMMENT: I realize space is an issue but can you give information about how race and ethnicity are ascertained in Natality files?

(2) RESPONSE: Maternal race and ethnicity on the U.S. birth certificate (which is used for the natality files) are supposed to be collected from the mother directly using the "Mother's Worksheet for Child's Birth Certificate." Mothers are asked two questions: "Q9. Are you Spanish/Hispanic/Latina? If not Spanish/Hispanic/Latina, check the "No" box. If Spanish/Hispanic/Latina, check the appropriate box. " And "Q10. What is your race? (Please check one or more races to indicate what you consider yourself to be)."

We cite the "Mother's Worksheet for Child's Birth Certificate" in our Methods section and describe maternal race/ethnicity as self-reported. We don't elaborate further because of word count limits.

TEXT: (Lines 47-48) *Maternal race and ethnicity were self-reported.*[6]

6. Mother's Worksheet for Child's Birth Certificate. National Center for Health Statistics. Accessed November 4, 2024. https://www.cdc.gov/nchs/data/dvs/moms-worksheet-2016-508.pdf

Reviewer #2:

This is an international time series analysis of US natality data files from 2019 - 2022 following removal of the race and ethnicity fields from the MFMU VBAC calculator, with replacement by the field chronic hypertension requiring treatment.

Included were live singleton cephalic term deliveries with up to 2 prior cesareans. The authors compared demographic characteristics and TOLAC and VBAC rates for the overall population and by specific racial and ethnicity groups using a single unit interrupted time series analysis. The authors found that there were no immediate or longer term changes in rates of TOLAC, or in overall rate successful VBAC. However differences in the rates of successful VBAC across specific racial and ethnic groups persisted both before and after the change.

The manuscript addresses a significant issue and uses national data to evaluate trends, which is of interest but perhaps not exactly novel, as there are other analyses of VBAC with and without race and ethnicity in national registries. The limitations of the analysis are explained in the Appendix. These include the assumption that all patients with one or two prior cesareans are eligible for TOLAC, without additional data.

RESPONSE: We have added a brief acknowledgement of the limitations of defining the study population.

TEXT: (Lines 90-93) *Our study is limited by the inability to exclude individuals potentially ineligible for TOLAC for reasons not documented in the natality data (e.g. prior myomectomy or uterine rupture, placenta accreta spectrum); however, we would expect these to be rare and therefore not significantly impact our findings.*

Reviewer #3:

The objective of this research letter was to describe TOLAC and VBAC rates before and after updates to the VBAC calculator were made. Overall, the manuscript was well written and uses some novel statistical methods. However, the selection of the study population (i.e. analysis included patients with 1-2 prior cesareans, but the calculator was based on data with patients that had 1 prior cesarean) and inconsistent reporting of the denominators is questionable.

(1) REVIEWER COMMENT: Lines 36-37: Suggest rewording the description of the updated calculator. The updated model was based on re-running the model selection algorithm that did not consider race and ethnicity. The race-ethnicity factor was not simply "replaced" with another variable.

(1) RESPONSE: Thank you for highlighting this issue. In deriving the modified VBAC calculator, race and ethnicity were first excluded, and a new logistic regression model was derived through backward elimination of other variables (Grobman, 2021). The authors found that the inclusion of a new variable "chronic hypertension requiring treatment" yielded a model that was almost identical in terms of prediction to the original model albeit with slightly different coefficients for each of the input variables (see below for the two logistic regression equations). We now explain to the reader that race and ethnicity were removed from the calculator, and do not further suggest that they were replaced with another variable.

2007 Calculator (Grobman 2007):

Predicted probability (%) of VBAC = exp(w)/[(1+exp(w)], where w=3.766 – 0.039(age) – 0.060(prepregnancy body mass index) – 0.671(African-American race) – 0.680(Hispanic race) + 0.888(any prior vaginal delivery) + 1.003(vaginal delivery after prior cesarean) – 0.632(recurring indication for cesarean)

2021 Calculator (Grobman 2021):

Predicted probability (%) of VBAC = exp(w)/[1+exp(w)])*100, where w = –5.952 – 0.023(age) – 0.024(pre-pregnancy weight) + 0.056(height) – 0.597(arrest indication) + 0.868(previous vaginal delivery only before prior cesarean) + 1.869(previous VBAC) – 0.966(treated chronic hypertension)

Grobman WA, Lai Y, Landon MB, et al. Development of a nomogram for prediction of vaginal birth after cesarean delivery. Obstet Gynecol. 2007;109(4):806-812. doi:10.1097/01.AOG.0000259312.36053.02

Grobman WA, Sandoval G, Rice MM, et al. Prediction of vaginal birth after cesarean delivery in term gestations: a calculator without race and ethnicity. Am J Obstet Gynecol. 2021;225(6):664.e1-664.e7. doi:10.1016/j.ajog.2021.05.021

TEXT: (Lines 37-39) *Due to concern that this systematized medical racism and perpetuated racial inequities, a revised calculator without race and ethnicity was published in 2021.*

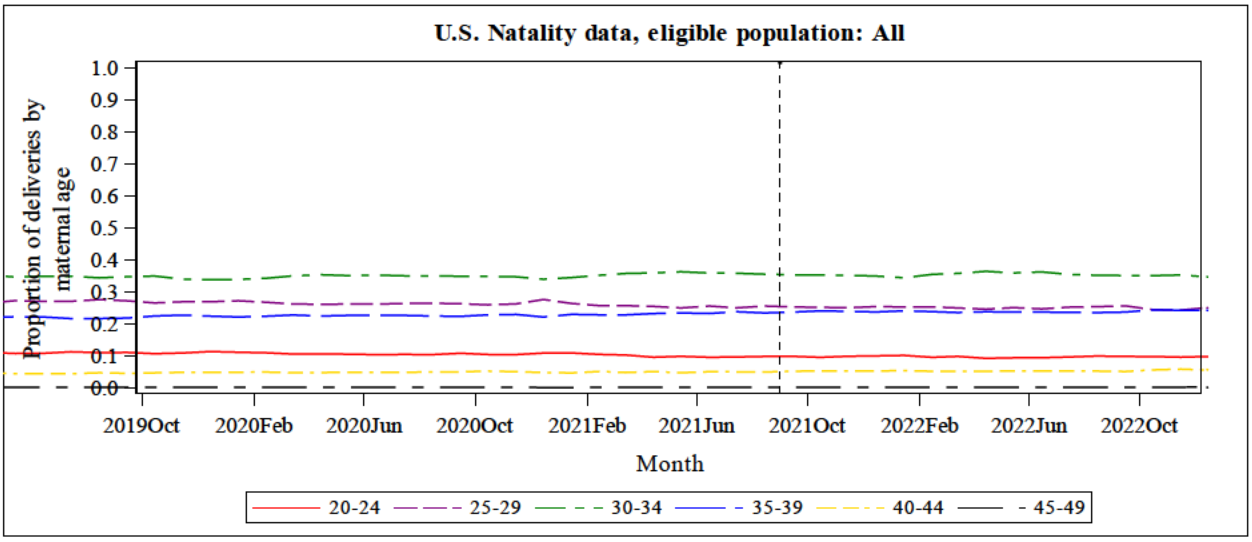
(2) REVIEWER COMMENT: Lines 41-65: Please specify the statistical software used and level of statistical significance used for this analysis. Additionally, please provide a description of the test of comparisons that were done for Table 1.

(2) RESPONSE: We have added a sentence to our Methods section stating that we used SAS version 9.4 for all analyses. In terms of the level of statistical significance used for the interrupted time series analysis, we assessed whether or not the 95% confidence intervals of the level and slope rate ratios included the null (e.g. 1.00), which we point out in the Results.

Statistical comparisons before and after the VBAC calculator changed were not performed for Table 1. This is consistent with STROBE recommendations, which state "significance tests should be avoided in descriptive tables" (Vandenbroucke, 2014). To avoid the interpretation that we performed statistical testing for Table 1, we have rephrased this in the text (see below).

The purpose of Table 1 is to show the reader that characteristics of the deliveries included in our analysis were not meaningfully different before vs after the VBAC calculator change. If there were a meaningful difference, and it occurred around the time of the calculator change, that could indicate that our study findings were confounded. We visually assessed time trends in maternal characteristics overall and by race and ethnic groups before conducting the interrupted time series analysis to make sure there were not abrupt changes in maternal characteristics around the time of the VBAC calculator change.

See below for an example that shows the proportion of deliveries in our study population by maternal age over time, with no abrupt change detected:



Vandenbroucke JP, von Elm E, Altman DG, et al. Strengthening the Reporting of Observational Studies in Epidemiology (STROBE): explanation and elaboration. Int J Surg Lond Engl. 2014;12(12):1500-1524. doi:10.1016/j.ijsu.2014.07.014

TEXT: (Line 75-76) *Characteristics of the study population appeared similar before and after the calculator modification (**Table 1**).*

(3) REVIEWER COMMENT: Lines 43-44: Please include a citation for the U.S. natality files and when these were accessed for this analysis.

(3) RESPONSE: This has been added to our references (citation #5). We added that we accessed these files in March 2024.

(4) REVIEWER COMMENT: Lines 43-45: Authors provide an explanation with their STROBE checklist detailing how they retrieved their study population. Some elements of these details should be included in the text. For example, the calculator was developed using data from those that had 1 prior cesarean delivery. However, this analysis includes patients with 1-2 prior cesarean deliveries. The authors should explain why patients with 2 cesarean deliveries were included, or if they considered running their analysis with only those that had 1 cesarean delivery.

(4) RESPONSE: While the VBAC calculator was derived using a cohort of patients with only one prior cesarean, the calculator was subsequently validated in patients with two prior cesarean sections (Metz, 2015). Further, in clinical practice, there is widespread use of the VBAC calculator for any patient eligible for TOLAC, including those with two prior cesareans:

Counseling Regarding Approach to Delivery After Cesarean and the Use of a Vaginal Birth After Cesarean Calculator Practice Advisory: https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2021/12/counseling-regarding-approach-to-delivery-after-cesarean-and-the-use-of-a-vaginal-birth-after-cesarean-calculator

Metz TD, Allshouse AA, Faucett AM, Grobman WA. Validation of a vaginal birth after cesarean delivery prediction model in women with two prior cesarean deliveries. Obstet Gynecol. 2015;125(4):948-952. doi:10.1097/AOG.0000000000000744

To estimate the impact of the VBAC calculator change on a population level, we sought to examine the population eligible for TOLAC including those with two prior cesareans, whose counseling may have included the use of the VBAC calculator. We have added more details to clarify the rationale behind our population selection throughout the text, as outlined below.

TEXT: (Lines 33-36) *The Maternal-Fetal Medicine Units Network's VBAC calculator is a clinical tool that predicts the likelihood of VBAC. It was derived from a cohort of people with singleton, vertex, term gestations and one prior cesarean delivery who underwent trial of labor after cesarean (TOLAC), and was subsequently validated in those with two prior cesarean deliveries.*[2,3]

2. Grobman WA, Lai Y, Landon MB, et al. Development of a nomogram for prediction of vaginal birth after cesarean delivery. Obstet Gynecol. 2007;109(4):806-812. doi:10.1097/01.AOG.0000259312.36053.02

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(Lines 45-47) This population-based retrospective cohort study used U.S. natality files (2019-2022) and included live, singleton, cephalic term deliveries to people aged 20-49 years with 1-2 prior cesarean deliveries to best capture those eligible for TOLAC.

(5) REVIEWER COMMENT: Lines 52-55, Table 1: There are several different denominators and it's not clear which is correct. The text has n=1568452; the sum of the denominators (first row) of Table 1 are n=1405663 (=938148 + 467515); for some of the variables in Table 1, the sum of the counts is n=1047478. The authors should check and make sure this is consistent in the text and tables. If there are missing data, then those should be noted appropriately in the tables.

(5) RESPONSE: Thank you for pointing out this error. The first row of Table 1 should have included the total sample sizes overall, which were: Before (Jan 2019-Aug 2021) n= 1,047,478 and After (Sep 2021-Dec 2022) n= 520,974. We double checked the numbers in the table and found two more small transcription errors, which we fixed. We also added "none" rows for diabetes and hypertension. We changed the percentages to display one digit past the decimal place instead of two, to simplify the table. There are no missing data rows in Table 1.

(6) REVIEWER COMMENT: Lines 62-63: Offset values for Poisson models typically specify the time period. Please clarify what is meant by "offset for the number of live births".

(6) RESPONSE: This has been corrected to specify the time period for the offset

TEXT: (Line 64) *We used Poisson regression models, offset for the number of live births per month…*

(7) REVIEWER COMMENT: Lines 64-65: The average reader may not understand this terminology. Please include a brief explanation and interpretation of what "level" and "slope" means for this analysis.

(7) RESPONSE: In the methods, we specify that the level change represents an immediate change and the slope change represents a trend change; however, due to limitations in space we are unable to further explain and interpret this terminology in the main text. However, we have added an interpretation to the Figure 1 caption.

TEXT: (Lines 66-67) *…level ("immediate") change at the interruption point, as well as the slope ("trend") change after the interruption point.*

Figure 1: Level change represents the immediate effect of the calculator revision and slope change represents the change in slope over time.

(8) REVIEWER COMMENT: Lines 69-71: Highly suggest including confidence intervals for the overall average TOLAC and VBAC rates.

(8) RESPONSE: We have added confidence intervals for the overall average TOLAC and VBAC rates to the Results text and to Appendix 1.

TEXT: (Lines 72-74) *During 2019-2022, the average TOLAC rate was 22.0 (95% CI: 21.9-22.0) per 100 deliveries (ranged from 21.2 in Hispanic and NH White to 24.9 in NH Black) and VBAC rate was 16.4 (95% CI: 16.4-16.5) per 100 deliveries (ranged from 15.8 in Hispanic to 16.7 in NH Black).*

(9) REVIEWER COMMENT: Lines 71-72: Please see previous comment. Statistical test for comparisons should be specified.

(9) RESPONSE: We present VBAC and TOLAC percentages by race and ethnicity for context for the reader; however, these comparisons are not the main purpose of this paper and have previously been reported elsewhere. So, we did not add statistical tests for these comparisons to this research letter. We added the 95% CI for the rates by race and ethnic group to Appendix 1 so the reader can see that the 95% CI are fairly narrow.

(10) REVIEWER COMMENT: Lines 72-73: Highly suggest including confidence intervals for the successful VBAC percentage.

(10) RESPONSE: We have added 95% CIs for the successful VBAC percentage to the table in Appendix 1. We do not report these 95% CIs in the Results due to word count limits and because it made the results very hard to read.

(11) REVIEWER COMMENT: Table 1: Please see previous comment. Unclear why the sum of the counts and the denominators do not match. What does "Live birth order" mean here?

(11) RESPONSE: We have corrected our transcription errors in Table 1 (see response to comment #5).

“Live birth order” indicates what number live birth the present birth represents. It differs from parity in that it counts the total number of prior live births rather than the total number of prior pregnancies resulting in a stillbirth or livebirth (i.e. it excludes previous fetal demise and accounts for each individual neonate born from a multi-gestation pregnancy). Because parity (inclusive of sillbirths) is not directly captured on the birth certificate, we use “live birth order” as a measure of obstetrical history. We added a footnote to Table 1 explaining what “live birth order” means.

For more information, the Facility Worksheet for the Live Birth Certificate describes how live birth order is collected:

Facility Worksheet for the Live Birth Certificate. National Center for Health Statistics. Available at: https://www.cdc.gov/nchs/data/dvs/facility-worksheet-2016.pdf

(12) REVIEWER COMMENT: Appendix 1: Suggest including confidence intervals around the VBAC percentages.

(12) RESPONSE: We revised the table in the appendix to add TOLAC 95% CI, VBAC 95% CI, and successful VBAC 95% CI. We did not add all these 95% CI to the Results text because doing so adds greatly to the word count and reduces the readability of the results.