

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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Date: Apr 18, 2022
To: "Ann M Bruno" [REDACTED]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-22-550

RE: Manuscript Number ONG-22-550

What is the optimal cesarean rate?

Dear Dr. Bruno:

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

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

To facilitate our review, we prefer that the cover letter you submit with your revised manuscript include each reviewer and Editor comment below, followed by your response. That is, a point-by-point response is required to each of the EDITOR COMMENTS (if applicable), REVIEWER COMMENTS, STATISTICAL EDITOR COMMENTS (if applicable), and EDITORIAL OFFICE COMMENTS below. Your manuscript will be returned to you if a point-by-point response to each of these sections is not included.

The revised manuscript should indicate the position of all changes made. Please use the "track changes" feature in your document (do not use strikethrough or underline formatting).

Your submission will be maintained in active status for 21 days from the date of this letter. If we have not heard from you by May 09, 2022, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1:

Thank you for this well-written commentary regarding the importance and challenges of defining an optimal cesarean rate that optimizes maternal and neonatal outcomes and the need for evidence-based targets. Current and historical international and national recommendations for cesarean rate reduction are listed, along with attempts to refine risk stratification and classification for better comparisons. As there so far is not an evidence-based cesarean rate that minimizes harm, targets that are set are thus arbitrary and need further refinement to help guide further cesarean reduction recommendations. Clinical prediction models (such as for TOLAC candidates) and the subjective nature of cesarean deliveries in relation to electronic fetal monitoring interpretation are reviewed, along with the limitations of focusing on cesarean rate for quality without looking at other interventions that improve outcomes. Possible maternal and neonatal outcome data to help define this target are discussed (listed in Table 2). Varying risk profiles of different patient populations, the role of shared decision making, and value-based care are reviewed as other considerations to help define an optimal cesarean target.

Questions to Authors:

Purpose: No issues — well stated

Commentary design: This commentary is persuasive in setting the background regarding the importance of cesarean rate reduction, the previous studies used to define targets and their limitations, and considerations of possible criteria to help define these rates.

1. What should be done with existing cesarean rate reduction recommendations? Should these be targets but not hard goals? This is difficult especially as these are often used as quality metrics (as noted in line 38) and compared as proxy of quality outcomes.

- a. Are most of these calls from global epidemiological studies?
 - b. Are the recommended rates from expert opinion listed in lines 30-41? If not evidence-based, how were these determined?
2. Have published cesarean rate reduction recommendations for 10-20% (lines 68-69) (and measures/toolkits to support this, as reasons for cesareans are multifactorial) been successful in reducing cesareans? I see the example from the Maryland Perinatal-Neonatal Quality Care Collaborative (lines 113-119). Are there others from some of the other published recommendations, such as Healthy People 2020, or the recommendations from the WHO?
3. As you note in lines 178-181, varying risk factors influence cesarean rates — would risks be calculated based on these individual calculations? How would that be reflected on a national scale? Would that instead still drill down to one "low risk" rate that didn't have any other listed factors?
4. Have cesarean rates also mirrored other societal trends, such as the relative increased proportions of patients undergoing ART, patients who are of advanced maternal age, or patients with obesity?
5. Has the shift to predominantly cesareans for breech presentation at full term significantly increased the cesarean rate itself (lines 184-185)?
6. It seems unlikely that electronic fetal monitoring will be phased out without an evidence-based alternative, especially for higher risk patients who do not qualify for intermittent auscultation. It seems that these same higher risk patients themselves already be at higher risk for cesarean due to risks of placental insufficiency.
7. Excluding elective and repeat cesareans, would it also help to look at the change in the percentiles of indications for cesarean over time? I found it interesting that non-reassuring fetal status was the largest contributor to the increase in primary cesarean (lines 142-143), what are other notable differences over time?

Scientific validity: high-quality citations noted

Conclusions: returns to the difficulty of assessing evidence-based cesarean rate targets; needs for resources, and importance of implementing interventions that affect neonatal/perinatal outcomes

Reviewer #2:

Abstract:

1. Recommend clearly stating the objective of this commentary.
2. Provide a brief overview of what this commentary will be discussing.

Introduction:

1. An overview of this study was clearly stated.
2. Recommend clearly stating the objective of this commentary.
3. A summary of line 47-52 should also be included in the abstract.

Body:

1. Commentary does well to summarize the multiple factors that make identifying an ideal cesarean rate with the lowest maternal and neonatal adverse outcomes difficult.
2. The author highlights that ascertainment of a rate is unlikely to tackle the problem, especially in the United States and to focus more on individualized patient centered approach.
3. Additionally, the author does a good job highlighting the limitations of EFM and previous studies conducted to address cesarean rates and changing clinical practice based on short term outcomes without incorporating long term findings of these studies.
4. Consider discussing the litigious landscape of obstetric care in the US and how that could influence practitioners' delivery plan especially in light of the majority of unplanned cesareans are due to non-reassuring FHT.
5. I recommend discussing more solutions as to how best optimize maternal and neonatal outcomes when determining mode of delivery. Such as incorporating Robson criteria into a clinical calculator weighing the risk of requiring a cesarean section and perinatal outcomes based on the patients' demographics. Or developing a reliable risk stratification tool which identifies which patients are at low, moderate and severe risk of cesarean and poor perinatal outcomes.
6. Another solution to be highlighted is incorporating legislature and policies to incentivize hospital administration and practitioners who utilize interventions that reduce cesarean rate and perinatal outcomes. Specifically, developing reimbursement incentives through policy changes for VBAC and vaginal deliveries which could influence practice habits,

especially since there are higher healthcare costs associated with cesareans.

7. Recommend the author look up and review a similar dilemma (to the problem of cesarean rate and balancing perinatal outcomes) in other specialties and on how that problem was managed.

Conclusion:

1. Appropriate and summarizes the topics addressed in the body.

Figures and Tables:

1. Appropriate.

References:

1. Appropriate.

Checklist:

1. N/a

Reviewer #3:

This is an extremely important topic and a well-written commentary. It is critical to balance many factors when determining an optimal cesarean rate. The goal of reducing the rate of cesarean delivery can have unintended implications for patients, providers, and hospitals. This commentary provides an update to prior similar commentaries and brings up the potential harms of lowering the rate of cesarean delivery.

Lines 27-29: If there are so many risks to cesareans, why are they done at all? At some point in the manuscript, state clearly that they do have some advantage, or else explain why it has been challenging to decrease the rate.

Lines 63-65: It is important to discuss the idea that the correlation between cesarean rate and infant mortality is an association and does not imply a causal relationship. The author mentioned that the cited study adjusted for maternal age, fetal sex, and country wealth, but there are many other factors that are likely confounding this relationship (e.g., risk factors for cesarean delivery that are also risk factors for neonatal complications.)

Lines 75-79: Explain the use of ICD diagnosis of low-risk and high-risk to stratify cesarean deliveries? Has this method been validated? Do providers accurately code deliveries? What are some examples of ICD codes used?

Lines 85-88: Discuss the "risk-adjustments" and clarify how they affected the hospital differences? All hospitals likely should not have the same benchmark, as some hospitals care for patients with more complications, are a referral center, etc.

Lines 91-99: Provide a brief overview of the Robson classification system. Consider including this as an additional table.

Lines 100-108: Articulate the intuitive idea that cesareans do have clear benefit in many situations somewhere in this paragraph or elsewhere in the manuscript.

Lines 127-138: Great discussion of VBAC success prediction model and the 70% cutoff for morbidity equivalence. Consider including a discussion on clinical prediction tools for successful induction of labor. These could be of value in populations at higher risk of complications (patients with obesity, hypertension, etc) that are mentioned in the paper as being a limitation to a one-size fits all cesarean rate target. If higher risk of a cesarean due to a failed induction of labor/arrest disorder could be predicted, an unlabored cesarean section might improve outcomes.

Lines 153-157: By what criteria are EFM-based guidelines "seemingly objective"? This contradicts several mentions of EFM management being subjective. Please clarify. Are providers using certain criteria to guide decision-making regarding EFM and cesarean delivery? Additionally, are providers using appropriate or standardized criteria to guide their decisions to move to cesarean delivery in the setting of abnormal labor curves?

Lines 181-183: Great point about patient values. The risks of cesarean delivery are highlighted constantly in the literature and to patients, but the risks of vaginal delivery are rarely discussed and are not negligible. The risks of a cesarean delivery after a long labor that the provider persisted towards in the name of preventing a cesarean are also worth considering. If we had better prediction models and chose appropriate candidates for primary cesarean section, would they be associated with improved outcomes?

Lines 184-197: This is an interesting discussion, but is it clinically relevant, as there are so few providers offering breech vaginal delivery today? I would consider omitting this paragraph, as it is probably largely historical at this point.

Line 201-202: Similarly to before, this association likely has many confounders

EDITORIAL OFFICE COMMENTS:

1. If your article is accepted, the journal will publish a copy of this revision letter and your point-by-point responses as supplemental digital content to the published article online. You may opt out by writing separately to the Editorial Office at em@greenjournal.org, and only the revision letter will be posted.

2. When you submit your revised manuscript, please make the following edits to ensure your submission contains the required information that was previously omitted for the initial double-blind peer review:

- * Funding information (ie, grant numbers or industry support statements) should be disclosed on the title page and at the end of the abstract. For industry-sponsored studies, describe on the title page how the funder was or was not involved in the study.
- * Include clinical trial registration numbers, PROSPERO registration numbers, or URLs at the end of the abstract (if applicable).
- * Name the IRB or Ethics Committee institution in the Methods section (if applicable).
- * Add any information about the specific location of the study (ie, city, state, or country), if necessary for context.

3. Obstetrics & Gynecology's Copyright Transfer Agreement (CTA) must be completed by all authors. When you uploaded your manuscript, each coauthor received an email with the subject, "Please verify your authorship for a submission to Obstetrics & Gynecology." Please ask your coauthor(s) to complete this form, and confirm the disclosures listed in their CTA are included on the manuscript's title page. If they did not receive the email, they should check their spam/junk folder. Requests to resend the CTA may be sent to em@greenjournal.org.

4. ACOG uses person-first language. Please review your submission to make sure to center the person before anything else. Examples include: "Patients with obesity" instead of "obese patients," "Women with disabilities" instead of "disabled women," "women with HIV" instead of "HIV-positive women," "women who are blind" instead of "blind women."

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 has adopted the use of the reVITALize definitions. Please access the obstetric data definitions at <https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-obstetrics-data-definitions> and the gynecology data definitions at <https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-gynecology-data-definitions>. If use of the reVITALize definitions is problematic, please discuss this in your point-by-point response to this letter.

6. Make sure your manuscript meets the following word limit. The word limit includes the manuscript body text only (for example, the Introduction through the Discussion in Original Research manuscripts), and excludes the title page, précis, abstract, tables, boxes, and figure legends, reference list, and supplemental digital content. Figures are not included in the word count.

Current Commentary: 3,000 words

7. Specific rules govern the use of acknowledgments in the journal. Please review the following guidelines and edit your title page as needed:

- * 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 or indicate whether the meeting was held virtually).
- * If your manuscript was uploaded to a preprint server prior to submitting your manuscript to Obstetrics & Gynecology, add the following statement to your title page: "Before submission to Obstetrics & Gynecology, this article was posted to a preprint server at: [URL]."
- * Do not use only authors' initials in the acknowledgement or Financial Disclosure; spell out their names the way they appear in the byline.

8. Be sure that each statement and any data in the abstract are also stated in the body of your manuscript, tables, or figures. Statements and data that appear in the abstract must also appear in the body text for consistency. Make 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 manuscript.

In addition, the abstract length should follow journal guidelines. Please provide a word count.

Current Commentary: 250 words

9. 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.

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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 as a Microsoft Word document. Your revision's cover letter should include a point-by-point response to each of the received comments in this letter. Do not omit your responses to the EDITOR COMMENTS (if applicable), the REVIEWER COMMENTS, the STATISTICAL EDITOR COMMENTS (if applicable), or the EDITORIAL OFFICE COMMENTS.

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

Again, your manuscript will be maintained in active status for 21 days from the date of this letter. If we have not heard from you by May 09, 2022, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

Dwight J. Rouse, MD
Deputy Editor, Obstetrics

2020 IMPACT FACTOR: 7.661
2020 IMPACT FACTOR RANKING: 3rd out of 83 ob/gyn journals

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

May 8, 2022

Dear Editors,

Thank you for the opportunity to revise our manuscript, "What is the optimal cesarean rate?" We appreciate the review and constructive suggestions. I can confirm that I have read the 'Instructions for Authors.' Attached is the revised manuscript with tracked changes. Below are the Editor, Reviewer, and Editorial Office comments with point-by-point responses including how and where the manuscript text was modified when able. All authors have reviewed and approve of the submitted revision.

Thank you for your ongoing consideration of our work.

Sincerely,

Ann Bruno

REVIEWER COMMENTS:

Reviewer #1:

Thank you for this well-written commentary regarding the importance and challenges of defining an optimal cesarean rate that optimizes maternal and neonatal outcomes and the need for evidence-based targets. Current and historical international and national recommendations for cesarean rate reduction are listed, along with attempts to refine risk stratification and classification for better comparisons. As there so far is not an evidence-based cesarean rate that minimizes harm, targets that are set are thus arbitrary and need further refinement to help guide further cesarean reduction recommendations. Clinical prediction models (such as for TOLAC candidates) and the subjective nature of cesarean deliveries in relation to electronic fetal monitoring interpretation are reviewed, along with the limitations of focusing on cesarean rate for quality without looking at other interventions that improve outcomes. Possible maternal and neonatal outcome data to help define this target are discussed (listed in Table 2). Varying risk profiles of different patient populations, the role of shared decision making, and value-based care are reviewed as other considerations to help define an optimal cesarean target.

Questions to Authors:

Purpose: No issues — well stated

Commentary design: This commentary is persuasive in setting the background regarding the importance of cesarean rate reduction, the previous studies used to define targets and their limitations, and considerations of possible criteria to help define these rates.

1. What should be done with existing cesarean rate reduction recommendations? Should these be targets but not hard goals? This is difficult especially as these are often used as quality metrics (as noted in line 38) and compared as proxy of quality outcomes.

- a. Are most of these calls from global epidemiological studies?
- b. Are the recommended rates from expert opinion listed in lines 30-41? If not evidence-based, how were these determined?

Thank you for these thoughtful comments and questions. We outline concerns that the current cesarean rate targets are arbitrary, and advocate that we need an evidence-based target that better considers morbidity outcomes and additional factors than have previously been used in defining a target cesarean rate. Until such a time when we have an evidence-based target, efforts to reduce the cesarean rate should continue. We may continue to use them as targets while understanding their significant limitations. We now state this clearly in the text.

The selected cesarean thresholds (outlined in lines 34-46) reflect expert opinion and global epidemiological studies. The details of these specific studies are included later in the text (lines 60-78 and Table 1). An additional sentence has been added to the manuscript for clarity.

Textual edits –

- Lines 42-43: “These selected cesarean targets reflect expert opinion and translation of results from global epidemiologic studies.”

2. Have published cesarean rate reduction recommendations for 10-20% (lines 68-69) (and measures/toolkits to support this, as reasons for cesareans are multifactorial) been successful in reducing cesareans? I see the example from the Maryland Perinatal-Neonatal Quality Care

Collaborative (lines 113-119). Are there others from some of the other published recommendations, such as Healthy People 2020, or the recommendations from the WHO?

Thank you for this question. Prior to the Maryland Perinatal-Neonatal Quality Care Collaborative study finding a statewide reduction in the cesarean rate after a 30-month safety-bundle implementation, the California Maternal Quality Care Collaborative (CMQCC) published a similar study. In this analysis, the change in the nulliparous, term, singleton vertex (NTSV) cesarean rate from 2014-2019 after California hospitals implemented a statewide safety bundle were compared to rates from non-California U.S. hospitals. The California cesarean rate declined at a statistically significant higher rate of 3.2% (95% CI 1.7-3.5%) than the cesarean rate in non-California states.¹ We selectively included the Maryland study as the most recent publication of these two similar state-level studies. However, we are happy to include other studies if the reviewers or editors feel strongly.

In a cluster-randomized controlled trial of 32 hospitals in Quebec, Canada, use of an “audit and feedback” program – whereby indications for cesarean were audited and feedback to practitioners provided – resulted in statistically significant cesarean rate reduction compared to no intervention (22.5% to 21.8% reduction with intervention vs 23.2% to 23.5% without intervention; aOR 0.9, 95% CI 0.80-0.99).² Reference to this study has been added to the manuscript text.

There are no studies to our knowledge demonstrating successful reduction in cesarean rates at a national or international level in response specifically to the Healthy People 2020 or WHO recommendations. Rather, national vital statistics continue to show increased or plateaued cesarean rates in the three most recent years with data available (32.0% in 2017; 31.9% in 2018; 31.7% in 2019) in the United States.³⁻⁵

Textual edits –

- Lines 251-253: “Implementation of an “audit and feedback” program to evaluate indications for cesarean and provide feedback to practitioners in 32 hospitals in Quebec, Canada resulted in reduced cesarean rates with cost savings.^{79,80”}

3. As you note in lines 178-181, varying risk factors influence cesarean rates — would risks be calculated based on these individual calculations? How would that be reflected on a national scale? Would that instead still drill down to one “low risk” rate that didn't have any other listed factors?

Thank you for this question. This issue is complex. While the NTSV population is valuable for standardized assessment for comparison of cesarean rates between hospitals, the use of the NTSV population alone is not representative of the diverse patients cared for throughout the U.S. or world (Lines 205-208). Therefore, patient level risk factors and individual clinical scenarios must be considered. It could be stated that this clinical variation is an argument against setting a single population level cesarean rate target. Rather, we posit it requires nuance with consideration of varying “optimal” rates for differing patient populations. We have added language about patient level risk factors. However, the specifics of how to define these sub-groups for varying targets is beyond the scope of this commentary.

Textual edits –

- Lines 208-211: “As national cesarean rates have increased, so have population level trends in risk factors for cesarean. While increasing patient level risk factors alone

cannot explain the current cesarean delivery rates, these factors should be considered in risk stratification and cesarean target development.⁴⁵"

4. Have cesarean rates also mirrored other societal trends, such as the relative increased proportions of patients undergoing ART, patients who are of advanced maternal age, or patients with obesity?

Thank you for this question. As you note, pregnancies among individuals with obesity, advanced maternal age, and use of assisted reproductive technologies (ART) are on the rise at a population level. In analyses limited to the NTSV population with elimination of those individuals with significant individual risk factors, wide cesarean delivery rate variation persists suggesting additional influences such as behavior are contributing to the variation.⁶ In other analyses including individuals with risk factors for cesarean, rising cesarean rates have not been explained by these factors alone. For example, in a retrospective cohort study of 485,451 deliveries in nulliparous individuals in Canada, the cesarean delivery rate increased over time (12.5% in 1992 to 24% in 2018; test of trend $p < 0.001$). Rates of maternal risk factors including advanced maternal age, obesity, and pre-pregnancy hypertension also increased. In stratified analyses, the rate of cesarean increased in those with or without risk factors, and the population-attributable risk did not change over time.⁷ While the contribution of individual risk factors to cesarean delivery rates should be considered, increasing rates of population level risk factors alone likely do not explain current cesarean delivery rates (i.e., reducing obesity likely will not by itself reduce rates of cesarean). Additional language has been added to the manuscript to clarify this (and the prior) question.

Textual edits –

- Lines 208-211: "As national cesarean rates have increased, so have population level trends in risk factors for cesarean. While increasing patient level risk factors alone cannot explain the current cesarean delivery rates, these factors should be considered in risk stratification and cesarean target development.⁴⁵"

5. Has the shift to predominantly cesareans for breech presentation at full term significantly increased the cesarean rate itself (lines 184-185)?

Thank you for this question. As you highlight, cesarean delivery for breech presentation contributes only slightly to the overall rates of cesarean. The breech singleton vaginal delivery section was included as an illustrative example of risk-benefit tradeoffs considering patient autonomy and values. We kept this discussion but added clarification regarding the small contribution of cesarean delivery for breech to the larger discussion of cesarean rates.

Textual edits –

- Lines 227-229: "While cesarean deliveries for term breech singletons contribute only a small proportion to the overall cesarean rate, such a clinical scenario emphasizes the value of informed counseling, patient autonomy, and person-centered decision making.^{63,64}"

6. It seems unlikely that electronic fetal monitoring will be phased out without an evidence-based alternative, especially for higher risk patients who do not qualify for intermittent auscultation. It seems that these same higher risk patients themselves already be at higher risk for cesarean due to risks of placental insufficiency.

Thank you for this input. We agree that elimination of electronic fetal monitoring (EFM) is unlikely in the absence of an alternative monitoring approach given its widespread and instilled use in obstetrics. The discussion of cesarean rates must consider our reliance on EFM and the impact of its subjective interpretation. We added language to the manuscript reflecting the unlikelihood of EFM being eliminated.

- Lines 178-180: "Yet, EFM is unlikely to be abandoned anytime soon in the absence of alternative evidence-based fetal monitoring options and the current medico-legal landscape."

7. Excluding elective and repeat cesareans, would it also help to look at the change in the percentiles of indications for cesarean over time? I found it interesting that non-reassuring fetal status was the largest contributor to the increase in primary cesarean (lines 142-143), what are other notable differences over time?

Thank you for these questions. In the Barber et al study, in addition to the indication of non-reassuring fetal status, which was the largest contributor to the increasing primary cesarean delivery rate, additional contributors were labor arrest, preeclampsia, and suspected macrosomia. The authors concluded that more "subjective" indications were driving the rate.⁸ A sentence further exploring this has been added to the manuscript text. The Robson classification system also is a means for categorizing cesareans to help understand which indications are contributing to cesarean delivery rates. As outlined in lines 110-113, repeat cesarean deliveries accounted for the largest increase in an analysis of deliveries in the U.S. from 2005-2014.⁹

Textual edits –

- Lines 161-162: "Labor arrest, preeclampsia, and suspected macrosomia were additional contributors to the increasing primary cesarean rate."⁴⁴

Scientific validity: high-quality citations noted

Conclusions: returns to the difficulty of assessing evidence-based cesarean rate targets; needs for resources, and importance of implementing interventions that affect neonatal/perinatal outcomes

Thank you for your comments, questions, and constructive feedback.

Reviewer #2:

Abstract:

1. Recommend clearly stating the objective of this commentary.
2. Provide a brief overview of what this commentary will be discussing.

Thank you for this input. Additional language has been added to the abstract consistent with these recommendations.

Textual edits –

- Lines 18-20: “This commentary summarizes current national and international cesarean rate targets, discusses the challenges of identifying an evidence-based national cesarean rate target, and explores future considerations for best defining a cesarean rate target.”

Introduction:

1. An overview of this study was clearly stated.
2. Recommend clearly stating the objective of this commentary.
3. A summary of line 47-52 should also be included in the abstract.

Thank you for these comments. The overview of this commentary is outlined in lines 52-57, and as suggested, this has been summarized and added to the abstract.

Textual edits –

- Lines 18-20: “This commentary summarizes current national and international cesarean rate targets, discusses the challenges of identifying an evidence-based national cesarean rate target, and explores future considerations for best defining a cesarean rate target.”

Body:

1. Commentary does well to summarize the multiple factors that make identifying an ideal cesarean rate with the lowest maternal and neonatal adverse outcomes difficult.
2. The author highlights that ascertainment of a rate is unlikely to tackle the problem, especially in the United States and to focus more on individualized patient centered approach.
3. Additionally, the author does a good job highlighting the limitations of EFM and previous studies conducted to address cesarean rates and changing clinical practice based on short term outcomes without incorporating long term findings of these studies.

Thank you for these comments.

4. Consider discussing the litigious landscape of obstetric care in the US and how that could influence practitioners' delivery plan especially in light of the majority of unplanned cesareans are due to non-reassuring FHT.

Thank you for this input. We discuss the high contribution of cesareans for non-reassuring fetal heart tones to the overall cesarean rates, and our concern about the subjectivity of this cesarean indication (lines 156-174). In particular, electronic fetal monitoring (EFM) is instilled in obstetric practice despite its significant limitations. For medico-legal reasons, as well as our oath “to do no harm,” cesarean delivery becomes the path chosen for EFM findings of “non-reassurance,” despite the uncertainties. We have added language to the manuscript addressing the litigious aspect of this decision making.

Textual edits –

- Lines 177-180: “However, the criteria imperfectly, and even poorly, correlate with clinical outcomes, making the approach flawed. Yet, EFM is unlikely to be abandoned anytime soon in the absence of alternative evidence-based fetal monitoring options and the current medico-legal landscape.”

5. I recommend discussing more solutions as to how best optimize maternal and neonatal outcomes when determining mode of delivery. Such as incorporating Robson criteria into a clinical calculator weighing the risk of requiring a cesarean section and perinatal outcomes based on the patients' demographics. Or developing a reliable risk stratification tool which identifies which patients are at low, moderate and severe risk of cesarean and poor perinatal outcomes.

Thank you for this feedback. We propose that to identify a cesarean target, we must define a measurement of ‘optimal’ outcomes. Some proposed ideas include use of standardized maternal and neonatal morbidity outcomes (lines 184-201; Table 3). We also emphasize that individual patient characteristics must be considered, as well as patient values (lines 202-215), when developing solutions.

As you highlight, clinical calculators may be a useful tool to address outcomes by mode of delivery. We discuss the TOLAC calculator to help inform morbidity risk (lines 149-153) and recommend further study of decision tools (lines 153-155). In response to your feedback, we have additionally added reference to the development and validation of a seven variable risk calculator for cesarean delivery in individuals undergoing induction of labor.¹⁰ We highlight that this model has merits to guide counseling and inform patient risk.

Textual edits –

- Lines 238-242: “Rossi et al developed and validated a seven variable predictive risk calculator for cesarean delivery among individuals with liveborn singletons undergoing induction of labor between 32- and 42-weeks’ gestation.⁶⁹ Prediction models can inform an individual’s risk and guide counseling. However, care must be taken to consider the larger clinical context and not rely on a single predicted value alone to guide care.”

6. Another solution to be highlighted is incorporating legislature and policies to incentivize hospital administration and practitioners who utilize interventions that reduce cesarean rate and perinatal outcomes. Specifically, developing reimbursement incentives through policy changes for VBAC and vaginal deliveries which could influence practice habits, especially since there are higher healthcare costs associated with cesareans.

Thank you for this comment. Beyond the individual patient impact, the current cesarean delivery rate is a significant hospital, community, state, and national problem. The solution likely requires both a top-down and bottom-up approach with engagement of all stakeholders. Hospital-level policies and legislative agendas may be beneficial. The commentary discusses the Maryland Perinatal-Neonatal Quality Care Collaborative success of reducing cesarean rates among the nulliparous, term, singleton, vertex (NTSV) population at a state-level (lines 129-133). We also outline the current use of cesarean rates as a quality metric (lines 43-46). We added language about the successful implementation of an “audit and feedback” hospital program in Quebec, Canada resulting in a reduction in cesarean rate with cost savings.^{2,11} Textual edits also reflect the potential benefit of incentivization for practices reducing cesarean delivery.

We hesitate to emphasize this point further as there are also untoward effects of setting such policies. Cesarean delivery thresholds, as set by Healthy People 2020, the WHO, and state collaboratives, we argue in this commentary are themselves arbitrary policies. In the United Kingdom, using cesarean rates as a quality metric has received increasing pushback (lines 203-205) based on concerns that the cesarean rate itself, rather than morbidity and patient-centered outcomes, were being overemphasized. Also, emphasizing cesarean reduction strategies too much, may cause the commentary to lose focus on the main points.

Textual edits –

- Lines 251-254: “Implementation of an “audit and feedback” program to evaluate indications for cesarean and provide feedback to practitioners in 32 hospitals in Quebec, Canada resulted in reduced cesarean rates with cost savings.^{79,80} Hospital policies incentivizing practitioners who utilize interventions that reduce cesarean may be cost saving in the long-term and reduce morbidity.”

7. Recommend the author look up and review a similar dilemma (to the problem of cesarean rate and balancing perinatal outcomes) in other specialties and on how that problem was managed.

Thank you for this interesting idea. The mother-fetal dyad is unique to obstetrics, and therefore, a directly comparable clinical dilemma from another field is difficult to identify. No textual edits have been made. We are open to further exploring this idea if desired by the reviewers/editors.

Conclusion:

1. Appropriate and summarizes the topics addressed in the body.

Figures and Tables:

1. Appropriate.

References:

1. Appropriate.

Checklist:

1. N/a

Reviewer #3:

This is an extremely important topic and a well-written commentary. It is critical to balance many factors when determining an optimal cesarean rate. The goal of reducing the rate of cesarean delivery can have unintended implications for patients, providers, and hospitals. This commentary provides an update to prior similar commentaries and brings up the potential harms of lowering the rate of cesarean delivery.

Thank you for these comments.

Lines 27-29: If there are so many risks to cesareans, why are they done at all? At some point in the manuscript, state clearly that they do have some advantage, or else explain why it has been challenging to decrease the rate.

Thank you for this comment and question. In lines 116-118, we discuss the concept that there is likely a cesarean delivery rate that is “too low” and acknowledge the necessity of cesarean in clinical practice. Additional language has been added to this paragraph to help strengthen the point that cesarean delivery is not without any advantage.

Textual edits –

- Lines 118-119: “Cesarean delivery can be life-saving and morbidity reducing in specific clinical scenarios.”³

Lines 63-65: It is important to discuss the idea that the correlation between cesarean rate and infant mortality is an association and does not imply a causal relationship. The author mentioned that the cited study adjusted for maternal age, fetal sex, and country wealth, but there are many other factors that are likely confounding this relationship (e.g., risk factors for cesarean delivery that are also risk factors for neonatal complications.)

Thank you for this comment. The studies discussed in lines 60-78 (and Table 1) are population level analyses (global ecologic studies) using international data to explore the relationship between national cesarean rates and neonatal and maternal mortality. As observational studies, these cannot demonstrate causation. The current language describing these studies is appropriate for their design (e.g., correlation, association). To further emphasize this point, additional language has been added to the manuscript.

Textual edits –

- Line 73: “These studies do not demonstrate causation, but ...”

Lines 75-79: Explain the use of ICD diagnosis of low-risk and high-risk to stratify cesarean deliveries? Has this method been validated? Do providers accurately code deliveries? What are some examples of ICD codes used?

Thank you for this question. The Agency for Healthcare Research and Quality (AHRQ) and the Joint Commission first developed a definition of the “low risk” nulliparous, term, singleton vertex (NTSV) population using International Classification of Diseases (ICD) diagnosis codes.¹² This definition was adapted and validated by the Society for Maternal Fetal Medicine (SMFM) using claims data from approximately 860,000 deliveries in the Nationwide Inpatient Sample database.¹³ Upon transition from ICD 9th revision codes to 10th revision codes, SMFM updated this definition to be consistent with modern ICD coding.¹⁴ We added additional language explaining this background to the manuscript text. The SMFM ICD code list to produce this

defined population is extensive and not included, but a few examples of SMFM coded conditions have been added.

Use of ICD codes within insurance claims databases risks under ascertainment based on the limitations of coding. However, these data sources can be optimal for specific research questions based on their large sample size and defined and validated ICD codes for diagnoses. Further discussion of the benefits and limitations of research using ICD codes is beyond the scope of this commentary.

Textual edits –

- Lines 82-87: “Initially developed by the Agency for Healthcare Research and Quality (AHRQ) and the Joint Commission (JC), SMFM further adapted and validated a “low risk” for cesarean delivery definition using International Classification of Diseases (ICD) diagnosis codes.²⁸⁻³⁰ The codes used by SMFM exclude individuals with contraindications to vaginal delivery (e.g., placenta previa), as well as those with “high risk” conditions (e.g., diabetes mellitus).”

Lines 85-88: Discuss the “risk-adjustments” and clarify how they affected the hospital differences? All hospitals likely should not have the same benchmark, as some hospitals care for patients with more complications, are a referral center, etc.

Thank you for this question and comment. The specific study (Main et al) discussed was a cross-sectional study of livebirths in California hospitals between 2016 and 2017. The primary analysis was ‘risk-adjusted’ through restriction to the nulliparous, term, singleton vertex (NTSV) population (consistent with Joint Commission definition). The authors completed a secondary analysis that was further restricted to the “lowest risk” individuals, which was defined as exclusion of individuals 35+ years, with a body mass index (BMI) >35 kg/m², with gestational age >40 weeks’ gestation, or with additional maternal comorbid conditions including preeclampsia).⁶ To address your question, we added further details of this study to the manuscript text to clarify the additional “risk adjustment.”

We agree that consideration of the risk for cesarean of patients served at a specific hospital (e.g., based on patient co-morbidities) is impactful for the cesarean rate. The goal of the restriction approach is to “equalize” for comparison (i.e., eliminate those with the highest risk factors for cesarean), and therefore, allow for comparisons among hospitals and providers of similar patients. As you highlight, restriction is not a perfect methodology. Further, as we outline, a concern with restriction approaches is the production of cesarean rate target that does not address the full patient population we care for, including those with comorbid conditions.

Textual edits –

- Lines 96-99: “Further risk-adjustment (excluding individuals ages 35+, with body mass index > 35 kg/m², >40 weeks’ gestational age, or with medical complications) did not significantly alter the between hospital differences.^{32”}

Lines 91-99: Provide a brief overview of the Robson classification system. Consider including this as an additional table.

Thank you for this recommendation. An additional table has been added reflecting the Robson 10-group cesarean classification system.

Textual edits –

- Addition of Table 2

Table 2. Robson Classification System

Group	Description
1	Nulliparous, singleton, cephalic, ≥37 weeks Spontaneous labor
2	Nulliparous, singleton, cephalic, ≥37 weeks Induced labor or cesarean before labor
3	Multiparous without history of cesarean, singleton, cephalic, ≥37 weeks Spontaneous labor
4	Multiparous without history of cesarean, singleton, cephalic, ≥37 weeks Induced labor or cesarean before labor
5	Multiparous with history of cesarean, singleton, cephalic, ≥37 weeks
6	Nulliparous, breech
7	Multiparous with or without history of cesarean, breech
8	Multifetal pregnancy with or without history of cesarean
9	Abnormal fetal lie with or without history of cesarean
10	Singleton, with or without history of cesarean, cephalic, <37 weeks

Lines 100-108: Articulate the intuitive idea that cesareans do have clear benefit in many situations somewhere in this paragraph or elsewhere in the manuscript.

Thank you for this comment. In this paragraph, we discuss that while we work towards a reduction in cesarean rates, there is likely a cesarean rate that is “too low” and would result in increasing morbidity and mortality. The language has been further strengthened to specifically state that cesarean deliveries can be lifesaving and morbidity reducing.

Textual edits –

- Lines 118-119: “Cesarean delivery can be life-saving and morbidity reducing in specific clinical scenarios.”³

Lines 127-138: Great discussion of VBAC success prediction model and the 70% cutoff for morbidity equivalence. Consider including a discussion on clinical prediction tools for successful induction of labor. These could be of value in populations at higher risk of complications (patients with obesity, hypertension, etc) that are mentioned in the paper as being a limitation to a one-size fits all cesarean rate target. If higher risk of a cesarean due to a failed induction of labor arrest disorder could be predicted, an unlabored cesarean section might improve outcomes.

Thank you for this comment. We selected the VBAC prediction model and this specific study as an illustrative example of how a clinical tool can help inform morbidity risk. As you highlight, there are additional risk prediction models for many clinical scenarios, including the one developed by Rossi et al for prediction of cesarean delivery among individuals undergoing induction of labor.¹⁰ We did not previously include this specific study (or other prediction models) as most others do not specifically correlate to morbidity outcomes. In response to your input, we added the Rossi et al reference to the manuscript.

Textual edits –

- Lines 238-242: “Rossi et al developed and validated a seven-variable risk calculator for cesarean delivery among individuals with liveborn singletons undergoing induction of

labor between 32- and 42-weeks' gestation.⁶⁹ Prediction models can inform an individual's risk and guide counseling. However, care must be taken to consider the larger clinical context and not rely on a single predicted value alone to guide care."

Lines 153-157: By what criteria are EFM-based guidelines "seemingly objective"? This contradicts several mentions of EFM management being subjective. Please clarify. Are providers using certain criteria to guide decision-making regarding EFM and cesarean delivery? Additionally, are providers using appropriate or standardized criteria to guide their decisions to move to cesarean delivery in the setting of abnormal labor curves?

Thank you for these questions. Electronic fetal monitoring (EFM) guidelines use objective criteria to define categories of fetal heart rate tracings (e.g., Categories I-III).¹⁵ Category II tracings, which account for 80% of tracings, include a wide swath of characteristics. While review articles and guidelines exist to help guide management of Category II tracings, there is significant uncertainty and subjectivity of decision making for these tracings.¹⁶ We made additional edits to the text to clarify this language.

Textual edits –

- Lines 166-168: Guidelines categorize fetal heart rate tracings to determine level of reassurance (e.g., Category I) or non-reassurance (e.g., Category III), but the majority of tracings are Category II.^{46,47"}

Lines 181-183: Great point about patient values. The risks of cesarean delivery are highlighted constantly in the literature and to patients, but the risks of vaginal delivery are rarely discussed and are not negligible. The risks of a cesarean delivery after a long labor that the provider persisted towards in the name of preventing a cesarean are also worth considering. If we had better prediction models and chose appropriate candidates for primary cesarean section, would they be associated with improved outcomes?

Thank you for these comments and question. We agree that the decision-making around mode of delivery can be complex. We agree that in certain clinical scenarios, an outright cesarean may be preferred, and beneficial in the larger effort of morbidity reduction. We added some additional examples where this nuance may be at issue (e.g., arrest of descent, fetal growth restriction). We also discuss the development of a prediction model for cesarean in individuals undergoing induction that may inform these decisions.¹⁰

Textual edits –

- Lines 232-242: "Further examples of complex clinical scenarios requiring intentional decision making abound. The frequency of operative vaginal delivery has declined while the rate of cesarean delivery has increased for arrest of descent in the second stage of labor.⁶⁵ Operative vaginal delivery can avoid cesarean and its associated morbidity, but risks of failed operative delivery and long-term pelvic floor dysfunction are necessary considerations.⁶⁶⁻⁶⁸ A cesarean delivery from the outset may be preferred in some clinical scenarios (e.g., fetal anomalies, fetal growth restriction, maternal cardiac conditions) to reduce overall morbidity. Rossi et al developed and validated a seven-variable risk calculator for cesarean delivery among individuals with liveborn singletons undergoing induction of labor between 32- and 42-weeks' gestation.⁶⁹ Prediction models can inform an individual's risk and guide counseling. However, care must be taken to consider the larger clinical context and not rely on a single predicted value alone to guide care."

Lines 184-197: This is an interesting discussion, but is it clinically relevant, as there are so few providers offering breech vaginal delivery today? I would consider omitting this paragraph, as it is probably largely historical at this point.

Thank you for this input. We agree that this is a rather unique, and increasingly rare, clinical question. However, we included the breech singleton vaginal delivery paragraph as an illustration of the risk-benefit tradeoffs of this scenario and necessity to consider patient autonomy and values. We kept this paragraph in the current draft but are open to omitting if preferred by the reviewers/editors.

Line 201-202: Similarly, to before, this association likely has many confounders.

Thank you for this comment. See above regarding language modifications surrounding association and causality.

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Thank you for this information. The current draft reflects person-first language.

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 has adopted the use of the reVITALize definitions. Please access the obstetric data definitions at <https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-obstetrics-data-definitions> and the gynecology data definitions at <https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-gynecology-data-definitions>. If use of the reVITALize definitions is problematic, please discuss this in your point-by-point response to this letter.

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Thank you for this information. We intend to follow the traditional publication route.

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