

# OBSTETRICS & GYNECOLOGY



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

**Date:** Oct 26, 2018  
**To:** "Elliott Main" emain@stanford.edu  
**From:** "The Green Journal" [REDACTED]  
**Subject:** Your Submission ONG-18-1828

RE: Manuscript Number ONG-18-1828

Safety Assessment of a Large-Scale-Improvement Collaborative to Reduce Nulliparous Cesarean Rates

Dear Dr. Main:

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 Nov 16, 2018, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

REVIEWER #1:

This is an analysis of a state wide maternal quality care collaborative initiated to reduce primary cesarean rates in California. Hospitals with nulliparous term singleton vertex (NTSV) rate above 23.9% were solicited to join and use a CMQCC toolkit to attempt to reduce their NTSV primary cesarean rates. Over two years, among all hospitals, the NTSV rate fell from 29.3% to 25.0%. None of the six maternal and neonatal safety measures showed any difference in this time period, including those hospitals with the greatest decline. No measure was worse and, in fact, severe unexpected newborn complications \*UNC) actually improved. The authors conclude that their findings support the safety of efforts to reduce primary cesarean rates utilizing ACOG/SMFM guidelines. Ways in which this may could be improved include:

1. Lines 100-101: I would highlight why OVD was not emphasized here rather than waiting until the commentary.
2. Lines 257-259: This sentence reads awkwardly, I would rewrite it for clarity.
3. Lines 292-293: What is meant by we did not focus on the second stage? Weren't the hospitals allowed to make their own decisions about what portions of the toolkit to implement?
4. Line 343: I do not think you need to repeat this comparison, one is enough to give the scale of your study.

REVIEWER #2:

Overall: Well written description of the QU effort of the largest perinatal collaborative in the Unites States Incorporation of an initiative to increase the vaginal birth rate for uncomplicated term singleton vertex births. The CMQCC initiative incorporated many of the national guidelines developed over the last 10 years and can be anticipated to be applicable to many hospitals in the u tied states. The effect on the cesarean rate comparted favorably to an initiative in Quebec that had a modest effect.

The manuscript does not examine why a substantial proportion of the hospitals (did not experience reduced cs rate - e.g. the third tercile. The manuscript fails to address recommendations were made regarding second stage. limiting comments to issue of op vaginal delivery. The op vaginal delivery rates should be placed in context of these rates being higher than national data.

Note I don't see a description of NTSV in either the abstract or introduction

#### Abstract

1. Design- Describe the study type - retrospective cohort
2. Results Line 52 should state among all participating hospitals "to be clear it is not all hospitals in the collaborative

#### Manuscript

3. Line 60 I would remove the redundant adjective "very" large reductions and just say large
4. Line 79 Should read American Academy of Family Physicians (not Family Medicine)
5. Line 87- "described elsewhere"- where? \_ will reference be added?
6. LINES 88-90 This sentence describes an outcome of the study. Could rephrase that study was initiated to analyze effect of the QI project on the CS rate and any accompanying effect on neonatal or maternal outcome.
7. Line 94 Why were hospitals that were not above the Healthy People Goal 2020 rate not invited to participate. The goal is modest and as noted in the article well above the overall cesarean rate for 1999.
8. 98 Were the mentor teams local or from other regions?
9. Line 109 -? more details "...will be published elsewhere" needs reference or further explanation
10. Line 101 - what does this mean op vaginal deliveries were not "emphasized" - were indications for use in prolonged second stage they included in the on the collaborative effort or not?
11. Note that the overall op vaginal delivery rates in the study are 2-3 times higher than current operative vaginal delivery rates in the US. Hence encouraging an increase may not have been wise but more info is needed.
12. Line 227- Hospitals in the lowest tercile did not have a meaningful decrease in NTSV cesareans- why? Will this be presented in another paper? If not, an analysis is warranted.

#### Discussion

13. Should efforts be made to decrease CS rates further as 23.9% is still quite high for NTSV?
14. Did this initiative address indications outside of NTSV such as increasing the proportion of women offered ECV or were vaginal deliveries encouraged for twins when A is in cephalic presentation. The AIM Safety bundle encourages breech version, instrumented delivery, and twin delivery protocols
15. Line 281- discussion describes studies of preventing second stage cesareans but the article lacks data on what the collaborative had to say about second stage management. - increasing op vaginal is only one method- the ACOG consensus statement describes manual OP rotation and giving more time for SVD.
16. Line 296 In discussion would consider why the California hospital have op vaginal delivery rates 2-3 times' national rates. The comment that the small decrease in op vaginal delivery rates may explain the decrease in 3RD/4TH lacerations and shoulder removed unless the authors formally look at the effect of other changes in clinical practice especially the reduction of midline episiotomies that has been occurring nationwide
17. Table 3 change NICU levels to Neonatal care or bevor care levels since level one and most level 2 would not be described as NICU

#### REVIEWER #3:

The purpose of this study was to examine if reductions in the NTSV Cesarean rate, after introduction of CMQCC supporting vaginal birth collaborative, were associated with changes/increases in maternal and neonatal outcomes.

The study was carried out in California hospitals with baseline NTSV Cesarean rates of greater than or equal to 24% (benchmark goal articulated by Healthy People 2020 document).  
56 hospital participated and there were 126,480 NTSV births during the study period of 2015-2017.

The overall NTSV Cesarean rate significantly decreased from 29.1% to 24.6%.

Rates of severe unexpected newborn complications did not change over the study period, even in hospitals with the highest decline in NTSV Cesarean rates.

The decline in NTSV Cesarean rate was not accompanied by increase in operative vaginal deliveries.

The authors conclude that reductions in (NTSV) Cesarean rates need not be accompanied by more adverse maternal and neonatal outcomes.

This study, conducted by leaders in patient safety initiatives at the CMQCC, supports the safe reduction in primary CS.

#### Questions/Critique:

1. The challenge of collecting data from 56 different hospitals with different EMRs must be formidable. As there were no formal study data collection teams, how did the authors ascertain and verify that the collected data (NTSV and maternal/neonatal outcomes) were accurate?
2. Although not specified, the NTSV rates are assumed to be consistent with the JC PC-02 quality measure. Can the authors comment on the suitability of this measure compared with the more recently proposed SMFM measure (Armstrong et al. Grey J Feb 2016)?
3. Although the NTSV Cesarean rate declined over the study period, no information is provided on why that decline occurred. How did the individual indications for Cesarean (suspected fetal compromise, labor disorders, failed inductions) change from 2015 to 2017?
4. Obesity is a risk factor for Cesarean delivery, in isolation and in association with co-morbidities. Obesity comprised approximately 20% of the nulliparous population in this study. Were the authors able to analyze whether Cesarean rates declined in the setting of maternal obesity (classes 1,2,3) or did these rates remain unchanged despite the initiatives that were introduced to lower Cesarean rates?
5. Do the authors have any information on change in breast feeding rates in concert with the reduction in Cesarean rates?
6. The tables and figure do not include statistical information or p values; these should be added.

#### STATISTICAL EDITOR'S COMMENTS:

1. Table 1: Need units for maternal age and BMI.
2. Table 3: The counts for 5 min Apgar < 5 are relatively low. Thus, there is little power to discern differences and thus to generalize re: neonatal safety from that metric. Also, the counts (except for overall comparisons) are too few to allow for adjustment for 9 covariates. Similarly, the absolute counts in Comparison group E were too few for both transfusions and for severe unexpected newborn complications to allow for adjustment with 9 covariates. Given the number of comparisons (70) in this Table, there is no adjustment of the inference threshold for multiple hypothesis testing. Likely at least some of those significant at  $p < .05$  level are spurious.
3. Are there data from the non-collaborative hospitals during these same time periods to assess whether CD rates also fell at hospitals that did not implement these changes?

#### 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, as well as subsequent author queries. If you opt out of including your response, only the revision letter will be posted. Please reply to this letter with one of two responses:
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  2. OPT-OUT: No, please do not publish my response letter and subsequent email correspondence related to author queries.
2. Based on the forms that have been submitted, the following people have not met the criteria for authorship: Valerie Cape, Christa Sakowski, Julie Vasher. On the third page of the agreement form, under the section labeled "Authorship," items #2-4, in addition to either 1a or 1b, MUST be checked off in order to qualify for authorship. These people should be moved to the acknowledgments, or they could resubmit a revised author agreement form if they filled it out erroneously the first time. All updated and missing forms should be uploaded with the revision in Editorial Manager.

3. 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."  
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5. 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 will be transitioning as much as possible to use of the reVITALize definitions, and we encourage authors to familiarize themselves with them. The obstetric data definitions are available at <http://links.lww.com/AOG/A515>, and the gynecology data definitions are available at <http://links.lww.com/AOG/A935>.

6. 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 appendixes).

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

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 Nov 16, 2018, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

The Editors of Obstetrics & Gynecology

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