

OBSTETRICS & GYNECOLOGY



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

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obgyn@greenjournal.org.

Date: Jul 18, 2019
To: "Pierre Barker" [REDACTED]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-19-1072

RE: Manuscript Number ONG-19-1072

A Quality Improvement (QI) Initiative in Brazilian Hospitals to Increase Vaginal Delivery

Dear Dr. Barker:

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

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

Your paper will be maintained in active status for 21 days from the date of this letter. If we have not heard from you by Aug 08, 2019, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1: Precis - quality improvement initiative for low risk women resulted in a 62% increase in vaginal delivery

Abstract - objective - assess improvement of QI initiative to increase vaginal deliveries

Design - 28 hospitals were followed over 20 months - 13 hospital had complete data; hospitals from Sao Paulo were identified: 5 intervention and 8 nonintervention

Results - 119,378 targeted deliveries in 13 hospitals - vaginal delivery increased from 21.5% in 2014 to 34.8% in 2016; it increased from 16 to 23% in 5 intervention hospitals and from 11 to 13% in nonintervention ones
 Conclusion - the QI initiative increased vaginal deliveries

Introduction - Problem with overuse of cesarean delivery (CD), Brazil has the highest CD rate - 30-40% in the public sector and 80-90% in the private sector
 available knowledge indicates that most Brazilian women prefer vaginal deliveries but get a c-section
 intervention - QI collaborative model

Methods - Context - QI approach

Intervention - hospitals were identified from all 5 regions in Brazil - 28 hospitals (24 private and 4 public), comparison group was 8 nonintervention hospitals

Drivers of change - 4 drivers of vaginal delivery: 1) coalition of stakeholders; 2) empowerment of pregnant women; 3) new care models; 4) information system for continuous learning, ideas for improvement were gathered
 teams met to review plans and simulation of vaginal delivery was performed

Study of Intervention - changes in patient outcomes

Measures - primary outcome - percentage of vaginal deliveries and net promoter score - indication of likelihood to recommend and complications

Analysis - monthly data reports - what changes and the strength of those changes

Ethical considerations - no IRB consent as QI project

Results - hospital and female population characteristics of the 28 hospitals - 2 withdrew - 84, 151 women were targeted
 changes in clinical care practices, changes made that were more in favor of vaginal deliveries

vaginal delivery - increase from 21.5% to 34.8% - a 62% increase

Comparative analysis - intervention hospitals - increase from 15.6% to 23%, nonintervention hospitals increase from 11-13%

Secondary outcomes - NICU admission, adverse events, likelihood to recommend didn't change

Theory of change - responses/feedback, drivers of change/ideas modified and condensed

Discussion - Summary - hospital participation led to an increase in vaginal delivery rate by 62% without a change in rate of harm

drivers for change included engaging women in decision making

Interpretation - evidence based changes are known to decrease CD

Limitations - prenatal care was not a part of the intervention - clinical training and feedback, learning system that assessed progress and political and social factors to change and increase vaginal delivery

Conclusions - there are lessons to reverse rise in CD - evidence based interventions allow change

Comments - The cesarean delivery rate is so exorbitantly high, it does need to change. Even after these interventions it is still too high, but at least shows progress in the right direction. It is just not clear to me what changes were made. The context of the manuscript is very vague and abstract. I think the whole think needs to be considerably condensed to summarize the issue.

The cesarean delivery rate was too high because of these issues: what are the issues - is it financial, social, etc, address the details of the problem.

We made these educational changes: whatever they are - it is so vague that I don't really understand what was done. It seems that prenatal intervention would be important yet it was not a part of this. Was it primarily reminding physicians of how to practice evidence based medicine? I don't understand the interventions.

Then, state the noted change - there is still a long way to go, but there is some documented improvement.

The manuscript needs to be condensed and include more specific detail to better understand the interventions. The CD rate is still unreasonably high, but at least this shows some improvement.

Reviewer #2: Introduction:

Excellent description of the problem. However, "lack of evidence for population-level benefit for CD rates above 10%" should be qualified with the statement that the optimal population-level CD rate is unknown.

Available knowledge - some percentages of women who want VD and of those, who receive CD would improve this section.

Methods:

This is a good description of a complicated intervention. A bit more description about why the 28 hospitals were chosen and the other 12 not may be helpful.

Can you include the percent vaginal births in the study periods in the entire country and Sao Paulo for comparison?

Results:

Please include which subpopulations were studied in each hospital in a table

Discussion:

Page line 306-307 - the statement about low risk women in California is incomplete

Discussion of operative vaginal delivery and how this was incorporated (or not) into the intervention would be interesting

Figure 2 is the same as figure 3?

Tables - total number of births in each category should be added

Reviewer #3:

General Comments:

Increasing the proportion of vaginal deliveries in the general population and in particular for low risk women is an important issue globally. I appreciate that the authors sought to share their nationwide quality improvement approach with the international community as all can benefit from targeted quality initiatives.

In general I found the paper lacked an important distinction- was this a study of the quality improvement initiative, the implementation or both? This is a theme for clarification that is common throughout the numbered suggestions below.

Abstract

1- Line 47: The objective states to assess the impact of a quality improvement initiative to increase vaginal delivery.

Nowhere in the abstract do the authors state what the intervention was. This is not stated until the results section and Table 2. What was the initiative?

2- The SQUIRE outline <http://www.equator-network.org/reporting-guidelines/squire/> is a good model for formatting a quality improvement study. For the abstract, it includes: Background, methods, intervention, results and consultation. The lack of intervention discussed throughout the paper should be addressed.

3- This is an example of an article that while it does not follow the SQUIRE model exactly, it is clear what the intervention and study outcome is: Lannon C, Kaplan HC, Friar K, et al. Using a State Birth Registry as a Quality Improvement Tool. *Am J Perinatol* (United States), 08 2017, 34(10) p958-965

Introduction

4- Line 81-82: Previous interventions have shown to have "limited impact in reducing CD". What makes this study different? Please address.

5- Line 85: What are the theoretical drivers?

6- In addition to problem description, and available knowledge, the SQUIRE outline for introduction includes Rationale and Specific aim. The rationale to decrease CD in favor of increasing VD is obvious to our reader base. The specific aim of your study was not. This come back to the original question- is the aim to study which implementation approach is best or which interventions are best?

Methods

7- Line 95: "Pilot QI intervention" this should be explicitly stated.

8- Line 103: This is the first use of PPA, I do not see this acronym stated before. It is used several times and I do not know what it stands for.

9- Line 114: You mention eligibility criteria. This is not explicitly stated. The flow and read can be made easier by clearly stating inclusion and exclusion criteria.

10- Lines 126-127: This is an important point, I'm not sure it belongs here as much as it does in the discussion of limitations.

11- Line 154- Missing reference.

12- Throughout "Intervention and implementation design" There is no mention of the intervention.

13- Lines 229-232- In tying this analysis to your results I do not see an analysis of the theory of change mentioned in the results Lines 278-283. Why were these chosen, why were they implemented, what data did the authors use?

Results

14- 252-253- This should be discussed.

STATISTICAL EDITOR'S COMMENTS:

1. lines 256-258: It appears that the only adjustment was for clustering at the hospital level. What data were obtained to verify that the clinical/demographic risk profiles for the various cohorts were comparable for the group wise and temporal comparisons? It seems from the analysis that it was assumed that the risk profiles were static and interchangeable.

2. Tables 3, 4: Need to include, either in these tables or in supplemental, the "N" associated with each % estimate. Need to clearly state the primary outcome of interest. Was it the IRR for the various populations in Table 3 or was it the IRR for comparison of intensive vs comparison group?

3. Table 5: Need to include the counts for the number of adverse events and the number of NICU admits. The differences were NS, but was there adequate power to discern differences?

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.

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

*The manuscript's guarantor.

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

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: Clinical Practice and Quality articles 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 (NNT_h). 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 Journal's Production Editor had the following to say about the figures in your manuscript:

"Figure 3: This is identical to Figure 3. Please update or explain."

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.

Art that is low resolution, digitized, adapted from slides, or downloaded from the Internet may not reproduce.

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Please note that if your article is accepted, you will receive an email from the editorial office asking you to choose a publication route (traditional or open access). Please keep an eye out for that future email and be sure to respond to it promptly.

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 Aug 08, 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.

Point -by-Point Response to Reviewers

Reviewer 1

<p>Comments - The cesarean delivery rate is so exorbitantly high, it does need to change. Even after these interventions it is still too high, but at least shows progress in the right direction. It is just not clear to me what changes were made. The context of the manuscript is very vague and abstract. I think the whole think needs to be considerably condensed to summarize the issue.</p>	<p><i>We agree that our use of language was confusing and that the actual changes that were tested to increase VD were buried in a section titled “ Drivers of change”. This section has now been labelled “Interventions”. In this section we describe the 4 specific changes that were introduced to drive up VD rates</i></p>
<p>The cesarean delivery rate was too high because of these issues: what are the issues - is it financial, social, etc, address the details of the problem.</p>	<p><i>The causes of very high CS rates in middle income countries are not known. In the “Available Knowledge” section, we describe reported Brazilian women’s preferences and in the “context” section, we describe failed financial incentives. We have also added a new paragraph describing a published framework of causes of excess CS in Brazil.</i></p>
<p>We made these educational changes: whatever they are - it is so vague that I don't really understand what was done. It seems that prenatal intervention would be important yet it was not a part of this. Was it primarily reminding physicians of how to practice evidence based medicine? I don't understand the interventions.</p>	<p><i>We agree that the specific changes that were tested are not clear. We have now clearly differentiated between the intervention (changes) and the methods (QI). We have summarized the main initial changes in the text (as described above) and provided further details of the final set of changes that were adopted after testing in figure 5.</i></p>
<p>Then, state the noted change - there is still a long way to go, but there is some documented improvement.</p>	<p><i>We acknowledge in the final conclusion that “despite rapid progress, the CD rate at the end of PPA remained more than double the average in high income nations” and we discuss the additional ideas being tested to drive the CD rate down further</i></p>
<p>The manuscript needs to be condensed and include more specific detail to better understand the interventions.</p>	<p><i>More details are now given about the changes that were tested.</i></p>
<p>The CD rate is still unreasonably high, but at least this shows some improvement.</p>	<p><i>Agree. The proposed next steps for further reduction are given in the conclusion section.</i></p>

Reviewer #2:

<p>Introduction: Excellent description of the problem. However, "lack of evidence for population-level benefit for CD rates above 10%" should be qualified with the statement that the optimal population-level CD rate is unknown.</p>	<p><i>Thank you – the statement has been qualified as suggested by the reviewer, with new reference added</i></p>
<p>Available knowledge - some percentages of women who want VD and of those, who receive CD would improve this section.</p>	<p><i>We have now added the specific data to the paper (...studies show that 70-80% of Brazilian women delivering in the private sector prefer a vaginal delivery (VD (11))</i></p>
<p>Methods:</p>	
<p>This is a good description of a complicated intervention. A bit more description about why the 28 hospitals were chosen and the other 12 not may be helpful.</p>	<p><i>We have added the description of why only 28 hospitals were selected.</i></p>
<p>Can you include the percent vaginal births in the study periods in the entire country and Sao Paulo for comparison?</p>	<p><i>In the Introduction we state the latest available data for Brazil CD rates in private and public sectors for 2016 (the year of the intervention).</i></p>
<p>Results:</p>	
<p>Please include which subpopulations were studied in each hospital in a table</p>	<p><i>We have added the actual number of deliveries for each of the subpopulations in the methods section. There are 26 hospitals and, for reasons of space (there are already 5 tables), we would prefer not to add a new table detailing which sub-population was studied in each hospital. We will do so if requested by the editor.</i></p>
<p>Discussion:</p>	
<p>Page line 306-307 - the statement about low risk women in California is incomplete Discussion of operative vaginal delivery and how this was incorporated (or not) into the intervention would be interesting</p>	<p><i>We added the following statement to elaborate on the California results. PPA included three of the interventions used in the California Collaborative (no elective CD before 39 weeks gestation, feedback to physicians on their rates of CS, multidisciplinary teams).</i></p>
<p>Figure 2 is the same as figure 3?</p>	<p><i>This is an error – apologies. Figure 3 is the percentage Vaginal births in the target</i></p>

	<i>population of 13 hospitals in the Intensive Group reporting continuously throughout the Baseline, Intervention and Follow up periods. We have removed Figure 2, and re-numbered all the Figures correctly.</i>
Tables - total number of births in each category should be added	<i>We have added births for tables 3 and 4</i>

Reviewer #3:

General Comments:

Increasing the proportion of vaginal deliveries in the general population and in particular for low risk women is an important issue globally. I appreciate that the authors sought to share their nationwide quality improvement approach with the international community as all can benefit from targeted quality initiatives.

In general I found the paper lacked an important distinction- was this a study of the quality improvement initiative, the implementation or both? This is a theme for clarification that is common throughout the numbered suggestions below.

Abstract	
1- Line 47: The objective states to assess the impact of a quality improvement initiative to increase vaginal delivery. Nowhere in the abstract do the authors state what the intervention was. This is not stated until the results section and Table 2. What was the initiative?	We agree with the reviewer that we did not clearly state what the intervention was. As described for Reviewer 1, we have now spelled out the changes that were tested in a section that is newly labelled as ““Specific Changes tested to increase VD””
2- The SQUIRE outline http://www.equator-network.org/reporting-guidelines/squire/ is a good model for formatting a quality improvement study. For the abstract, it includes: Background, methods, intervention, results and consultation. The lack of intervention discussed throughout the paper should be addressed.	We have re-written the abstract to conform to Squire Guidelines.
3- This is an example of an article that while it does not follow the SQUIRE model exactly, it is clear what the intervention and study outcome is: Lannon C, Kaplan HC, Friar K, et al.	Thank you for pointing out this confusion – we have made it clear now what the intervention is.

Introduction	
4- Line 81-82: Previous interventions have shown to have "limited impact in reducing CD". What makes this study different? Please address.	In the Introduction and Discussion we attempted to describe how our study differed from previous studies. Previous studies showed small scale effects or were conducted on a small scale. Previous QI studies were conducted in high income settings. Our study produced large effects and was conducted at a large scale in a Middle Income country.
5- Line 85: What are the theoretical drivers?	The four "theoretical drivers" are now listed as "Interventions" in the methods section and in Figure 4 (coalition, new models of care, empowerment of women, using data for improvement), and are now stated in the abstract . We have referred to these changes as "interventions" to avoid confusion and removed the phrase "theoretical drivers"
6- In addition to problem description, and available knowledge, the SQUIRE outline for introduction includes Rationale and Specific aim. The rational to decrease CD in favor of increasing VD is obvious to our reader base. The specific aim of your study was not. This come back to the original question- is the aim to study which implementation approach is best or which interventions are best?	We have included the SQUIRE outline in the Introduction section to cover these two headings, with the following added text: <i>Rationale: Using a QI collaborative model (19), we tested four drivers of increased VD (coalition building, new care models, empowerment of women, using data for improvement)</i> <i>Specific Aim: Our specific aim was to increase VD in 28 Brazilian hospitals by 100% over 20-months (May 2015 to December 2016).</i>
Methods	
7- Line 95: "Pilot QI intervention" this should be explicitly stated.	We expanded this sentences to include the interventions: <i>"The second, a pilot project in 2012 (21) in one hospital in Brazil, used QI methods to test interventions (models of care that</i>

	<i>supported natural birth, payment reforms, real-time data, and empowerment of women) and showed a decrease in CD rates from 80% to 47% over nine months (22)</i>
8- Line 103: This is the first use of PPA, I do not see this acronym stated before. It is used several times and I do not know what it stands for.	The term has been defined: <i>Project Parto Adequarto (“Project Appropriate Birth”, PPA)</i>
9- Line 114: You mention eligibility criteria. This is not explicitly stated. The flow and read can be made easier by clearly stating inclusion and exclusion criteria.	<i>The Hospital selection criteria are described in the Methods (“Selection of Hospitals). The number of hospitals that we could include was limited by available project resources. New text describes how two hospitals were excluded from the analysis (one closed down, the other did not submit any data). This is described in the Methods Section (analysis). We have now included the flow diagram of which hospitals were included and excluded in Figure 1, which hopefully makes the process clearer.</i>
10- Lines 126-127: This is an important point, I'm not sure it belongs here as much as it does in the discussion of limitations.	<i>This sentence has been moved to the “limitations” section: Unlike for Intervention hospitals, we were unable to risk-stratify deliveries in the Comparator hospitals. Therefore, we could only compare trends in VD rates of all (i.e. not just low-risk) deliveries at these hospitals. This whole population analysis necessarily resulted in a lower measured change in VD rates in the Intensive hospitals compared to low-risk subpopulation analyses at these same hospitals.</i>
11- Line 154- Missing reference.	<i>This reference has been added</i>
12- Throughout "Intervention and implementation design" There is no mention of the intervention.	<i>We have now defined the “intervention” as the specific changes that were introduced and “implementation” as the QI methods used to implement the interventions</i>

13- Lines 229-232- In tying this analysis to your results I do not see an analysis of the theory of change mentioned in the results Lines 278-283. Why were these chosen, why were they implemented, what data did the authors use?	<i>We now have clarified the components of the table in text. We hope this more clearly explains the analysis.</i>
Results	
14- 252-253- This should be discussed.	<i>We prefer that we not duplicate the details of the table in the text. We are happy to do so if instructed by the editor</i>

STATISTICAL EDITOR'S COMMENTS:

1. lines 256-258: It appears that the only adjustment was for clustering at the hospital level. What data were obtained to verify that the clinical/demographic risk profiles for the various cohorts were comparable for the group wise and temporal comparisons? It seems from the analysis that it was assumed that the risk profiles were static and interchangeable.	<i>Thank you - Given the expected stability of the population over 20 month, we feel that it is a reasonable assumption that the risk profile remained stable over this time</i>
2. Tables 3, 4: Need to include, either in these tables or in supplemental, the "N" associated with each % estimate. Need to clearly state the primary outcome of interest. Was it the IRR for the various populations in Table 3 or was it the IRR for comparison of intensive vs comparison group?	<i>The "n"s have been added to tables 3 and 4. Both intragroup comparisons (before and after within intervention and comparator hospitals) and between group (intervention and comparator) comparisons are important. These comparisons are now explicit in the Tables .</i>
3. Table 5: Need to include the counts for the number of adverse events and the number of NICU admits. The differences were NS, but was there adequate power to discern differences	<i>The counts of adverse events and NICU admits are now given in Table 5</i>

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.

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