

OBSTETRICS & GYNECOLOGY



NOTICE: This document contains correspondence generated during peer review and subsequent revisions but before transmittal to production for composition and copyediting:

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

**The corresponding author has opted to make this information publicly available.*

Personal or nonessential information may be redacted at the editor's discretion.

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

Date: Jul 09, 2020
To: "Joshua D. Dahlke" [REDACTED]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-20-1679

RE: Manuscript Number ONG-20-1679

Seeing the Forest for the Trees: The Case for Standardizing Cesarean Delivery Technique

Dear Dr. Dahlke:

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).

Due to the COVID-19 pandemic, your paper will be maintained in active status for 30 days from the date of this letter. If we have not heard from you by Aug 08, 2020, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1: Cesarean delivery is the most common abdominal surgery in the world. Despite many articles regarding this surgery, this procedure is not standardized. This article is a commentary which evaluates over 370 randomized-controlled trials and proposes an evidence-based standardized approach to cesarean delivery (CD).

(49-54) The abstract makes 3 valid arguments as to why CDs should be standardized, and consistency and uniformity in procedures certainly improve patient safety. Therefore, this is an important article which makes an argument for standardization of CD to improve overall patient outcomes.

(66-67) Although uniformity is important in optimizing patient safety, it is equally important for resident physicians to understand that there are many steps to a CD and that each different step may not have a concrete answer as to how it should be done.

(125-136) I fully appreciate the scenario of a resident physician scrubbing and trying to remember what the attending physician's particular nuances are for a CD. As a learner, it can be frustrating to have to remember all the different ways to do a CD. Part of residency training is learning different ways to achieve the same outcome.

(154-162) The author brings up the subject of why would standardizing CD be beneficial when randomized controlled trials do not demonstrate a benefit of a certain technique over the other. I am pleased that the author addresses this, as many who read this article will be asking themselves the same question. If RCTs don't prove a technique or omission of the technique is optimal, then this goes back to physician preference and comfort level.

(258-269) Uterine repair (in situ or exteriorized) has been demonstrated to provide various outcomes both ways. The authors' recommendation to repair the uterine incision via exteriorization is not a strong argument and should not be standard. A patient with extensive scar tissue should not have the uterus exteriorized which could lead to intraabdominal injury. As much as CDs should be standardized, there will always be exceptions to the rule.

(272-291) Recommendation for single uterine closure based on the CORONIS trial is understandable. However, one must review the many RCTs besides the CORONIS trial which conclude double layer closure leads to fewer uterine ruptures. I don't feel a recommendation of single layer closure should be standardized based on 1 RCT selectively chosen by the authors.

I appreciate the authors' desire to standardize the most common abdominal surgery in the world. However, this article does not add new information to the previous articles published regarding recommendations during each step of the

procedure. This is another article which reviews each particular step of a CD and attempts to standardize this procedure. While I agree that CDs should be standardized as much as possible, there are so many confounding variables during the surgery that unless multiple RCTs strongly favor a technique or omission of a technique, ultimately it returns to a physician's preference and training.

Reviewer #2: In their commentary, Dr. Dahlke et al. review the evidence surrounding individual components of the cesarean delivery and advocate for the adoption of a standardized approach. They outline how a cesarean delivery should be performed, in their opinion, guided by the data. The review is thoughtful and timely, and the proposal for a universal technique is interesting and fitting for a commentary piece.

To strengthen their argument, the authors could consider the following points, which more skeptical readers may raise:

- 1) The authors suggest that standardizing certain aspects of cesarean deliveries has improved patient outcomes, specifically interventions to reduce surgical site infections. There is no high quality evidence that standardizing the entire cesarean delivery approach results in improved outcomes. Perhaps the first step towards universal adoption of a standardized technique is a trial comparing standardization vs. non-standardization. The authors cite a study of standardization, but it is observational, and the protocol was different than the one proposed. What would the authors propose as a primary outcome for such a study (infection, time, complications)? What would the net benefit need to be to advocate for its use?
- 2) The authors suggest that standardization could allow for quality assessment, and they cite using time as a means for comparison. Is there evidence to suggest that these time comparisons would be meaningful?
- 3) How do the authors envision a "standard" cesarean delivery in practice? They outline their proposed technique based on the review of the evidence today, but how do they propose the "standard" practice be updated? (For example, would an update be envisioned annually?) How do you think this would impact dissemination or adoption in practice?
- 4) In the absence of overwhelming evidence for its use, universal adoption of a single technique seems unlikely. Other than proposing it as a concept, how do the authors envision such a protocol would be rolled out in clinical practice? Is it the responsibility of individual clinician, hospitals, professional societies, or payers to ensure compliance? How would you get buy-in from clinicians who have seen practice recommendations related to cesarean change over time?

[As a minor note, the authors might consider rephrasing or expanding their section on "Other CD Technical Aspects." While I understand their intention, the recommendation to "omit reiki/prayer" seems a bit off-putting and might be better specifically stated as "Omit reiki/prayer for post-operative pain control" or something similar, if they feel compelled to include it.]

Reviewer #3: The authors from 4 different major academic institutions present the case for standardizing the surgical approach to cesarean delivery pulling from the medical-educational-safety cultures of medicine. They summarize 370 RCTs, and make recommendations about standard surgical steps/techniques common to all cesareans. Like all modern day recommendations there are competing forces between standardization and personalization.

I commend the authors for translating the information into clinical recommendations. This is well written and easy to read. because cesarean is common to every single institution it is important! Yet when change is recommended there is always pushback. I would lend 1-2 paragraphs discussing either clinical situations that mandate a change from your standardization example BMI of 50-60 with an overhanging panus: still a pfannenstiel? Does one still use a pfannenstiel on the 6th cesarean. No bladder flap during a second stage cesarean? I think validating that there will be necessary deviations in surgical technique is important. DO you expect that surgical technique can be followed 70-80% of the time? After all we are also taught to problem solve for complex situations. Are there scenarios when sharp subcutaneous and fascia dissection will need to be done ?or when the rectus muscle is adhered to the uterus and needs to be cut?

I don't think you will get much pushback from the institutional list and I imagine that MOST hospitals have adopted cesarean bundles. The major change is the individual surgeon especially in private practice settings where they have done "individual standardization" (based on their own training in residency) over the years that works for them, There is a tendency for this commentary to simplify cesarean.

Please comment on "Not all cesareans are equal" There are 5-6 different common clinical scenarios that i recommend you discuss

1. Higher order cesarean number, Each week many women are needing a 4,5,6,7 th repeat cesarean
2. Morbid obesity: Each week women with BMIs of 40.50,60s have cesareans

3. Late labor cesareans for second stage arrest when anatomy is distorted and the biggest mistake is going to low
4. Emergencies" prolapsed cord,
5. Preterm less than 32 weeks/ the micro premies at 23- 24 weeks
6. fibroids

EDITOR COMMENTS:

We no longer require that authors adhere to the Green Journal format with the first submission of their papers. However, any revisions must do so. I strongly encourage you to read the instructions for authors (the general bits as well as those specific to the feature-type you are submitting). The instructions provide guidance regarding formatting, word and reference limits, authorship issues and other relevant topics. Adherence to these requirements with your revision will avoid delays during the revision process by avoiding re-revisions on your part in order to comply with formatting.

Numbers below refer to line numbers.

30. The précis is a single sentence of no more than 25 words, written in the present tense and stating the conclusion(s) of the report (ie, the bottom line). The précis should be similar to the abstract's conclusion. Do not use commercial names, abbreviations, or acronyms in the précis. Precis should be the "hook" for people who scan the Table of Contents to see what to read. It shouldn't not include statements like "in this study" or "we found". Just state what you found.

The journal style does not support the use of the virgule (/) except in mathematical expressions. Please remove here and elsewhere.

48. It's not clear what you mean here. There are certainly more than 17 technical aspects of performing a cesarean. Do you mean that of the many steps in performing a cesarean, you have identified 17 that have significant evidence from your reviews and that of these, 10 should be incorporated and 7 should not?

49. I recommend you move lines 49-54 the 2nd sentence in your abstract. You need to convince the reader why this is important right up front

101. What do you mean by "education"? Whose education?

105. What do you mean by "the previous systematic review"? You've already said that there were several and the preceding 2 paragraphs discuss 2 of them? Please name the one and give the year specifically of the one you are referencing here.

136. This may be a good place to address reviewers' comments regarding "exceptions" to the standardized approach you are recommending. In particular, these exceptional circumstances are likely to be opportunity for learners to gain experience from experienced obstetricians about how to address these exceptions, for which there is less likely to be standardized approaches with strong evidence. I really encourage you to make a comment up front before your individual recommendations that just as important as standardization, one must practice and teach when non standard approaches are warranted. The 80/20 rule likely applies here.

144. Did this study demonstrate any improvement in patient outcome or other patient centered outcome?

247. Since you state that the one RCT did not demonstrate benefit, it is surprising to see that you recommend it "when placental membranes are seen". Is that what the RCT showed? Was it non beneficial if membranes were not seen, but beneficial if there were membranes seen? Perhaps the recommendation should read "perform intrauterine wiping ONLY when placental membranes are seen. "

252. what do you mean by "our previous review"? Did this author group publish a prior review?

300. OMG...Dr. Cefalo who was my division director and mentor just rolled over in his grave...how many times did I hear him say "The solution to pollution is dilution"????

305. Should this be "and it was a technical step"? You provide the findings of the CORONIS study here specifically to support your recommendation but not the other RCT and systematic review. Did they report the same thing?

320: Given the RCT showing a significant decrease in composite wound complications, which I believe was the primary outcome of the study, why are you recommending against it? The individual rates were likely secondary outcomes and papers are generally not powered to these individual components of a composite outcome.

333. You don't provide any comment in your background for this recommendation re: locked vs unlocked. Please do—otherwise, all you've provided background for is absorbable v non absorbable.

On page 30 you start with "Appendix 1" and it gets very confusing from there. You don't even mention the institutional standardization from your appendix in the paper and it contains important information. I recognize that there are word limits and you likely struggled with how to include this content. I recommend that you mention in the manuscript that you addressed, in a similar fashion, non-surgeon related steps at the institutional level and the recommendations are included in the table in the manuscript, but that the explanations for why you made these explanation are in supplemental digital content.

APPENDIX: contains a lot of material that is surgeon dependent, not institutional, or duplicates material from the main body of the manuscript.

53. Is there any data on effect of lateral tilt intraoperatively on maternal nausea? Also, it seems there is weak evidence here for the outcomes of note.

124. I don't understand "Incisional adhesive drapes". I am familiar with drapes that are adhesive with a wide window without an adhesive material for the incision built into the drape—I would consider these an "adhesive drape". Are you instead reporting on a drape with an adhesive over the entire surgical field through which the surgeon makes her incision?

I've provided some examples below but it's not exhaustive. Please put all of the surgical step techniques in the main body of the paper and the institutional steps in the appendix.

line 134 Duplicates content from manuscript starting on line 193 in main manuscript
159 is a surgical step.

167-183: duplicative of manuscript content

185: move to manuscript

220—276 : duplicative

278: move to manuscript

284-317-Duplicative

I suspect there was some version control issue in your submission but it's really quite confusing from page 30 on.

EDITORIAL OFFICE COMMENTS:

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

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

2. Obstetrics & Gynecology uses an "electronic Copyright Transfer Agreement" (eCTA). When you are ready to revise your manuscript, you will be prompted in Editorial Manager (EM) to click on "Revise Submission." Doing so will launch the resubmission process, and you will be walked through the various questions that comprise the eCTA. Each of your coauthors will receive an email from the system requesting that they review and electronically sign the eCTA.

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

3. 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.

4. 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.

5. 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).

6. 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 limit for Current Commentary articles is 250 words. Please provide a word count.

7. 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.

8. 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.

9. The manuscript has a few mentions of the CORONIS trial being the largest multicenter RCT. Please make sure you have a citation to support this statement. You could probably also reduce the number of times you state that fact.

10. 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.

11. Each supplemental file in your manuscript should be named an "Appendix," numbered, and ordered in the way they are first cited in the text. Do not order and number supplemental tables, figures, and text separately. References cited in appendixes should be added to a separate References list in the appendixes file.

12. Authors whose manuscripts have been accepted for publication have the option to pay an article processing charge and publish open access. With this choice, articles are made freely available online immediately upon publication. An information sheet is available at <http://links.lww.com/LWW-ES/A48>. The cost for publishing an article as open access can be found at <https://wkauthorservices.editage.com/open-access/hybrid.html>.

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

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

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

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

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

***Again, your paper will be maintained in active status for 30 days from the date of this letter. If we have not heard from

you by Aug 08, 2020, we will assume you wish to withdraw the manuscript from further consideration.***.

Sincerely,

Nancy C. Chescheir, MD
Editor-in-Chief

2019 IMPACT FACTOR: 5.524

2019 IMPACT FACTOR RANKING: 6th out of 82 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.

21 July, 2020

The Editor

Obstetrics & Gynecology

RE: Seeing the Forest for the Trees: The Case for Standardizing Cesarean Delivery

Technique

Dear Editors:

Thank you for the opportunity to revise our manuscript for consideration for publication in the *Obstetrics & Gynecology*. I time and comments provided by the peer reviewers are very much appreciated as well. Enclosed in this cover letter are our responses and recommended changes made to our manuscript:

Reviewer #1: Cesarean delivery is the most common abdominal surgery in the world. Despite many articles regarding this surgery, this procedure is not standardized. This article is a commentary which evaluates over 370 randomized-controlled trials and proposes an evidence-based standardized approach to cesarean delivery (CD).

(49-54) The abstract makes 3 valid arguments as to why CDs should be standardized, and consistency and uniformity in procedures certainly improve patient safety. Therefore, this is an important article which makes an argument for standardization of CD to improve overall patient outcomes.

Thank you for the comment

(66-67) Although uniformity is important in optimizing patient safety, it is equally important for resident physicians to understand that there are many steps to a CD and that each different step may not have a concrete answer as to how it should be done.

Thank you for the comment. We recognize the variation of CD surgical technique taught throughout residencies. An important goal of our commentary is to acknowledge that the number of RCTs and systematic reviews/meta-analyses has exceeded clinicians' and residents' ability to stay current on evidence based techniques and our approach provides a standardized, evidence-based template for most cesareans.

(125-136) I fully appreciate the scenario of a resident physician scrubbing and trying to remember what the attending physician's particular nuances are for a CD. As a learner, it can be frustrating to have to remember all the different ways to do a CD. Part of residency training is learning different ways to achieve the same outcome.

Thank you for the comment. Our position is that a standardized approach should be the default way to teach CD and that this would likely improve outcomes.

(154-162) The author brings up the subject of why would standardizing CD be beneficial when randomized controlled trials do not demonstrate a benefit of a certain technique over the other. I am pleased that the author addresses this, as many who read this article will be asking themselves the same question. If RCTs don't prove a technique or omission of the technique is optimal, then this goes back to physician preference and comfort level.

Thank you for the comment. We believe that standardization may have more benefit as it relates to system efficiency, patient outcomes, resident training and evaluation, and improved future trials than physician preference and comfort level.

(258-269) Uterine repair (in situ or exteriorized) has been demonstrated to provide various outcomes both ways. The authors' recommendation to repair the uterine incision via exteriorization is not a strong argument and should not be standard. A patient with extensive scar tissue should not have the uterus exteriorized which could lead to intraabdominal injury. As much as CDs should be standardized, there will always be exceptions to the rule.

Thank you for the comment and your point is well taken. We have included the following in the manuscript to address the concern: "We acknowledge that not all cesareans are created equal and alterations to our standardized approach will be necessary in certain circumstances in which physician judgement and experience should play an important role. If a standardized approach becomes the primary technique taught to trainees, opportunities to highlight clinical scenarios that warrant modifications to this technique become strengthened. For example, a history of multiple prior cesarean deliveries or significant obesity may require modifications to abdominal entry techniques, and uterine exteriorization may not be possible when there is extensive intraabdominal adhesive disease."

(272-291) Recommendation for single uterine closure based on the CORONIS trial is understandable. However, one must review the many RCTs besides the CORONIS trial which conclude double layer closure leads to fewer uterine ruptures. I don't feel a recommendation of single layer closure should be standardized based on 1 RCT selectively chosen by the authors.

Thank you for the comment. As mentioned in the manuscript, we acknowledge uterine closure remains controversial. We prioritized CORONIS trial long-term (3-year follow up) data because it addresses the most clinically relevant outcome, uterine rupture. While the other RCTs are well designed, there is no compelling evidence that a thicker residual myometrial thickness has clinical relevance or implications for future pregnancy outcomes.

I appreciate the authors' desire to standardize the most common abdominal surgery in the world. However, this article does not add new information to the previous articles published regarding recommendations during each step of the procedure. This is another article which reviews each particular step of a CD and attempts to standardize

this procedure. While I agree that CDs should be standardized as much as possible, there are so many confounding variables during the surgery that unless multiple RCTs strongly favor a technique or omission of a technique, ultimately it returns to a physician's preference and training.

Thank you for the comment. Two previous systematic reviews on this topic (Berghella et al, AJOG 2005 and Dahlke et al, AJOG 2013) recommended 5 surgical techniques with high-quality evidence: blunt cephalad-caudad uterine expansion, spontaneous placental removal, subcutaneous tissue suture closure if >2cm depth, omission of manual cervical dilation and omission of subcutaneous drains based on high quality evidence. We believe our review adds substantial information to this topic. Based on new information incorporated in this review of the additional 217 RCTs, systematic reviews or meta-analyses, the following surgical techniques would be recommended with the same high-quality evidence: Prophylactic antibiotics, omission of lateral tilt, omission of supplemental oxygen, chlorhexidine-alcohol for skin preparation, vaginal preparation in those labored, abdominal entry, omission of bladder flap development, uterine atony prevention, omission of peritoneal closure, and skin closure with suture. After accounting for these, there are few technical steps that not have been evaluated in RCTs. As such, it is our position that standardization may have more benefit as it relates to system efficiency, patient outcomes, resident training, and improved future trials than physician preference.

Reviewer #2: In their commentary, Dr. Dahlke et al. review the evidence surrounding individual components of the cesarean delivery and advocate for the adoption of a standardized approach. They outline how a cesarean delivery should be performed, in their opinion, guided by the data. The review is thoughtful and timely, and the proposal for a universal technique is interesting and fitting for a commentary piece.

To strengthen their argument, the authors could consider the following points, which more skeptical readers may raise:

1) The authors suggest that standardizing certain aspects of cesarean deliveries has improved patient outcomes, specifically interventions to reduce surgical site infections. There is no high quality evidence that standardizing the entire cesarean delivery approach results in improved outcomes. Perhaps the first step towards universal adoption of a standardized technique is a trial comparing standardization vs. non-standardization. The authors cite a study of standardization, but it is observational, and the protocol was different than the one proposed. What would the authors propose as a primary outcome for such a study (infection, time, complications)? What would the net benefit need to be to advocate for its use?

Thank you for the comment. We acknowledge the paucity of studies comparing standardized vs non-standardized CD and one of the goals of this manuscript is to provide a template for future studies. In the observational trial by Pallister et al that was cited, the standardized approach included the same skin, subcutaneous, fascia

and peritoneum entry, omission of a bladder flap, uterine entry and expansion technique, omission of abdominal irrigation, non-closure of the peritoneum, and non-reapproximation of the rectus muscles. Differences in techniques in their study than those proposed in our commentary included surgeon preference for 1- or 2- layer closure of the uterus and skin closure techniques. We believe that there is high quality evidence to recommend 1- layer uterine closure and suture skin closure as outlined in our manuscript. As suggested by the reviewer, outcomes for a comparative trial could include infection, overall operative time, and wound complications. However, the overall design of such a trial is outside the scope of our already long manuscript.

2) The authors suggest that standardization could allow for quality assessment, and they cite using time as a means for comparison. Is there evidence to suggest that these time comparisons would be meaningful?

Thank you for the comment. Our discussion of time intervals of different steps related to resident surgical experience. Conceptually, we believe this may be meaningful to both the trainee and trainer as it would offer objective data and may allow future inquiry into residency competency of various aspects of the procedure.

3) How do the authors envision a "standard" cesarean delivery in practice? They outline their proposed technique based on the review of the evidence today, but how do they propose the "standard" practice be updated? (For example, would an update be envisioned annually?) How do you think this would impact dissemination or adoption in practice?

Thank you for the comment. Incorporating evidence-based practices into daily practice remains a challenge in clinical medicine. Undoubtedly, updates to the current proposed standardized approach will be warranted as future trials inform best practices. The 7-8 year timeframe between Berghella et al's systematic review (2005), Dahlke et al's updated review (2013) and this Commentary seems like a reasonable timeframe. As noted, the number of trials should dictate this as well given the fact that from 1960-2013 there were about 150 studies on this subject and in the past 7 years there has been over 200. One of the main goals of this Commentary is to address residents learning this procedure in as standardized a fashion as possible because ultimately, they will be performing this surgery for decades to follow.

4) In the absence of overwhelming evidence for its use, universal adoption of a single technique seems unlikely. Other than proposing it as a concept, how do the authors envision such a protocol would be rolled out in clinical practice? Is it the responsibility of individual clinician, hospitals, professional societies, or payers to ensure compliance? How would you get buy-in from clinicians who have seen practice recommendations related to cesarean change over time?

Thank you for the comment. We acknowledge the uphill battle of universal adoption of our proposal but also appreciate clinicians' desire to practice and teach future surgeons. As clinicians ourselves, we recognize that changing long-held practices is difficult. We strongly believe that standardization for most CDs is not only feasible, but the right approach. We do not believe that non-compliance to our proposed technique should be punitive and would welcome professional societies to include a

CD checklist that incorporates both institutional standardization and surgeon standardization practices. We have included a template for such checklist to facilitate this. We hope our Commentary appeals to the teacher and learner dynamic of medical training to foster the buy-in described.

[As a minor note, the authors might consider rephrasing or expanding their section on "Other CD Technical Aspects." While I understand their intention, the recommendation to "omit reiki/prayer" seems a bit off-putting and might be better specifically stated as "Omit reiki/prayer for post-operative pain control" or something similar, if they feel compelled to include it.]

Thank you for this comment and your point is well taken. The recommendation has been changed to "Omit reiki/prayer for post-operative pain control"

Reviewer #3: The authors from 4 different major academic institutions present the case for standardizing the surgical approach to cesarean delivery pulling from the medical-educational-safety cultures of medicine. They summarize 370 RCTs, and make recommendations about standard surgical steps/techniques common to all cesareans. Like all modern day recommendations there are competing forces between standardization and personalization.

I commend the authors for translating the information into clinical recommendations. This is well written and easy to read. because cesarean is common to every single institution it is important! Yet when change is recommended there is always pushback. I would lend 1-2 paragraphs discussing either clinical situations that mandate a change from your standardization example BMI of 50-60 with an overhanging pannus: still a pfannenstiel? Does one still use a pfannenstiel on the 6th cesarean. No bladder flap during a second stage cesarean? I think validating that there will be necessary deviations in surgical technique is important. DO you expect that surgical technique can be followed 70-80% of the time? After all we are also taught to problem solve for complex situations. Are there scenarios when sharp subcutaneous and fascia dissection will need to be done ?or when the rectus muscle is adhered to the uterus and needs to be cut?

Thank you for your comment and your point is well taken. As indicated above, we have included the following to address these considerations: : "We acknowledge that not all cesareans are created equal and alterations to our standardized approach will be necessary in certain circumstances in which physician judgement and experience should play an important role. If a standardized approach becomes the primary technique taught to trainees, opportunities to highlight clinical scenarios that warrant modifications to this technique become strengthened. For example, a history of multiple prior cesarean deliveries or significant obesity may require modifications to abdominal entry techniques, and uterine exteriorization may not be possible when there is extensive intraabdominal adhesive disease."

I don't think you will get much pushback from the institutional list and I imagine that MOST hospitals have adopted cesarean bundles. The major change is the individual

surgeon especially in private practice settings where they have done "individual standardization" (based on their own training in residency) over the years that works for them, There is a tendency for this commentary to simplify cesarean.

Thank you for the comment. It is unclear how many institutions have adopted cesarean bundles, but fully endorse an approach to those steps that are amenable to standardization in institutions. Our intent in the Commentary is certainly not to simplify cesarean. In contrast, by highlighting and synthesizing over 370 trials on the subject, we hope to improve it, not simplify it. We believe that because CD is such a high-volume procedure performed all over the world, it provides a unique opportunity to standardize care across large and diverse populations.

Please comment on "Not all cesareans are equal" There are 5-6 different common clinical scenarios that i recommend you discuss

1. Higher order cesarean number, Each week many women are needing a 4,5,6,7 th repeat cesarean
2. Morbid obesity: Each week women with BMIs of 40.50,60s have cesareans
3. Late labor cesareans for second stage arrest when anatomy is distorted and the biggest mistake is going to low
4. Emergencies" prolapsed cord,
5. Preterm less than 32 weeks/ the micro premies at 23- 24 weeks
6. Fibroids

Thank you for the comment and your point is well taken. It is beyond the scope of our Commentary to discuss in detail modifications to the clinical scenarios you describe, however we have included the following to address these concerns (and adopted the phrase 'not all cesareans are created equal'): "We acknowledge that not all cesareans are created equal and alterations to our standardized approach will be necessary in certain circumstances in which physician judgement and experience should play an important role. If a standardized approach becomes the primary technique taught to trainees, opportunities to highlight clinical scenarios that warrant modifications to this technique become strengthened. For example, a history of multiple prior cesarean deliveries or significant obesity may require modifications to abdominal entry techniques, and uterine exteriorization may not be possible when there is extensive intraabdominal adhesive disease."

EDITOR COMMENTS:

We no longer require that authors adhere to the Green Journal format with the first submission of their papers. However, any revisions must do so. I strongly encourage you to read the instructions for authors (the general bits as well as those specific to the feature-type you are submitting). The instructions provide guidance regarding formatting, word and reference limits, authorship issues and other relevant topics. Adherence to these requirements with your revision will avoid delays during the revision process by avoiding re-revisions on your part in order to comply with formatting.

Numbers below refer to line numbers.

30. The précis is a single sentence of no more than 25 words, written in the present tense and stating the conclusion(s) of the report (ie, the bottom line). The précis should be similar to the abstract's conclusion. Do not use commercial names, abbreviations, or acronyms in the précis. The précis should be the "hook" for people who scan the Table of Contents to see what to read. It shouldn't include statements like "in this study" or "we found". Just state what you found.

The journal style does not support the use of the virgule (/) except in mathematical expressions. Please remove here and elsewhere.

Removed, thank you

48. It's not clear what you mean here. There are certainly more than 17 technical aspects of performing a cesarean. Do you mean that of the many steps in performing a cesarean, you have identified 17 that have significant evidence from your reviews and that of these, 10 should be incorporated and 7 should not?

The abstract has been modified to remove this confusion.

49. I recommend you move lines 49-54 the 2nd sentence in your abstract. You need to convince the reader why this is important right up front

Thank you for this recommendation. Our three arguments for standardization was moved to the forefront of the abstract.

101. What do you mean by "education"? Whose education?

This was a typo and removed, thank you

105. What do you mean by "the previous systematic review"? You've already said that there were several and the preceding 2 paragraphs discuss 2 of them? Please name the one and give the year specifically of the one you are referencing here.

This has been changed as recommended, thank you

136. This may be a good place to address reviewers' comments regarding "exceptions" to the standardized approach you are recommending. In particular, these exceptional circumstances are likely to be opportunity for learners to gain experience from experienced obstetricians about how to address these exceptions, for which there is less likely to be standardized approaches with strong evidence. I really encourage you to make a comment up front before your individual recommendations that just as important as standardization, one must practice and teach when non standard approaches are warranted. The 80/20 rule likely applies here.

Thank you for this recommendation. The following paragraph has been included to address the reviewers' comments: "We acknowledge that not all cesareans are created equal and alterations to our standardized approach will be necessary in

certain circumstances in which physician judgement and experience should play an important role. If a standardized approach becomes the primary technique taught to trainees, opportunities to highlight clinical scenarios that warrant modifications to this technique become strengthened. For example, a history of multiple prior cesarean deliveries or significant obesity may require modifications to abdominal entry techniques, and uterine exteriorization may not be possible when there is extensive intraabdominal adhesive disease.”

144. Did this study demonstrate any improvement in patient outcome or other patient centered outcome?

There were not significant differences in the secondary outcomes of blood loss, SSI rate, maternal length of stay, or maternal or neonatal injury in the 303 CDs analyzed.

247. Since you state that the one RCT did not demonstrate benefit, it is surprising to see that you recommend it “when placental membranes are seen”. Is that what the RCT showed? Was it non beneficial if membranes were not seen, but beneficial if there were membranes seen? Perhaps the recommendation should read “perform intrauterine wiping ONLY when placental membranes are seen. “

This has been changed as recommended, thank you

252. what do you mean by “our previous review”? Did this author group publish a prior review?

This has been removed and cited, thank you. (4 of the 6 current authors were also co-authors of the 2013 updated systematic review)

300. OMG....Dr. Cefalo who was my division director and mentor just rolled over in his grave...how many times did I hear him say “The solution to pollution is dilution”????
I personally empathize with this. My gyn-oncology mentors Dr. Terry Harrison and Dr. Michael McHale at the Naval Medical Center, San Diego were incessant in their making fun of our newly endorsed method of blunt expansion of tissue layers, likening it to ‘the digging dog’.

305. Should this be “and it was a technical step”? You provide the findings of the CORONIS study here specifically to support your recommendation but not the other RCT and systematic review. Did they report the same thing?

This has been changed as recommended. The Cochrane review also reported no clear benefit of peritoneal closure.

320: Given the RCT showing a significant decrease in composite wound complications, which I believe was the primary outcome of the study, why are you recommending against it? The individual rates were likely secondary outcomes and papers are generally not powered to these individual components of a composite outcome.

The recent RCT conflicts with previous studies that showed no benefit. The manuscript has been modified to clarify this recommendation: “Intra-operative glove change was

previously not recommended with moderate certainty. In contrast to previous studies, one RCT reported a significant decreased risk of a composite wound complication, but no difference individual rates of seroma, hematoma, wound separation or infection with glove change prior to fascia closure. Given insufficient and conflicting data, routine glove change is not recommended.”

333. You don't provide any comment in your background for this recommendation re: locked vs unlocked. Please do—otherwise, all you've provided background for is absorbable v non absorbable.

Thank you for noting this. While fascia closure is generally a running suture, this is not directly delineated in the RCT. The recommendation has been changed to 'Continuous with delayed absorbable suture'.

On page 30 you start with “Appendix 1” and it gets very confusing from there. You don't even mention the institutional standardization from your appendix in the paper and it contains important information. I recognize that there are word limits and you likely struggled with how to include this content. I recommend that you mention in the manuscript that you addressed, in a similar fashion, non-surgeon related steps at the institutional level and the recommendations are included in the table in the manuscript, but that the explanations for why you made these explanation are in supplemental digital content.

APPENDIX: contains a lot of material that is surgeon dependent, not institutional, or duplicates material from the main body of the manuscript.

53. Is there any data on effect of lateral tilt intraoperatively on maternal nausea? Also, it seems there is weak evidence here for the outcomes of note.

In the Cochrane review cited, nausea was an outcome in one study of 40 women. For this outcome, lumbar pelvic wedge was favored over horizontal. The GRADE has been modified to 2C- weak recommendation, low-quality evidence

124. I don't understand “Incisional adhesive drapes”. I am familiar with drapes that are adhesive with a wide window without an adhesive material for the incision built into the drape—I would consider these an “adhesive drape”. Are you instead reporting on a drape with an adhesive over the entire surgical field through which the surgeon makes her incision?

Incisional adhesive drapes are indeed adhesive over the entire surgical field. This description has been included in the manuscript.

I've provided some examples below but it's not exhaustive. Please put all of the surgical step techniques in the main body of the paper and the institutional steps in the appendix.

line 134 Duplicates content from manuscript starting on line 193 in main manuscript

159 is a surgical step.

167-183: duplicative of manuscript content

185: move to manuscript

220—276 : duplicative

278: move to manuscript

284-317-Duplicative

I suspect there was some version control issue in your submission but it's really quite confusing from page 30 on.

Thank you for the recommendation. All surgeon techniques have been moved to the manuscript only and the Appendix contains those that can be incorporated by institution. The following was included in the Appendix to describe this: "All technical aspects of CD with evidence based recommendations, corresponding GRADE strength of evidence and references are summarized in order of performance in Table 2. References noted in this Table include all RCTs, meta-analyses or systematic in the current systematic review as well as those from the prior systematic review.² The Commentary reviewed all CD surgical steps that can be incorporated by the surgeon and the Appendix includes those that can be incorporated by institutions."

EDITORIAL OFFICE COMMENTS:

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

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

OPT-IN. Thank you

2. Obstetrics & Gynecology uses an "electronic Copyright Transfer Agreement" (eCTA). When you are ready to revise your manuscript, you will be prompted in Editorial Manager (EM) to click on "Revise Submission." Doing so will launch the resubmission process, and you will be walked through the various questions that comprise the eCTA. Each of your coauthors will receive an email from the system requesting that they review and electronically sign the eCTA.

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

3. 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.

4. 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.

5. 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).

6. 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 limit for Current Commentary articles is 250 words. Please provide a word count.

The Abstract word count is 186 words, thank you

7. 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.

8. 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.

Noted and removed, thank you

9. The manuscript has a few mentions of the CORONIS trial being the largest multicenter RCT. Please make sure you have a citation to support this statement. You could probably also reduce the number of times you state that fact.

This description, which was used once, has been removed, thank you

10. 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.

Checklist guide was reviewed for each table and they conform to recommendations, thank you

11. Each supplemental file in your manuscript should be named an "Appendix," numbered, and ordered in the way they are first cited in the text. Do not order and number supplemental tables, figures, and text separately. References cited in appendixes should be added to a separate References list in the appendixes file.

The Appendix has been modified as recommended. The submitted supplemental file

contains the systematic review of techniques not included in the commentary, two

tables and all references cited in the appendix.

12. Authors whose manuscripts have been accepted for publication have the option to pay an article processing charge and publish open access. With this choice, articles are made freely available online immediately upon publication. An information sheet is

available at <http://links.lww.com/LWW-ES/A48>. The cost for publishing an article as open access can be found at <https://wkauthorservices.editage.com/open-access/hybrid.html>

Please do not hesitate to contact me for any additional needed information. We are looking forward to further evaluation of our article.

Best Regards,

Joshua D. Dahlke MD

Methodist Women's Hospital and Perinatal Center

[REDACTED]

[REDACTED]

[REDACTED]