OBSTETRICS & GYNECOLOGY

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

Date: Mar 08, 2019
To: "Jennifer A Callaghan-Koru" [redacted]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-18-1619R1

RE: Manuscript Number ONG-18-1619R1

Implementation of the safe reduction of primary cesarean births safety bundle in Maryland

Dear Dr. Callaghan-Koru:

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 Mar 29, 2019, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1: The authors present their revised manuscript regarding safe reduction of primary cesarean births safety bundle in Maryland.

1. The abstract is written clearly, and contains an appropriate amount of information.

2. The introduction is well written and sets the stage for the remainder of the manuscript.

3. Materials and methods - it is not clear whether or not the hospitals were instructed on best practices for implementation (the 15 strategies described) during the roll out. Please clarify.

4. The results section is a bit difficult to follow for those who are not familiar with the bundle prior to reading your article. Consider further editing to perhaps define the 15 implementation strategies and the bundle items prior to providing the percentage compliance with each.

5. Table 2 may be better represented in graphical format as a bar graph.

Reviewer #2: This preliminary report of the first year of implementation of the state of Maryland's collaborative effort to initiate the Alliance for Innovation in Maternal Health's (AIM) suggested 26 "bundles" (that are designed to reduce cesarean deliveries for low risk term patients) fails to provide any useful information for our field. The report was based on a survey of the one collaborative leader at each of the 27 responding hospitals and the results could not, in any way, be validated; nor did the results demonstrate any useful data. The most you could conclude was that "Hospitals reported substantial variability in implementation of most bundle practices". It is too early to discern if there has been any impact on cesarean utilization.

Reviewer #3: The authors sought to describe status of a statewide implementation of maternal primary cesarean delivery patient safety bundle one year after implementation in Maryland. An online survey was completed by participating hospitals one year after the bundle was initiated. There were 26 practices recommended in the bundle and 15

implementation strategies that were evaluated. It was then determined whether hospital characteristics and implementation strategies were associated with bundle implementation. The only hospital characteristic found to be associated with significantly more bundle implementation was hospitals that had >20 obstetricians. Six specific implementation strategies were associated with full implementation of more bundle practices.

A bundle is a structured set of practices that, when implemented together, improve patient care and outcomes. Each component by itself might not directly improve outcomes, but when used together, can positively impact outcomes. Therefore, implementation of each aspect of a bundle is of utmost importance in achieving the end goal. Identifying barriers to implementation of bundle components and implementation strategies that are associated with greater implementation rates are crucial.

-The bundle components are a "list of evidence-based clinical practice" (lines 143-144) that are "designed to be adaptable, allowing each hospital to choose which bundle components to implements and in what order, given local context" (line 147-148). While this allows flexibility of implementation for very different hospitals with different characteristics and needs, I wonder if this allows for deviation such that a component of the bundle changes significantly depending on one hospitals interpretation and implementation of that bundle element. The components of the bundle are very general. There could be great variation in practice implementation of the same bundle element. This would effectively "un-bundle" the bundle and affect patient outcomes.

-Lines 358-365: If this bundle component is of higher importance, should more effort be made to facilitate earlier implementation of this element? Though there is difference in practice and hospital culture, there are guidelines for labor arrest diagnosis. Were these guidelines implemented, or was it left up to each hospital to determine their own set of guidelines? Similarly, for non-reassuring fetal status- how do we ensure that all hospital guidelines for interpretation and management are concordant with established guidelines?

- Six strategies were associated with more bundle component implementation. More research will be needed to determine if these should be the focus for implementation strategies and ultimately if it impacts patient outcomes.

-Strengths of the study include number of participating hospitals in Maryland (31 of 32 hospitals), high number of completed surveys (27 of 31 hospitals), and variation in hospital characteristics (level 1 to level 4 hospitals, rural and non-rural, teaching and private hospitals, presence of midwives, etc).

Patient outcomes before and after bundle implementation will be very interesting to examine. This will help to validate those implementation strategies that are associated with full implementation of more bundle practices. On the premise that complete implementation of the bundle is associated with best patient outcomes, identifying implementation strategies that facilitate this will be imperative.

Reviewer #4: This is an article reporting on the implementation of patient safety bundles in response to rising rates of primary cesarean deliveries. The report reviews Maryland hospital implementation, both prior to and during the first year of the collaboration.

In reading the article, there are a couple general concerns that come up initially. It appears that the year in review in academic year 2016-2017, between July 2017 and August 2017. And hospitals were assessed in their implementation prior to that (presumably 2015-2016). There seems to be a delay in the reporting of this data, and I would just ask the authors to explain the 18+ months? Second, I feel that the target audience might be a bit off here. As a feet-on-the-ground obstetrician-gynecologist, I am not sure what the interest level or applicability to practice might be? This appears to be targeted to hospital administrators, or health system leaders. That is not to say one cannot have a grass roots interest in this important topic.

Introduction:

Line 119 - I understand the sentence, but it does read as if a women experiencing a primary cesarean delivery is at risk for uterine rupture, etc, in the index pregnancy, as opposed to a subsequent pregnancy as I think intended.

Methods:

Line 213 - Curious what classifies as major, minor and non-teaching status.

Line 224 - Again, related to the delay in the reporting, would there have been a better way to get a complete data set on the 31 hospitals?

Results:

Line 237 - There seems to be a large distribution of what qualifies as a collaborative leader, which makes one thoughtfully

consider how the survey was answered, and what level of knowledge and participation the individual actually has.

Discussion:

Line 390 - The limitations I think limit the data and overall conclusions, especially the fact that the data could not be otherwise validated.

EDITOR COMMENTS:

1. I've read your manuscript and the divergent reviews of it. You are to be commended for the work of the MPQC in this arena. Hopefully you will be able to report the outcome. I think overall that the major criticism of the unenthusiastic reviewers is that its not clear what this should mean to the practicing Ob GYN. I've been involved in our own PQCNC projects and unfortunately, the lack of enthusiasm by some MD's seems to be part of the problem of these types of projects. In order to make it relevant to our readers (mostly clinicians) , you need to write this to them. As written, it seems to be targeted more at a QI, implementation Science or health administration audience. That's of course up to you, but my comments below will be made on the assumption that you intend this for a clinical audience.

Abstract: For those unfamiliar with AIM, bundles and quality collaborative, the abstracts is somewhat opaque. The objective is fine, but the Methods section should tell the reader a bit about MPQC, AIM and the bundle. Something like "The Alliance for Innovation in Maternal Safety bundle to decrease the first cesarean guides labor and delivery units in the adoption from among 26 evidence based practices that are hospital appropriate. Selection and implementation of the practices involve changes in physician, midwife, nursing and hospital administration practices. One year after the MPQC began this project, local hospital leaders for the AIM project were sent a computer-based survey to assess results. Descriptions of hospital characteristics were collected as part of MPQC.

In the Results section, its not clear if 8.6 practice adoptions is a lot? What does this mean to the doc in practice?

Address similar issues in the main article.
Line 119: Not clear here. Maybe say something like risks in future pregnancies for women with a prior cesarean.....and they increase with the number of prior cesareans.

162: is it relevant that you are the first to do this? If this is just bragging rights (which you have earned), probably should drop it from the paper. If its relevant, explain why. Also, how do you know?

In the methods, section or perhaps in the supplemental digital content, please provide some information about how the Collaborative project was organized

Line 168-171 is unclear. I can't tell from the sentence structure who began implementing the bundles. Perhaps:
The MPQC is coordinated by the Maryland Patient Safety Center and participation in the Collaborative project was voluntary. Of the 32 birthing hospitals in Maryland, 31 participated from xxx-yyyy (dates). The hospitals began implementing the cesarean bundle practices that they selected in June 2016.

In the tables, could you include a brief table grouped by level of care?
It might be interesting to present a big graphic with the individual components liste in column 1, with each hospital anonymously listed across the top.
You could then color code for each hospital whether they already had it in place prior to starting, and then what they did w/ that component (Started it, fully implemented, etc) That way the reader could see which bundle components had wide implementation and which did not.

In your discussion, please add some content that speaks to the doctors' involvement a bit more.

2. 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:

a. OPT-IN: Yes, please publish my response letter and subsequent email correspondence related to author queries.
b. OPT-OUT: No, please do not publish my response letter and subsequent email correspondence related to author queries.

3. 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.

Any author agreement forms previously submitted will be superseded by the eCTA. During the resubmission process, you are welcome to remove these PDFs from EM. However, if you prefer, we can remove them for you after submission.

4. 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.

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 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.

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 print appendixes) but exclude references.

7. 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).

8. 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.

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.

10. 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.

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. Figure 1: Please add axis labels and add color to the graph.

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.

14. If you choose to revise your manuscript, please submit your revision via Editorial Manager for Obstetrics & Gynecology at http://ong.editorialmanager.com. It is essential that your cover letter list point-by-point the changes made in response to each criticism. Also, please save and submit your manuscript in a word processing format such as Microsoft Word.

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 Mar 29, 2019, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

Nancy C. Chescheir, MD
Editor-in-Chief

2017 IMPACT FACTOR: 4.982
2017 IMPACT FACTOR RANKING: 5th out of 82 ob/gyn journals

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Date: Dec 18, 2018
To: "Jennifer A Callaghan-Koru" [redacted]
cc: "Andreea A. Creanga" [redacted]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-18-1619 - Audit Comments

RE: Manuscript Number ONG-18-1619

Implementation of the safe reduction of primary cesarean births safety bundle in Maryland

Dear Dr. Callaghan-Koru:

The comments from the audit of your submission are included below. Please note that the file is technically being categorized as a "Revision" by Editorial Manager. You will find the submission record under the Revision section of your Author account. When you are ready to resubmit an updated version of your submission, please use the 18-1619 submission record (do not create a New Submission). The manuscript will be assigned to Dr. Chescheir and sent for peer review.

If you have any questions, please contact Randi (rzung@greenjournal.org).

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 Jan 14, 2019, we will assume you wish to withdraw the manuscript from further consideration. If you need an extension, please let Randi know.

REVIEWER COMMENTS:

Audit Reviewer #1:

Terminology is confusing: in the intro, authors explain that an IHI patient safety bundle encompasses 3-5 interventions. Then they say that bundles through the AIM program include 12-15 components. In the Methods section, they explain that the AIM cesarean bundle has 14 components, under four domains and then derive 26 clinical practices in 19 steps. Then they looked at each of the 26 practices and assessed where on the 6-tier implementation spectrum a hospital was at the end of a year. And then they identified 15 implementation strategies, to see who was using which of the 15 possible strategies for any of the 26 practices. That's a lot of quality improvement jargon that is a tough chew for the practicing ob physician. The 19 step concept was mentioned once and was confusing, as it was never revisited. Nor do they discuss why AIM bundles have 12-15 components, which is many more components than the 3-5 interventions that the IHI initially described. Or are interventions not the same as components. The information provided is good, but the QI terms should be clarified.

The data correlating use of specific implementation strategies with actual implementation is most interesting; please suggest specifically how this could be understood or explored more thoroughly (l.5-8, pg 19).

Figure #1 is excellent in the color differentiation, although solid, as opposed to shaded, blocks, would be easier to grasp at a glance.

Explain how long the collaborative in Maryland is scheduled to be in place; at what point will/should implementation be externally imposed, for instance. On a philosophical note, the prompt implementation of hemorrhage and hypertension bundles may not carry over into cesarean reduction bundles, if there is not a true desire on the part of physicians to decrease cesarean rates. While physicians undoubtedly want less hemorrhage and stroke/seizure morbidity from hypertension, it is not at all clear that there is true personal motivation to decrease the cesarean rate.

The authors are to be commended for their restraint in not arguing forcibly that more should be done quickly, especially in purported level 3 and 4 hospitals, to implement these bundles.

Audit Reviewer #2:

Abstract, pg 6, lines 4-8: The statistics do not support these conclusions, based on small samples and low power.

Table 3: Since the sample size was n = 26, there would be little stats power to discern any differences and to generalize any NS findings. On the other hand, since 9 characteristics were tested, the inference threshold should be more conservative than .05, so that conclusion may be spurious.

Table 4: Same issue with low power and non-generalizability of NS findings. Again, should use a stricter threshold than .05, which would nullify the apparently significant associations.

Thank you again for allowing us to reconsider your manuscript.

Sincerely,
The Editors of Obstetrics & Gynecology

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