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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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Date:	Sep 11, 2019
То:	"Aude Girault"
From:	"The Green Journal" em@greenjournal.org
Subject:	Your Submission ONG-19-1470

### RE: Manuscript Number ONG-19-1470

Decreasing oxytocin and artificial rupture of the membranes without increasing intrapartum cesarean rates

Dear Dr. Girault:

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

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

Your paper will be maintained in active status for 21 days from the date of this letter. If we have not heard from you by Oct 02, 2019, we will assume you wish to withdraw the manuscript from further consideration.

### **REVIEWER COMMENTS:**

Reviewer #1: The authors aim to evaluate if guidelines limiting the use of oxytocin and AROM to women with labor arrest are associated with an increase in intrapartum cesarean rates. I have the following comments regarding the manuscript:

### Title

1. Rather than reporting the findings, the title should indicate what was being investigated.

### Precis

1. Needs to be reworked to clarify that the decrease in oxytocin and AROM was a result of changes in national guidelines. Otherwise the context for the reported finding is unclear.

### Intro

1. At the end of the Intro, the stated objective is to evaluate if there is a difference in indication for cesarean delivery. This is not included as part of the objectives in the abstract.

### Methods

Line 130. How were pregnancies with fetal anomalies handled? Were they retained in the low risk group?
Line 147. Why did the authors choose to use a surrogate for oxytocin administration (year of delivery) when they have chart abstracted information about oxytocin use? Why not just look directly at the proportion of women who received oxytocin or AROM and cesarean delivery rates?

3. Why just compare 2010 and 2016? One would assume that changes in practice occurred over time, and it sounds like the authors have very granular individual patient level data available. Why not evaluate effect over time (eg all years)?

### Results

1. What else was occurring over this time period? Did guidelines change for when to augment?

2. The cesarean rate is already so low (6.6%) that it would be hard to drive it even lower with active management of labor. Thus, it is not really surprising that the cesarean rate remained the same.

3. Figure 1. Would separate out fetal death from minor malformations in terms of the count of exclusion criteria.

4. Figure 1. Consider breaking down the exclusion criteria by year. For example, would be nice to know how many were excluded for induction in 2016 compared to 2010.

5. Figure 4. There was no change in the distribution of indications for cesarean delivery and no change in the overall cesarean rate, so why does it matter how many women received oxytocin of AROM? Was the length of time in labor different? Or time from final cervical dilation to c/s?

Reviewer #2: Girault and colleagues report results of a retrospective study derived from the 2010 and 2016 French population-based surveys of women giving birth in French maternity units during March of the respective years, regarding the relationship between active management of labor practices (i.e. oxytocin augmentation and artificial rupture of membranes) and cesarean rates. This reviewer would request the authors address the following questions and comments:

1. Line 41...Is it accurate to state active management of labor was adopted in "most countries", for I do not know if published data are available from the 200+ sovereign states worldwide.

2. Line 163...The software manufacturer and location should probably be mentioned.

3. Line 173...While there was a statistically significant increased incidence of older women, higher BMI, and increased epidural use from the first to the second period, the absolute differences seem negligible, and in any case would be expected to be associated with a higher need for active management and a higher cesarean rate in the second period. This may merit comment.

4. Line 196...In assessing the associations between active management of labor and cesarean rates, a striking void relates to the absence of neonatal outcome parameters (e.g. Apgar scores, umbilical cord gas analysis, NICU admission). From review of reference #20, it appears that Apgar scores and "neonatal transfer" were available in the dataset in the 2010 survey. It would seem appropriate to report available relevant neonatal outcome characteristics, which are essentially the other half of the equation as it relates to the clinical practice.

5. Line 192...Was there a change in operative vaginal delivery (i.e. forceps and vacuum) rates between the two epochs?

6. Line 207...Did any of these reported outcome data come from patient interviews, or just from chart review? If this paper does not contain data from interviews, did 6% of the women need to be excluded?

7. Line 216...Between 2010 and 2016, were there any other French national guidelines published and implemented that could have impacted intrapartum clinical practices and affected oxytocin, AROM and cesarean incidences?

8. Table 1...It appears that there was a significant increase in French women delivering in high-volume (>3,000 deliveries per year) facilities. Do the authors have any insight into factors (e.g. 24-hour in-house physicians & midwives, quality and safety infrastructure, etc.) that could have affected their results?

Thank you very much for requesting my review of this interesting manuscript.

Reviewer #3: The Authors did a cross-sectional population study based on data from the French national perinatal surveys. The French national perinatal surveys are population-based studies conducted routinely every six or seven years to monitor the main indicators of perinatal health, medical practices, and risk factors. The sample includes all live births and still-births at a gestational age of at least 22 weeks or a birth weight of at least 500 g during a full week in March in all French maternity units. Data are collected from the medical records and mother's interviews; each maternity unit completes a questionnaire to provide information about its characteristics and organization. The Authors included retrospectively 16 527 women who gave birth to a live- born fetus at term after spontaneous labor; they compared the trends of labor indicators and Cesarean section from 2010 with 2016 of three augmentation of labor indicators: the use of oxytocin infusion before the third stage of labor , the use of artificial rupture of the membranes and the combination of both during labor. They created three subgroups of population:

1-the group of nulliparous low obstetric risk women

2-the group of multiparous low obstetric risk women

3-the group of women with a previous cesarean section in trial of spontaneous labor after cesarean section;

The Authors performed a multivariable analyses for labor indicators and intrapartum Caesarean rates in order to compare the trends in 2010 with 2016. The inclusion and exclusion criteria are justified and allow for the study question to be evaluated.

The objective of the study was to confirm that the reduction in the use of oxytocin administration and artificial rupture of the membranes was influenced the intrapartum caesarean rate in low risk pregnancies.

The manuscript is well written but the following aspects should be clarified:

1- Line 1-2 : The title: in a study population with a Caesarean rate of 6.9 % in 2010 and 6.6 % in 2016 why is a goal to analyse this "traditional "active management of labor to decrease/increase caesarean rates? I suggest the Authors to revise the title ;

2- Line 69-71 : "active management of labor was proposed in the 1980's......resulting in a wide use of oxytocin administration and artificial rupture of the membranes " - it was introduced in the late 1960 and it was an early use of

artificial rupture of the membranes and oxytocin administration (Thornton JG, Lilford RJ. Active management of labour: current knowledge and research issues. BMJ. 1994 )

3- Line 81-82 : " Recently , ....." the reference 18 was published in 2003 ?

4- Line 117-121: I suggest the Authors to clarify if the active management of labour was an augmentation of labour because failure of labour to progress, systematically, in the active phase of labour, or an induction of labour because spontaneous labour's definition was not appropriate use ;

5- Line 154-158 : about " indications of cesarean section : cord prolapse, abnormal presentation etc" during labour - it can be diagnosed before an active management of labor, ! could the Authors explain the use of this indications ?

6- Line 225-226: Limitation of the study: the absence of detailed information on oxytocin administration - Could the Authors demonstrate (and also comment) appropriate use of oxytocin in order to show the influencing (increasing?) of the caesarean rate? The authors should indicate if, and how, they were able to overcome the limitations and whether or not the study is generalizable.

7- Line 386 : Table 1 : maternity unit volume deliveries by year - Was the French Perinatal Surveys a sample representative from the French population regarding the volume of deliveries from this analysed population ?

# STATISTICAL EDITOR'S COMMENTS:

1. Table 2: Should provide (could be supplemental material) the actual counts for oxytocin administration, AROM, both AROM and oxytocin administration and cesarean rates both overall and by the strata outlined by the characteristics.

2. Should also provide the crude ORs to contrast with the aORs. Should also state the counts and % change in AROM, oxytocin administration and use of both for 2010 vs 2016.

3. Figs 1, 3: For the subsets (nulliparous, multiparous and women with a previous c-section), there appears to be a more than adequate sample size for nulliparous and multiparous to perform multivariable adjustment. However, that was not clear re: the cohort with prior c-sections. Need to state the number of repeat c-sections in those women in 2010 and 2016. If the counts for repeat c-sections were < 70 for any year group, then the model may be over fitted and adjustment for 7 variables not possible. That would correspond to repeat c-section rates of ~ 14%. If rates were lower, then the model may be over fitted for analysis of that subset.

## Associate Editor's Comments:

If you have not already done so, please in your Discussion make reference to the cesarean delivery rate in the United States for women comparable in risk status to those in your cohort, and discuss the potential implications of our findings in higher cesarean delivery rate settings.

## EDITORIAL OFFICE COMMENTS:

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

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

2. As of December 17, 2018, Obstetrics & Gynecology has implemented an "electronic Copyright Transfer Agreement" (eCTA) and will no longer be collecting author agreement forms. When you are ready to revise your manuscript, you will be prompted in Editorial Manager (EM) to click on "Revise Submission." Doing so will launch the resubmission process, and you will be walked through the various questions that comprise the eCTA. Each of your coauthors will receive an email from the system requesting that they review and electronically sign the eCTA.

Please check with your coauthors to confirm that the disclosures listed in their eCTA forms are correctly disclosed on the manuscript's title page.

3. Responsible reporting of research studies, which includes a complete, transparent, accurate and timely account of what was done and what was found during a research study, is an integral part of good research and publication practice and not an optional extra. Obstetrics & Gynecology supports initiatives aimed at improving the reporting of health research, and we ask authors to follow specific guidelines for reporting randomized controlled trials (ie, CONSORT), observational

studies (ie, STROBE), meta-analyses and systematic reviews of randomized controlled trials (ie, PRISMA), harms in systematic reviews (ie, PRISMA for harms), studies of diagnostic accuracy (ie, STARD), meta-analyses and systematic reviews of observational studies (ie, MOOSE), economic evaluations of health interventions (ie, CHEERS), quality improvement in health care studies (ie, SQUIRE 2.0), and studies reporting results of Internet e-surveys (CHERRIES). Include the appropriate checklist for your manuscript type upon submission. Please write or insert the page numbers where each item appears in the margin of the checklist. Further information and links to the checklists are available at http://ong.editorialmanager.com. In your cover letter, be sure to indicate that you have followed the CONSORT, MOOSE, PRISMA, PRISMA for harms, STARD, STROBE, CHEERS, SQUIRE 2.0, or CHERRIES guidelines, as appropriate.

4. Standard obstetric and gynecology data definitions have been developed through the reVITALize initiative, which was convened by the American College of Obstetricians and Gynecologists and the members of the Women's Health Registry Alliance. Obstetrics & Gynecology has adopted the use of the reVITALize definitions. Please access the obstetric and gynecology data definitions at https://www.acog.org/About-ACOG/ACOG-Departments/Patient-Safety-and-Quality-Improvement/reVITALize. If use of the reVITALize definitions is problematic, please discuss this in your point-by-point response to this letter.

5. Because of space limitations, it is important that your revised manuscript adhere to the following length restrictions by manuscript type: Original Research reports should not exceed 22 typed, double-spaced pages (5,500 words). Stated page limits include all numbered pages in a manuscript (i.e., title page, précis, abstract, text, references, tables, boxes, figure legends, and print appendixes) but exclude references.

6. Specific rules govern the use of acknowledgments in the journal. Please note the following guidelines:

\* All financial support of the study must be acknowledged.

\* Any and all manuscript preparation assistance, including but not limited to topic development, data collection, analysis, writing, or editorial assistance, must be disclosed in the acknowledgments. Such acknowledgments must identify the entities that provided and paid for this assistance, whether directly or indirectly.

\* All persons who contributed to the work reported in the manuscript, but not sufficiently to be authors, must be acknowledged. Written permission must be obtained from all individuals named in the acknowledgments, as readers may infer their endorsement of the data and conclusions. Please note that your response in the journal's electronic author form verifies that permission has been obtained from all named persons.

\* If all or part of the paper was presented at the Annual Clinical and Scientific Meeting of the American College of Obstetricians and Gynecologists or at any other organizational meeting, that presentation should be noted (include the exact dates and location of the meeting).

7. The most common deficiency in revised manuscripts involves the abstract. Be sure there are no inconsistencies between the Abstract and the manuscript, and that the Abstract has a clear conclusion statement based on the results found in the paper. Make sure that the abstract does not contain information that does not appear in the body text. If you submit a revision, please check the abstract carefully.

In addition, the abstract length should follow journal guidelines. The word limits for different article types are as follows: Original Research articles, 300 words. Please provide a word count.

8. 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.

9. 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.

10. In your Abstract, manuscript Results sections, and tables, the preferred citation should be in terms of an effect size, such as odds ratio or relative risk or the mean difference of a variable between two groups, expressed with appropriate confidence intervals. When such syntax is used, the P value has only secondary importance and often can be omitted or noted as footnotes in a Table format. Putting the results in the form of an effect size makes the result of the statistical test more clinically relevant and gives better context than citing P values alone.

If appropriate, please include number needed to treat for benefits (NNTb) or harm (NNTh). When comparing two procedures, please express the outcome of the comparison in U.S. dollar amounts.

Please standardize the presentation of your data throughout the manuscript submission. For P values, do not exceed three decimal places (for example, "P = .001"). For percentages, do not exceed one decimal place (for example, 11.1%").

11. 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.

12. The American College of Obstetricians and Gynecologists' (ACOG) documents are frequently updated. These documents may be withdrawn and replaced with newer, revised versions. If you cite ACOG documents in your manuscript,

be sure the reference you are citing is still current and available. If the reference you are citing has been updated (ie, replaced by a newer version), please ensure that the new version supports whatever statement you are making in your manuscript and then update your reference list accordingly (exceptions could include manuscripts that address items of historical interest). If the reference you are citing has been withdrawn with no clear replacement, please contact the editorial office for assistance (obgyn@greenjournal.org). In most cases, if an ACOG document has been withdrawn, it should not be referenced in your manuscript (exceptions could include manuscripts that address items of historical interest). All ACOG documents (eg, Committee Opinions and Practice Bulletins) may be found via the Clinical Guidance & Publications page at https://www.acog.org/Clinical-Guidance-and-Publications/Search-Clinical-Guidance.

13. The Journal's Production Editor had the following to say about the figures in your manuscript:

"Figure 1: Please confirm the n values for the final boxes (5,994+6,829+1,099 does not equal 16,527).

Figure 2: Is this figure available in color?

Figure 3: Okay.

Figure 4: Is this figure available in color?

Please upload all figures as separate figure files on Editorial Manager."

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

When you submit your revision, art saved in a digital format should accompany it. Please upload each figure as a separate file to Editorial Manager (do not embed the figure in your manuscript file).

If the figures were created using a statistical program (eg, STATA, SPSS, SAS), please submit PDF or EPS files generated directly from the statistical program.

Figures should be saved as high-resolution TIFF files. The minimum requirements for resolution are 300 dpi for color or black and white photographs, and 600 dpi for images containing a photograph with text labeling or thin lines.

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\* \* \*

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

\* A confirmation that you have read the Instructions for Authors (http://edmgr.ovid.com/ong/accounts/authors.pdf),

and

\* A point-by-point response to each of the received comments in this letter.

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

Sincerely,

The Editors of Obstetrics & Gynecology

2018 IMPACT FACTOR: 4.965 2018 IMPACT FACTOR RANKING: 7th out of 83 ob/gyn journals

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





Paris, October 1<sup>st</sup> 2019

Dear Editor,

We submit for your consideration for publication in *Obstetrics & Gynecology* our revised manuscript entitled: "Reduction in oxytocin and artificial rupture of the membranes use and consequences on the cesarean delivery rate at a national level" under the number ONG-19-1470.

The authors are very grateful to the Reviewers for their constructive help. We think the paper has been much improved.

Each point raised by the reviewers and editors has been answered, and the manuscript revised accordingly. Responses of the authors are included below after each comment. The position of all changes made in the manuscript is indicated with "track changes".

The lead author, Aude Girault 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 have been explained. We intend to submit solely to *Obstetrics & Gynecology* and will not submit our manuscript elsewhere until a final decision has been made by the Editors of *Obstetrics & Gynecology*.

The data analyzed in this study are from the French National Perinatal Surveys which are approved by the National Council on Statistical Information (Comité du Label), the French Data Protection Authority (CNIL) and the INSERM (Institut National de la Santé et de la Recherche Médicale) ethics committee. This approval covers use of the data from the surveys by its coordinating team and our research team at the National Institute of Health and Medical Research. The commission did not require written informed consent. All women included in our study consented to the oral interviews. The 2016 approval numbers were 2016X703SA (Comité du Label), 915197 (CNIL) and IRB00003888 no.14-191 (INSERM ethics committee).

All the authors have read and approved the revised version of the paper.

We hope our manuscript now meets the standards of Obstetrics & Gynecology.

Yours sincerely,

Aude Girault

## **REVIEWER COMMENTS:**

Reviewer #1: The authors aim to evaluate if guidelines limiting the use of oxytocin and AROM to women with labor arrest are associated with an increase in intrapartum cesarean rates. I have the following comments regarding the manuscript:

## Title

1. Rather than reporting the findings, the title should indicate what was being investigated.

The authors thank the reviewer for this suggestion. The title has been changed to (line 1 to 2 of the revised manuscript): "Reduction in oxytocin and artificial rupture of the membranes use and consequences on the cesarean delivery rate at a national level". The authors have hesitated with the following title: "Relation between reduction in oxytocin and artificial rupture of the membranes use and cesarean delivery rate at a national level", and are willing to modify the title should the editor request it.

Precis

1. Needs to be reworked to clarify that the decrease in oxytocin and AROM was a result of changes in national guidelines. Otherwise the context for the reported finding is unclear.

The authors understand the reviewer's comment but are limited by the word count of the Precis (25 words) and the fact that the Precis "should be similar to the abstract's conclusion" <u>https://edmgr.ovid.com/ong/accounts/authors.pdf</u>). The authors have modified both the Precis and the manuscript's conclusion to match the abstract's conclusion. The modified manuscript now shows line 39 of the Precis: "The decrease in oxytocin and artificial rupture of the membranes was not accompanied by an increase in the intrapartum cesarean rate in France."; and line 350 to 363 of the conclusion: "In France, the significant reduction in the use of oxytocin and AROM which took place from 2010 to 2016 was not accompanied by an increase in the rate of intrapartum cesareans."

Intro

1. At the end of the Intro, the stated objective is to evaluate if there is a difference in indication for cesarean delivery. This is not included as part of the objectives in the abstract.

# The authors thank the reviewer for this comment and have added a sentence in the abstract, in the revised version of the manuscript line 48-49 "or a change in cesarean's indications."

### Methods

1. Line 130. How were pregnancies with fetal anomalies handled? Were they retained in the low risk group?

The rate of fetal anomalies in the low obstetric risk group (minor and major) was 1.6% in 2010 and 1.8% in 2016. The pregnancies with fetal anomalies were not excluded in the low obstetric risk group as the authors do not feel that labor management is different among women with fetal anomalies; that is if the anomaly does not require a planned cesarean delivery.

2. Line 147. Why did the authors choose to use a surrogate for oxytocin administration (year of delivery) when they have chart abstracted information about oxytocin use? Why not just look directly at the proportion of women who received oxytocin or AROM and cesarean delivery rates?

The authors thank the reviewer for this question. The year of delivery reflects the medical practices at the time of the survey as already stated in the manuscript (line 156-159 of the revised manuscript). The authors' aim was to explore whether the reduction in oxytocin administration and artificial rupture of the membranes between the two delivery years was associated with an increase or a decrease of cesarean delivery at a national level. The authors feel that if looking directly at the proportion of women who received oxytocin or AROM and cesarean delivery rates there would be an indication bias not allowing interpretation. Indeed, even if this bias is not measurable in our study, women having labor augmentation with oxytocin and/or AROM are probably those for whom the obstetrical teams could indicate a cesarean delivery for labor arrest. A paragraph has been added in the discussion section of the revised manuscript, lines 259 to 264: "Our analysis was performed at a national level to evaluate the

consequences of the changes in oxytocin administration and AROM use on cesarean delivery rates. We did not assess directly the cesarean delivery rates in women receiving oxytocin or AROM because of the potential indication bias. Indeed, even if this bias is not measurable in our study, women having labor augmentation with oxytocin and AROM are probably those for whom the obstetrical teams could indicate cesarean delivery for labor arrest." Also, the proportion of women receiving oxytocin, AROM and cesarean delivery rates has now been added as Appendix 1 as requested by the statistical reviewer.

3. Why just compare 2010 and 2016? One would assume that changes in practice occurred over time, and it sounds like the authors have very granular individual patient level data available. Why not evaluate effect over time (eg all years)?

These national surveys are not performed every year and data from the national medico-administrative databases do not include information on the administration of oxytocin and AROM. The two last perinatal surveys were conducted in 2010 and 2016, this is why those two years were compared. Moreover, the information on oxytocin, AROM and indication of cesareans was not available for the previous surveys. The authors nevertheless thank the reviewer for this question and hope that lines 104-109 of the revised manuscript will address this comment: "The French national perinatal surveys are population-based studies conducted routinely every six or seven years to monitor the main indicators of perinatal health, medical practices, and risk factors. Every survey follows the same protocol, which has been described elsewhere [20]. Briefly, the sample includes all live births and still-births at a gestational age of at least 22 weeks or a birth weight of at least 500 g during a full week in March in all French maternity units."

#### Results

1. What else was occurring over this time period? Did guidelines change for when to augment?

Thank you for this interesting comment. Except for the 2012 guidelines on "Delivery in women with previous cesarean section or other uterine surgery", which stated that the use of oxytocin was possible for induction and during labor of women with a scared uterus, there were no other French national guidelines regarding labor augmentation or other clinical practices during labor between 2010 and 2016. There are no previous guidelines on augmentation of labor in France. This point was partly discussed in the initial manuscript and to clarify this point the authors have modified their paragraph. Lines 243 to 257 of the revised manuscript now state: "One could argue that the reduction of augmentation of labor could be due to other changes in medical practices, like the mode of onset of labor or the rate of assisted delivery. But, the rate of cesareans before labor and of induction of labor slightly but significantly declined and the rate of assisted delivery was stable between 2010 to 2016 in France [14]. Moreover, except for the 2012 guidelines on "Delivery in women with previous cesarean section or other uterine surgery", which stated that the use of oxytocin was possible for induction and during labor of women with a scared uterus, there were no other French national guidelines regarding labor augmentation or other clinical practices during labor between 2010 and 2016.

2. The cesarean rate is already so low (6.6%) that it would be hard to drive it even lower with active management of labor. Thus, it is not really surprising that the cesarean rate remained the same.

The authors thank the reviewer for his comment. The rate of cesarean delivery in their selected population seems low but is comparable to other countries such as the US. Indeed, data from an American population-based study show a 12.3% cesarean rate in 2014 for Robson group 1 versus 10.5% in our population and a 4.4% rate for Robson group 3 versus 1.8% in our population. The authors have added a paragraph in their discussion section part to highlight this point, lines 282 to 287: "In the present study, the 10.5% and 1.8% cesarean rates, respectively for nulliparous and multiparous women in spontaneous labor at term with fetuses in vertex presentation (Appendix 1), are comparable to those reported in a retrospective population-based study in 2009-2011 in Nordic countries [25], and slightly lower than the 12.3% and 4.4% rate for nulliparous and multiparous women reported in an American population-based study in 2014 [24]."

Moreover, even though the rate is low our study has enough power to detect small changes in the rate of cesarean delivery. For example, 92% power to detect an increase in the cesarean rate from 6.9% to 7.9%.

3. Figure 1. Would separate out fetal death from minor malformations in terms of the count of exclusion criteria.

The authors are sorry for this misunderstanding the word "minor" meant "under-aged" in Figure 1. The minors and the women with intra-uterine fetal death were not interviewed due to the psychological context and were therefore excluded from the analysis. A precision has been made to Figure 1: "Minor (<18 years)"

4. Figure 1. Consider breaking down the exclusion criteria by year. For example, would be nice to know how many were excluded for induction in 2016 compared to 2010.

The authors thank the reviewer for this comment. The authors feel that Figure 1 is already complex and that adding information would make the figure too crowded. Moreover, information on the rates of induction in 2010 and 2016 already exists in the manuscript lines 251-253: "But, the rate of cesareans before labor and of induction of labor slightly but significantly declined and the rate of assisted delivery was stable between 2010 to 2016 in France [14]." The authors are nevertheless willing to add this information should the editor request it.

5. Figure 4. There was no change in the distribution of indications for cesarean delivery and no change in the overall cesarean rate, so why does it matter how many women received oxytocin of AROM? Was the length of time in labor different? Or time from final cervical dilation to c/s?

The authors thank the reviewer for this comment. There is a debate whether the reduction of augmentation of labor would increase the cesarean delivery rate. It is true that oxytocin administration and AROM are usually used to treat labor arrest, and the authors feel that the fact that the reduction in these interventions is not accompanied by an augmentation of the cesareans and moreover the cesareans for labor arrest is an important information. The comparison of the length of labor between 2010 and 2016 is impossible as duration of labor was not reported in the 2010 survey. As stated in the discussion part of the manuscript lines 331-332 : "The data from the French national perinatal surveys do not allow us to study this question further."

Reviewer #2: Girault and colleagues report results of a retrospective study derived from the 2010 and 2016 French population-based surveys of women giving birth in French maternity units during March of the respective years, regarding the relationship between active management of labor practices (i.e. oxytocin augmentation and artificial rupture of membranes) and cesarean rates. This reviewer would request the authors address the following questions and comments:

1. Line 41...Is it accurate to state active management of labor was adopted in "most countries", for I do not know if published data are available from the 200+ sovereign states worldwide.

The authors thank the reviewer for this comment and have modified their manuscript accordingly. In the revised version of the manuscript line 45 has been changed to "many countries"

2. Line 163...The software manufacturer and location should probably be mentioned.

The authors agree with the reviewer and have added the following sentence line 178-179 of the revised version of the manuscript: "StataCorp. 2017. *Stata Statistical Software: Release 15.* College Station, TX: StataCorp LLC."

3. Line 173...While there was a statistically significant increased incidence of older women, higher BMI, and increased epidural use from the first to the second period, the absolute differences seem negligible, and in any case would be expected to be associated with a higher need for active management and a higher cesarean rate in the second period. This may merit comment.

The authors agree with the reviewer that the absolute differences seem negligible but they are significant and were therefore considered as confounding factors. The multivariable analysis accounted for these factors. The authors are nevertheless willing to add a comment should the editor request it. 4. Line 196...In assessing the associations between active management of labor and cesarean rates, a striking void relates to the absence of neonatal outcome parameters (e.g. Apgar scores, umbilical cord gas analysis, NICU admission). From review of reference #20, it appears that Apgar scores and "neonatal transfer" were available in the dataset in the 2010 survey. It would seem appropriate to report available relevant neonatal outcome characteristics, which are essentially the other half of the equation as it relates to the clinical practice.

The authors thank the reviewer for this comment. The association with neonatal outcomes seems to the authors to be a separate subject with other confounding factors and could be the purpose of another article. For the reviewer's interest the rate of Apgar score <7 after 5 minutes in 2010 and 2016 were respectively 1.13% and 1.09%, p=0.82 and the NICU admission rate was 2.4% and 2.1%, p=0.23.

5. Line 192...Was there a change in operative vaginal delivery (i.e. forceps and vacuum) rates between the two epochs?

The rate of operative vaginal delivery was stable (14%) between 2010, and 2016. A sentence has been added in the modified version of the manuscript line 250-251:" and the rate of assisted delivery was stable between 2010 to 2016 in France".

6. Line 207...Did any of these reported outcome data come from patient interviews, or just from chart review? If this paper does not contain data from interviews, did 6% of the women need to be excluded?

The authors thank the reviewer for this comment. The interviews allow to check the socio-demographic information recorded in the medical files. As this information is used as confounding variables in the analysis the authors feel that it is legitimate to exclude the women for whom it has not been verified. The manuscript has been modified and now states line 131-133 of the revised manuscript: "Because the oral interviews allow to check the socio-demographic information recorded in the medical files, only women who consented to these oral interviews were included in this analysis."

7. Line 216...Between 2010 and 2016, were there any other French national guidelines published and implemented that could have impacted intrapartum clinical practices and affected oxytocin, AROM and cesarean incidences?

Thank you for this comment. Except for the 2012 guidelines on "Delivery in women with previous cesarean section or other uterine surgery, which stated that the use of oxytocin was possible for induction and during labor of women with a scared uterus, there were no other French national guidelines regarding labor augmentation or other clinical practices during labor between 2010 and 2016. This point has now been clarified in the revised version of the manuscript lines 253 to 257: "Moreover, except for the 2012 guidelines on "Delivery in women with previous cesarean section or other uterine surgery", which stated that the use of oxytocin was possible for induction and during labor of women with a scared uterus, there were no other French national guidelines regarding labor augmentation or other clinical practices during labor between 2010 and 2016.

8. Table 1...It appears that there was a significant increase in French women delivering in high-volume (>3,000 deliveries per year) facilities. Do the authors have any insight into factors (e.g. 24-hour in-house physicians & midwives, quality and safety infrastructure, etc.) that could have affected their results?

In France, the regulations concerning the premises and staff needed for the organization of the maternity wards are backed by their volume of activity. For example, it is mandatory that a maternity unit delivering more than 1500 women per year to have an on-site anesthesiologist and an obstetrician. The volume of delivery is therefore a proxy for the number of staff. In the perinatal surveys we do not have any other qualitative factors. To clarify this point, the authors have added a line to explain the "volume" variable lines 154-156: "The maternity unit's volume reflects the number of in-house staff as the regulation concerning the type and number of in-house staff depends on the latter."

Reviewer #3: The Authors did a cross-sectional population study based on data from the French national perinatal surveys. The French national perinatal surveys are population-based studies conducted routinely every six or seven years to monitor the main indicators of perinatal health, medical practices, and risk factors. The sample includes all live births and still-births at a gestational age of at least 22 weeks or a birth weight of at least 500 g

during a full week in March in all French maternity units. Data are collected from the medical records and mother's interviews; each maternity unit completes a questionnaire to provide information about its characteristics and organization. The Authors included retrospectively 16 527 women who gave birth to a live- born fetus at term after spontaneous labor; they compared the trends of labor indicators and Cesarean section from 2010 with 2016 of three augmentation of labor indicators: the use of oxytocin infusion before the

third stage of labor , the use of artificial rupture of the membranes and the combination of both during labor. They created three subgroups of population:

1-the group of nulliparous low obstetric risk women2-the group of multiparous low obstetric risk women3-the group of women with a previous cesarean section in trial of spontaneous labor after cesarean section;

The Authors performed a multivariable analyses for labor indicators and intrapartum Caesarean rates in order to compare the trends in 2010 with 2016. The inclusion and exclusion criteria are justified and allow for the study question to be evaluated.

The objective of the study was to confirm that the reduction in the use of oxytocin administration and artificial rupture of the membranes was influenced the intrapartum caesarean rate in low risk pregnancies.

The manuscript is well written but the following aspects should be clarified:

1- Line 1-2 : The title: in a study population with a Caesarean rate of 6.9 % in 2010 and 6.6 % in 2016 why is a goal to analyse this "traditional "active management of labor to decrease/increase caesarean rates? I suggest the Authors to revise the title ;

The authors thank the reviewer for his comment with which they agree. The title has been changed to: "Reduction in oxytocin and artificial rupture of the membranes use and consequences on the cesarean delivery rate at a national level", and a paragraph on the rate of cesarean delivery has been added in the discussion section of the revised manuscript, line 282 to 287 : "In the present study, the 10.5% and 1.8% cesarean rates, respectively for nulliparous and multiparous women in spontaneous labor at term with fetuses in vertex presentation (Appendix 1), are comparable to those reported in a retrospective population-based study in 2009-2011 in Nordic countries [24], and slightly lower than the 12.3% and 4.4% rate for nulliparous and multiparous women reported in an American population-based study in 2014".

2- Line 69-71 : "active management of labor was proposed in the 1980's.....resulting in a wide use of oxytocin administration and artificial rupture of the membranes " - it was introduced in the late 1960 and it was an early use of artificial rupture of the membranes and oxytocin administration (Thornton JG, Lilford RJ. Active management of labour: current knowledge and research issues. BMJ. 1994 )

The authors agree with the reviewer, even though the widespread use of oxytocin and AROM came after the publication of O'Driscoll in 1980 (O'Driscoll K, Meagher D.*Active management of labour. London: Saunders, 1980),* it is true that is was proposed in the 60's. The authors have modified their manuscript accordingly, line 43: "Active management of labor was proposed in the 1960's".

3- Line 81-82 : " Recently , ....." the reference 18 was published in 2003 ?

The authors agree with the reviewer and have changed the word "Recently" by "Since 2003," line 88 of the revised manuscript.

4- Line 117-121: I suggest the Authors to clarify if the active management of labour was an augmentation of labour because failure of labour to progress, systematically, in the active phase of labour, or an induction of labour because spontaneous labour's definition was not appropriate use;

The authors thank the reviewer for his comment. Women with induction of labor were excluded from the analyses, but it is impossible for the authors to determine whether augmentation of labor was performed in the passive phase of the first stage or in the active phase. The available data from the survey does not allow determining whether augmentation of labor was initiated after a misdiagnosis of spontaneous onset of labor. Two sentences have been added in the discussion part of the revised manuscript to highlight this point, lines 274-280: "Moreover, data from the survey does not allow determining whether

augmentation of labor was initiated because of a misdiagnosis of spontaneous onset of labor. Nevertheless, there is no reason to believe that the number of such misdiagnoses would differ between the two studied surveys"

5- Line 154-158 : about " indications of cesarean section : cord prolapse, abnormal presentation etc" during labour - it can be diagnosed before an active management of labor, ! could the Authors explain the use of this indications ?

The authors feel that the comparison of the indications of cesareans between the two periods is important to ensure that the significant reduction of augmentation of labor did not result in an increase of one specific cause of cesarean. The "other indications" is an heterogenous category with some indications potentially before or during the active phase of labor.

6- Line 225-226: Limitation of the study: the absence of detailed information on oxytocin administration - Could

the Authors demonstrate (and also comment) appropriate use of oxytocin in order to show the influencing (increasing?) of the caesarean rate? The authors should indicate if, and how, they were able to overcome the limitations and whether or not the study is generalizable.

The French National Perinatal Surveys are national surveys which aim at following key perinatal health indicators and French medical practices like the use of oxytocin and AROM. Unfortunately, the data is not detailed enough to determine whether the indications of oxytocin administration or AROM are appropriate.

7- Line 386 : Table 1 : maternity unit volume deliveries by year - Was the French Perinatal Surveys a sample representative from the French population regarding the volume of deliveries from this analysed population ?

The authors thank the reviewer for this comment. The volume of deliveries from this population was compared to the indicators obtained through the "program for medicalization of information systems" which collects the medico-economic data. The socio-demographic characteristics are compared to the annual national statistics. The French national perinatal surveys are representative from the French population especially since all maternity units participate in the surveys.

# STATISTICAL EDITOR'S COMMENTS:

1. Table 2: Should provide (could be supplemental material) the actual counts for oxytocin administration, AROM, both AROM and oxytocin administration and cesarean rates both overall and by the strata outlined by the characteristics.

# The authors thank the statistical editor for this comment and have added the requested information as supplemental information "Appendix 1.".

2. Should also provide the crude ORs to contrast with the aORs. Should also state the counts and % change in AROM, oxytocin administration and use of both for 2010 vs 2016.

# The authors agree with the statistical editor's comment. The information on crude OR has been added as supplemental information which now contains a table with the counts for oxytocin administration, AROM, both AROM and oxytocin administration and cesarean rates; and the crude ORs (Appendix 1).

3. Figs 1, 3: For the subsets (nulliparous, multiparous and women with a previous c-section), there appears to be a more than adequate sample size for nulliparous and multiparous to perform multivariable adjustment. However, that was not clear re: the cohort with prior c-sections. Need to state the number of repeat c-sections in those women in 2010 and 2016. If the counts for repeat c-sections were < 70 for any year group, then the model may be over fitted and adjustment for 7 variables not possible. That would correspond to repeat c-section rates of ~ 14%. If rates were lower, then the model may be over fitted for analysis of that subset.

The authors agree with the statistical editors' comment. In the cohort with prior c-section, the rate of repeat cesarean delivery was 22.0% (n=124) in 2010 and 20.6% (n=112) in 2016 therefore the model is not over-fitted for this subset. As requested in comment 1, the rates are now available in Appendix 1.

## Associate Editor's Comments:

If you have not already done so, please in your Discussion make reference to the cesarean delivery rate in the United States for women comparable in risk status to those in your cohort, and discuss the potential implications of our findings in higher cesarean delivery rate settings.

The authors thank the associate editor for his comment and have modified their manuscript accordingly in lines 282 to 287 of the revised version of the manuscript in the Discussion section: "In the present study, the 10.5% and 1.8% cesarean rates, respectively for nulliparous and multiparous women in spontaneous labor at term with fetuses in vertex presentation (Appendix 1), are comparable to those reported in a retrospective population-based study in 2009-2011 in Nordic countries [24], and slightly lower than the 12.3% and 4.4% rate for nulliparous and multiparous women reported in an American population-based study in 2014 [25]."

# The authors feel that the potential implications of their findings can be extrapolated to different international countries.

# EDITORIAL OFFICE COMMENTS:

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

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

2. As of December 17, 2018, Obstetrics & Gynecology has implemented an "electronic Copyright Transfer Agreement" (eCTA) and will no longer be collecting author agreement forms. When you are ready to revise your manuscript, you will be prompted in Editorial Manager (EM) to click on "Revise Submission." Doing so will launch the resubmission process, and you will be walked through the various questions that comprise the eCTA. Each of your coauthors will receive an email from the system requesting that they review and electronically sign the eCTA.

Please check with your coauthors to confirm that the disclosures listed in their eCTA forms are correctly disclosed on the manuscript's title page.

# I have checked with my co-authors, and confirm that the disclosures are correctly disclosed on the manuscript's title page.

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

at <u>http://ong.editorialmanager.com</u>. In your cover letter, be sure to indicate that you have followed the CONSORT, MOOSE, PRISMA, PRISMA for harms, STARD, <u>STROBE</u>, CHEERS, SQUIRE 2.0, or CHERRIES guidelines, as appropriate.

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	Page No
Title and abstract	1	( <i>a</i> ) Indicate the study's design with a commonly used term in the title or the abstract	3
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	5
Objectives	3	State specific objectives, including any prespecified hypotheses	5-6
Methods			
Study design	4	Present key elements of study design early in the paper	7
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	7
Participants	6	(a) Cohort study—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	7-8
		<i>Case-control study</i> —Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls	
		<i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and methods of selection of participants	
		(b) Cohort study—For matched studies, give matching criteria and number of exposed and unexposed	Not applicable
		<i>Case-control study</i> —For matched studies, give matching criteria and the number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	8-9
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	7-9
Bias	9	Describe any efforts to address potential sources of bias	8
Study size	10	Explain how the study size was arrived at	Not applicable

Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	9
Statistical methods	12	( <i>a</i> ) Describe all statistical methods, including those used to control for confounding	9
		(b) Describe any methods used to examine subgroups and interactions	8-9
		(c) Explain how missing data were addressed	9
		(d) Cohort study—If applicable, explain how loss to follow- up was addressed	Not applicable
		<i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed	
		<i>Cross-sectional study</i> —If applicable, describe analytical methods taking account of sampling strategy	
		( <u>e</u> ) Describe any sensitivity analyses	Not applicable

Continued on next page

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers	Figure1
i di ticipanto	15	potentially eligible, examined for eligibility, confirmed eligible, included	inguici
		in the study, completing follow-up, and analysed	
		(b) Give reasons for non-participation at each stage	Figure1
		(c) Consider use of a flow diagram	Figure1
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Table 1
		(b) Indicate number of participants with missing data for each variable of interest	Not applicabl
		(c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)	Not applicabl
Outcome data	15*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time	Not applicabl
		<i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure	Not applicabl
		<i>Cross-sectional study</i> —Report numbers of outcome events or summary measures	Appendix 1
Main results	16	( <i>a</i> ) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	Appendix 1
		(b) Report category boundaries when continuous variables were categorized	Tables
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	Not applicabl
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Figure 3 and 4
Discussion			
Key results	18	Summarise key results with reference to study objectives	12
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	12-13
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	13-14
Generalisability	21	Discuss the generalisability (external validity) of the study results	14
Other informati	on		•
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	1

\*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

**Note:** An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

4. Standard obstetric and gynecology data definitions have been developed through the reVITALize initiative, which was convened by the American College of Obstetricians and Gynecologists and the members of the Women's Health Registry Alliance. Obstetrics & Gynecology has adopted the use of the reVITALize definitions. Please access the obstetric and gynecology data definitions at <a href="https://www.acog.org/About-ACOG/ACOG-Departments/Patient-Safety-and-Quality-Improvement/reVITALize">https://www.acog.org/About-ACOG/ACOG-Departments/Patient-Safety-and-Quality-Improvement/reVITALize</a>. If use of the reVITALize definitions is problematic, please discuss this in your point-by-point response to this letter.

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6. Specific rules govern the use of acknowledgments in the journal. Please note the following guidelines:

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\* 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).

7. The most common deficiency in revised manuscripts involves the abstract. Be sure there are no inconsistencies between the Abstract and the manuscript, and that the Abstract has a clear conclusion statement based on the results found in the paper. Make sure that the abstract does not contain information that does not appear in the body text. If you submit a revision, please check the abstract carefully.

In addition, the abstract length should follow journal guidelines. The word limits for different article types are as follows: Original Research articles, 300 words. Please provide a word count.

8. Only standard abbreviations and acronyms are allowed. A selected list is available online at <a href="http://edmgr.ovid.com/ong/accounts/abbreviations.pdf">http://edmgr.ovid.com/ong/accounts/abbreviations.pdf</a>. 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.

9. 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.

10. In your Abstract, manuscript Results sections, and tables, the preferred citation should be in terms of an effect size, such as odds ratio or relative risk or the mean difference of a variable between two groups, expressed with appropriate confidence intervals. When such syntax is used, the P value has only secondary importance and often can be omitted or noted as footnotes in a Table format. Putting the results in the form of an effect size makes the result of the statistical test more clinically relevant and gives better context than citing P values alone.

If appropriate, please include number needed to treat for benefits (NNTb) or harm (NNTh). When comparing two procedures, please express the outcome of the comparison in U.S. dollar amounts.

Please standardize the presentation of your data throughout the manuscript submission. For P values, do not exceed three decimal places (for example, "P = .001"). For percentages, do not exceed one decimal place (for example, 11.1%").

11. Please review the journal's Table Checklist to make sure that your tables conform to journal style. The Table Checklist is available online here: <u>http://edmgr.ovid.com/ong/accounts/table\_checklist.pdf</u>.

12. The American College of Obstetricians and Gynecologists' (ACOG) documents are frequently updated. These documents may be withdrawn and replaced with newer, revised versions. If you cite ACOG documents in your manuscript, be sure the reference you are citing is still current and available. If the reference you are citing has been updated (ie, replaced by a newer version), please ensure that the new version supports whatever statement you are making in your manuscript and then update your reference list accordingly (exceptions could include manuscripts that address items of historical interest). If the reference you are citing has been withdrawn with no clear replacement, please contact the editorial office for assistance (<u>obgyn@greenjournal.org</u>). In most cases, if an ACOG document has been withdrawn, it should not be referenced in your manuscript (exceptions could include manuscripts that address items of historical interest). All ACOG documents (eg, Committee Opinions and Practice Bulletins) may be found via the Clinical Guidance & Publications page at https://www.acog.org/Clinical-Guidance-and-Publications/Search-Clinical-Guidance.

13. The Journal's Production Editor had the following to say about the figures in your manuscript:

"Figure 1: Please confirm the n values for the final boxes (5,994+6,829+1,099 does not equal 16,527).

The authors confirm the "n" values for the final boxes. The overall study population included 16,527 women but not all of the women of the overall population were included in a subgroup. For example, a multiparous woman with no previous cesarean delivery and chronic hypertension was included in the overall population but not in any subgroup. To clarify this point two sentences have been added in the result part, lines 186-190 of the revised manuscript: "The nulliparous low obstetric risk group included 5,994 women, the multiparous low obstetric risk group 6,829 women and the previous cesarean group 1,099 women. Twothousand six hundred and five women did not meet the criteria of any subgroups and were only analyzed in the overall population."

Figure 2: Is this figure available in color?

The authors feel that the contrast between the only two colors (grey and black) is clearly visible. Nevertheless, this figure can be available in color should the editor request it.

Figure 3: Okay.

Figure 4: Is this figure available in color?

The authors feel that the contrast between the only two colors (grey and black) is clearly visible. Nevertheless, this figure can be available in color should the editor request it.

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\* A point-by-point response to each of the received comments in this letter.

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