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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)*
- Email correspondence between the editorial office and the authors*

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

Date:	Sep 06, 2018		
То:	"Erica Holland"		
From:	"The Green Journal" em@greenjournal.org		
Subject:	Your Submission ONG-18-1502		

RE: Manuscript Number ONG-18-1502

Evaluation of a quality improvement intervention that eliminated routine use of opioids after cesarean

Dear Dr. Holland:

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 Sep 27, 2018, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1: This group used a multimodal approach to decrease unnecessary post-cesarean opioid use. This included 1.) eliminating routine opioid ordering in the hospital after cesarean, 2.) first-line pain management included neuraxial opioids + NSAID + acetaminophen, and 3.) used a novel approach to discharge prescribing at the time of discharge. The primary outcome measures evaluated were measures of opioid use and pain control.

1.) Line 78: It would be useful to describe the structure of post-partum physician care provided, ie how to the residents participate in care? Do they round with our without the attendings? Are the residents 1st call to answer pages from nurses about post-partum pain control? What level resident answers post-partum pages for pain control?

2.) Line 91: When a nurse calls for "poorly-controlled pain"..... did the physician routinely go do a physical exam? Or get vital signs?

3.) Line 103: Where patients with pre-eclampsia (with or without severe features) included in this study?

4.) Did you collect data on whether patents were using opioids before delivery?

5.) Line 155: How was this assessed? Did you speak with all of the patients at 6 week post-partum visit and ask them if they had received additional prescription? How many were lost to follow up?

6.) The major limitation of this study is that it does not report the impact of the intervention on nursing and physician staff (important balancing measures)... The need to assess pain, page physician (sometimes multiple times I imagine) and wait on meds from pharmacy certainly adds work volume to post-partum nursing staff and needs to be considered. In fact, this portion of the intervention (ie, not routinely ordering opioids as a prn medication post-operative) is really an invention designed to impact the nurses, not the patients. I think this is fine, you just need to acknowledge this limitation in the discussion.... There may be other strategies that could be considered to achieve the same results without increasing the burden on nursing staff.

Reviewer #2: The authors aim to evaluate the impact of eliminating routine use of oral opioids post cesarean delivery. I have the following comments for the authors' consideration:

Methods

1. Line 95-100. Where does the shared decision making piece come in? It is mentioned but not well-described. I wonder how much of this is shared decision making versus an order set change.

2. Line 104. It is interesting that vertical skin incision was a contraindication to this approach? Why?

3. Line 105. Presumably women who also had a tubal ligation at the time of cesarean were not excluded. Would clarify.

4. Line 107. Can any methodology be provided as to how the convenience sample was selected (ie can the authors provide some reassurance that the study staff did not select women who were happy with their pain control for sampling)?

5. Line 110. How was satisfaction with pain relief evaluated? On a standard scale?

Results

1. Any differences observed in intrapartum versus scheduled cesarean deliveries? I realize you adjusted for this, but may be worth including some mention of whether similar differences in opioid prescribing were observed in the subgroup of women with intrapartum cesareans.

2. Consider adding the denominators for the reported n's in the results section (especially in lines 146-55).

3. Figure 1. Consider adding a box with the total N in the cohort at the top and then divide into before and after intervention groups as you have done with n's.

Discussion

1. Line 194. The authors state that non-English speaking women were excluded. This is not stated in the Methods. Please add.

Reviewer #3: This is a low intervention but high impact study to potentially impact the amount of opioids prescribed to patients following a C-section. The authors demonstrate a method that could be easily replicated in other institutions with potentially high impact.

Reviewer #4: This is an important quality improvement intervention aimed at reducing the use of opioids after cesarean delivery and ultimately in the community at large. Overall it is very well described and written and is an excellent contribution to our field.

I have the following suggestions to improve the manuscript:

1) In the methods section, it would be helpful to include: how pain scores were assessed (who assessed them, how frequently, what is the scale used); the survey variables - possible satisfaction responses (very satisfied, satisfied, unsatisfied??, very unsatisfied??); how the survey was administered (by paper, verbally, both?)

2) In the results section, the sample is described as majority multiparous women undergoing primary cesarean delivery without labor. This struck me as very strange. In Table 1, however, I see that these characteristics are not necessarily coexisting in the same persons. This sentence should therefore be rewritten so as not to be so misleading, and not describing a single majority.

3) I would suggest clarifying the sentence: "No women in the post-intervention group requested a prescription for opioids during the 6 weeks after being discharged home."

The implications of the exclusion of non-English speaking women from the survey on satisfaction should not be minimized in the discussion. Women who are non-English speaking and are often not able to effectively communicate their pain or their needs and may be much less likely to be able to advocate for themselves and ask for pain medications. When prn pain medication is not ordered and it is unlikely to be offered, the impact on disempowered women who are un-surveyed leaves me with some concerns.

4) From Table 4, would it be accurate that on POD#3, 25% of patients are not satisfied, or very unsatisfied postintervention, compared to 12% pre-intervention. If this is the case, it is worth noting what percentage difference your survey study is powered to detect as statistically significant with only 50 subjects (pre) and 40 subjects (post), as this difference may seem relevant to many care providers and patients. Would it be more forthcoming to present this finding and discuss the reasons why it might be?

5) Given the questions above, I wonder whether the conclusions should be tempered a bit. For the patients who experienced dissatisfaction, was it the wait time in receiving additional pain medication? At many institutions, pain scores are used to guide nurses in offering additional pain medications. Is the thought here that taking away this type of mechanism and adding additional steps (some might say obstacles) will reduce the use of narcotics. The protocol could

still work well if refractory pain could be treated promptly, but if reaching a covering resident or provider is difficult or receiving an electronic order is delayed, patients with refractory pain could be left in pain for quite some time (for what purpose). It would be helpful to understand a bit more about the protocol in place for how nurses assess and respond to patients' pain so that the generalizability of this QI program can be considered. For example, if patients are found to have 8/10 pain, are the nurses asking the patient if they want narcotics, or are they waiting for the patient to ask for narcotics?

STATISTICAL EDITOR COMMENTS:

The Statistical Editor makes the following points that need to be addressed: lines 114-115, Table 2: Should clearly identify the primary outcome (% patients using and opioids in-hosp).

lines 115-120: Since these were identified as secondary outcomes, the tables, abstract (lines 19-25), results (lines 146-153) and discussion (lines 181-184), the format and emphasis should be first on the primary outcome, then on the secondary ones.

EDITOR COMMENTS:

1. Thank you for your submission to Obstetrics & Gynecology. In addition to the comments from the reviewers above, you are being sent a notated PDF that contains the Editor's specific comments. Please review and consider the comments in this file prior to submitting your revised manuscript. These comments should be included in your point-by-point response cover letter.

The notated PDF is uploaded to this submission's record in Editorial Manager. If you cannot locate the file, contact Randi Zung and she will send it by email - rzung@greenjournal.org.

- can you add that it didn't change pain scores? or would that be too many words? Could you say something like "It is possible to eliminate routinely ordering oral opioids after cesarean delivery and reduce post operative opioid consumption without increasing patients' pain scores. "

- Can you please clarify your patient population? All women had neuraxial anesthesia. Were these all cesarean other than those who had GA? only unlabored? Only primary CS? Also, your group has published on shared decision making which is part of component 3. Did they all get that as well (pre and post)

- Please state your primary and secondary outcomes.

- How many got breakthrough oral opioids? Were other pain treatments offered like lidocaine patches, gabapentin, etc?

- worth mentioning potential side effects of opioid use which can delay recovery from cesarean: nausea, decreased gut motility, drowsiness....etc.

- The 3500 patients referenced are all academic faculty patients or is that the total delivery # and the Brigham, and the faculty attend their own Plus the residents' practice?

- this is redundant from line 71. Keep it somewhere but not both places.

- The Journal style does not include the use of the virgule (/) except in numeric expressions. Please edit here and in all instances. Who developed the intervention? Since its likely that the new prescribing pattern would result in change for nursing, were they included in the planning? What about pharmacy?

- Is this a Study or QI?

- was it reported to them individually or just tracked? Did you have an EMR order set? Who manages the post op pain in your hospital: OB or anesthesia?

- was classical CS an exclusion?

- "surveyed" implies a standardized series of questions. Were these written or oral surveys? Who administered them?

- what do you mean "were surveyed prospectively"? the only survey you described was post-delivery.

- wow! 25%? Boston must be a tough place to be!!

- Please limit p values to 3 decimals. For data presented in the text, please provide the raw numbers as well as data such as percentages, effect size (OR, RR, etc) as appropriate and 95% CI's.

- We do no allow authors to describe variables or outcomes in terms that imply a difference (such us of the terms "trend" or "tendency" or "marginally different") unless there is a statistical difference. Please edit here and throughout.

- Can you get data from these same time periods from your patient satisfaction surveys to see if there were any differences in satisfaction on your delivered patients? At least one of your reviewers asked an important question about potential burden on the nursing staff to call for the 45% of patients who needed oral opioids?

- Where appropriate, please provide effect size measures and CI's.

2. Throughout your submission, you use cause and effect language. Since your study is not a RCT, this language is not appropriate. Please rephrase your text so that you are framing everything as an association.

For example, your Conclusion should say something like: "Eliminating the routine ordering of oral opioids after cesarean delivery is associated with a significant decrease in opioid consumption...".

3. 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:

1. OPT-IN: Yes, please publish my response letter and subsequent email correspondence related to author queries.

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

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

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

5. Standard obstetric and gynecology data definitions have been developed through the reVITALize initiative, which was convened by the American College of Obstetricians and Gynecologists and the members of the Women's Health Registry Alliance. Obstetrics & Gynecology will be transitioning as much as possible to use of the reVITALize definitions, and we encourage authors to familiarize themselves with them. The obstetric data definitions are available at http://links.lww.com/AOG/A515, and the gynecology data definitions are available at http://links.lww.com/AOG/A935.

6. Because of space limitations, it is important that your revised manuscript adhere to the following length restrictions by manuscript type: Clinical Practice and Quality articles should not exceed 22 typed, double-spaced pages (5,500 words). Stated page limits include all numbered pages in a manuscript (i.e., title page, précis, abstract, text, references, tables, boxes, figure legends, and appendixes).

Please limit your Introduction to 250 words and your Discussion to 750 words.

7. Titles in Obstetrics & Gynecology are limited to 100 characters (including spaces). Do not structure the title as a declarative statement or a question. Introductory phrases such as "A study of..." or "Comprehensive investigations into..." or "A discussion of..." should be avoided in titles. Abbreviations, jargon, trade names, formulas, and obsolete terminology also should not be used in the title. Titles should include "A Randomized Controlled Trial," "A Meta-Analysis," or "A Systematic Review," as appropriate, in a subtitle. Otherwise, do not specify the type of manuscript in the title.

8. Specific rules govern the use of acknowledgments in the journal. Please edit your acknowledgments or provide more information in accordance with 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 signature on the journal's author agreement 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).

9. Provide a précis on the second page, for use in the Table of Contents. 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. Please avoid phrases like "This paper presents" or "This case presents."

10. 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: Clinical Practice and Quality, 300 words. Please provide a word count.

11. 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.

12. 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.

13. 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.

14. The American College of Obstetricians and Gynecologists' (College) documents are frequently updated. These documents may be withdrawn and replaced with newer, revised versions. If you cite College documents in your manuscript, be sure the reference you are citing is still current and available. If the reference you are citing has been updated (ie, replaced by a newer version), please ensure that the new version supports whatever statement you are making in your manuscript and then update your reference list accordingly. If the reference you are citing has been withdrawn with no clear replacement, please contact the editorial office for assistance (obgyn@greenjournal.org). In most cases, if a College document has been withdrawn, it should not be referenced in your manuscript (exceptions could include manuscripts that address items of historical interest). All College documents (eg, Committee Opinions and Practice Bulletins) may be found via the Resources and Publications page at http://www.acog.org/Resources-And-Publications.

15. Figures

Figure 1: This may be re-submitted as-is.

Figure 2: Is this figure available at a higher resolution?

16. 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, that each author has given approval to the final form of the revision, and that the agreement form signed by each author and submitted with the initial version remains valid.

Again, your paper will be maintained in active status for 21 days from the date of this letter. If we have not heard from you by Sep 27, 2018, 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 If you would like your personal information to be removed from the database, please contact the publication office.

Dear Dr. Chescheir,

Thank you for your interest in our study and the very constructive suggestions for revision. Informed by the reviewers' and editors' comments, we have substantially revised the manuscript. We note our responses to each of the comments in bold below.

OPT-IN: Yes, please publish my response letter and subsequent email correspondence related to author queries.

I, Erica Holland, affirm that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

Sincerely, Erica Holland and co-authors

REVIEWER COMMENTS:

Reviewer #1: This group used a multimodal approach to decrease unnecessary post-cesarean opioid use. This included 1.) eliminating routine opioid ordering in the hospital after cesarean, 2.) first-line pain management included neuraxial opioids + NSAID + acetaminophen, and 3.) used a novel approach to discharge prescribing at the time of discharge. The primary outcome measures evaluated were measures of opioid use and pain control.

Thank you for all of the helpful comments. We have responded to each below.

1.) Line 78: It would be useful to describe the structure of post-partum physician care provided, ie how to the residents participate in care? Do they round with our without the attendings? Are the residents 1st call to answer pages from nurses about post-partum pain control? What level resident answers post-partum pages for pain control?

We have included information about the post-partum physician care provided as recommended in the methods section: *"Interns round daily on low-risk post-partum women with supervision by a chief resident and attending physician. Post-partum care for high-risk women is managed by a second and third-year resident team with direct attending supervision. In both scenarios, the rounding residents are the responding clinicians to nursing pages regarding pain control."*

2.) Line 91: When a nurse calls for "poorly-controlled pain"..... did the physician routinely go do a physical exam? Or get vital signs?

We have included answers to these questions in the methods section: "Clinicians were asked to use their clinical judgement when responding to nursing pages about pain control, and to use their communication with nursing in addition to patient vital signs to inform whether a patient needed to be evaluated in-person prior to ordering opioids."

3.) Line 103: Where patients with pre-eclampsia (with or without severe features) included in this study?

Yes, patients with preeclampsia were included in this study. This information has been included in the methods section.

4.) Did you collect data on whether patents were using opioids before delivery? Yes, we scanned the medical record for a history of opioid use prior to delivery and these patients were excluded from the quality improvement project. There were 4 patients in total who were excluded for chronic opioid use, which is represented in figure 1.

5.) Line 155: How was this assessed? Did you speak with all of the patients at 6 week post-partum visit and ask them if they had received additional prescription? How many were lost to follow up? Patients were not contacted post-partum. Rather, the "order history" section of the electronic medical record was reviewed for each patient to determine whether she had been prescribed opioids through our hospital system. If a patient had sought opioids outside the system, this would not have been picked up by our methodology. This limitation was added to the discussion section: "While we do not have information on pain scores after discharge, no patients in the post-intervention group were written for an opioid prescription in the hospital's electronic medical record in the six weeks after hospital discharge, an outcome which we used as a proxy for post-partum pain control. However, if a patient sought opioids outside the hospital network, this would not have been identified by our methods."

6.) The major limitation of this study is that it does not report the impact of the intervention on nursing and physician staff (important balancing measures)... The need to assess pain, page physician (sometimes multiple times I imagine) and wait on meds from pharmacy certainly adds work volume to post-partum nursing staff and needs to be considered. In fact, this portion of the intervention (ie, not routinely ordering opioids as a prn medication post-operative) is really an invention designed to impact the nurses, not the patients. I think this is fine, you just need to acknowledge this limitation in the discussion.... There may be other strategies that could be considered to achieve the same results without increasing the burden on nursing staff.

We anticipated an impact on nursing work flow and conducted weekly rounds with nursing staff and house staff, who were receiving the nurses' pages, to assess the burden of this quality improvement project. While we did not conduct a formal assessment of nursing or house staff, the commentary during weekly rounds was that the uptake in pages from nursing to house staff was not perceived as overly burdensome from either group. There were additionally no requests from either nursing or house staff to stop the project or change work-flow. The need for further evaluation in this area was added to the discussion: "Additional study is warranted to further characterize satisfaction in the context of this QI intervention, and to formally assess the impact of the intervention on care providers"

AM – reviewer 2

Reviewer #2: The authors aim to evaluate the impact of eliminating routine use of oral opioids post cesarean delivery. I have the following comments for the authors' consideration:

Thank you very much for these helpful comments. We have responded to each below.

Methods

 Line 95-100. Where does the shared decision making piece come in? It is mentioned but not welldescribed. I wonder how much of this is shared decision making versus an order set change.
 The shared decision making component was incorporated in the counseling around discharge medications, asking patients for input around anticipated need and use and tailoring recommendations based on this input. The specific computer-based decision aid described by Prabhu et al was not used in this study, though the content of this aid was incorporated as described. While we think that shared decision making likely played a role in the decreased opioids prescribed at discharge, the shared decision making component was not used to inform inpatient opioid consumption which also decreased during the post-intervention time period.

2. Line 104. It is interesting that vertical skin incision was a contraindication to this approach? Why? We assumed that patients with a vertical skin incision would experience more pain and require greater quantities of pain medication. Anecdotally, many of our patients with a vertical skin incision, including several who underwent cesarean hysterectomy did not require any opioid medication post-operatively. We hope to expand this quality improvement intervention to include this population.

3. Line 105. Presumably women who also had a tubal ligation at the time of cesarean were not excluded. Would clarify.

This has been included in the methods section as recommended. Women with tubal ligation were not excluded.

4. Line 107. Can any methodology be provided as to how the convenience sample was selected (ie can the authors provide some reassurance that the study staff did not select women who were happy with their pain control for sampling)?

Thank you for this important point. The sample was selected based on the availability of QI project staff and the presence of patients in their rooms when QI project staff approached patients to survey them. When a particular staff member was available for surveying, (s)he would survey every patient from the academic practice who was post-operative day 3 after cesarean and who was present in her post-partum room to complete the survey. On days when no staff were available, no patients were surveyed. This has been clarified in the methods section: *"A convenience sample of eligible patients was approached on post-operative day three and surveyed regarding satisfaction with pain relief and opioid-related side effects. The sample was based on the presence of patients in their post-partum rooms and the availability of QI project staff to administer surveys."*

5. Line 110. How was satisfaction with pain relief evaluated? On a standard scale? Satisfaction was evaluated with a 6-point Likert scale on a written survey. This has been clarified in the text.

Results

1. Any differences observed in intrapartum versus scheduled cesarean deliveries? I realize you adjusted for this, but may be worth including some mention of whether similar differences in opioid prescribing were observed in the subgroup of women with intrapartum cesareans. In the subgroup of women who labored prior to cesarean, 46.3% (N=31/67) received oral opioids inhospital after cesarean delivery after the intervention compared with 67.1% (N=53/79) before (p=0.01). The number of women discharged with a prescription for opioids in the subgroup also decreased following the intervention from 87.3% (N=69/79) to 37.3% (N=25/67) (p<0.001). This information was added to the results section.

2. Consider adding the denominators for the reported n's in the results section (especially in lines 146-55).

This has been changed, as suggested.

3. Figure 1. Consider adding a box with the total N in the cohort at the top and then divide into before and after intervention groups as you have done with n's. **This has been changed as suggested.**

Discussion

1. Line 194. The authors state that non-English speaking women were excluded. This is not stated in the Methods. Please add.

Non-English speaking women were excluded from participating in the written survey about satisfaction and symptoms, but they were included in the quality improvement intervention. This has been added the methods.

Reviewer #3: This is a low intervention but high impact study to potentially impact the amount of opioids prescribed to patients following a C-section. The authors demonstrate a method that could be easily replicated in other institutions with potentially high impact.

PM - Reviewer #4: This is an important quality improvement intervention aimed at reducing the use of opioids after cesarean delivery and ultimately in the community at large. Overall it is very well described and written and is an excellent contribution to our field.

I have the following suggestions to improve the manuscript:

Thank you for all of the helpful comments. We have addressed each below.

1) In the methods section, it would be helpful to include: how pain scores were assessed (who assessed them, how frequently, what is the scale used); the survey variables - possible satisfaction responses (very satisfied, satisfied, unsatisfied??, very unsatisfied??); how the survey was administered (by paper, verbally, both?)

The following information was added to the methods section: *"Pain scores were assessed by nursing using a 10-point numerical pain scale, before and after all pain management interventions, and before and after any pain-producing events per standard hospital protocol...*

Included patients were verbally asked to complete a brief written survey, recalling their level of satisfaction with pain relief on post-operative day one, post-operative day three (the day of survey administration), and overall, using a 6-point Likert scale including the options "very satisfied, satisfied, slightly satisfied, slightly dissatisfied, dissatisfied, and very dissatisfied." They were asked to quantify their experience with specific opioid-related side effects as "a lot," "some," or "none."

2) In the results section, the sample is described as majority multiparous women undergoing primary cesarean delivery without labor. This struck me as very strange. In Table 1, however, I see that these characteristics are not necessarily coexisting in the same persons. This sentence should therefore be rewritten so as not to be so misleading, and not describing a single majority.

The sentence was rewritten as suggested: "The majority of patients were white, non-Hispanic with nearly fifty percent of the women undergoing repeat cesarean. Approximately half of patients were publicly insured, and 25% carried a psychiatric diagnosis."

3) I would suggest clarifying the sentence: "No women in the post-intervention group requested a prescription for opioids during the 6 weeks after being discharged home."

The implications of the exclusion of non-English speaking women from the survey on satisfaction should not be minimized in the discussion. Women who are non-English speaking and are often not able to effectively communicate their pain or their needs and may be much less likely to be able to advocate for themselves and ask for pain medications. When prn pain medication is not ordered and it is unlikely to be offered, the impact on disempowered women who are un-surveyed leaves me with some concerns.

We agree and have restructured the discussion to reflect these concerns. In the education that nurses received around the intervention, they were encouraged to contact the responding clinician if a patient was in pain. We emphasized to both nursing and house staff that our goal was for pain to be well managed. The accepted culture had previously been to encourage opioids for all, including patients who didn't necessarily need them, in essence to "overtreat" and that is what this project was trying to address and change. We added the following to the discussion: "Though the patients included represent a diverse group of women with regards to race, ethnicity and insurance status, this was a single-center study and non-English speaking women were excluded from the survey regarding satisfaction and associated symptoms. Further work is needed to assess this intervention in other care settings among broader populations, including non-English speaking women, and patients excluded from the study for complex surgeries or contraindications to acetaminophen and NSAIDs."

4) From Table 4, would it be accurate that on POD#3, 25% of patients are not satisfied, or very unsatisfied post-intervention, compared to 12% pre-intervention. If this is the case, it is worth noting what percentage difference your survey study is powered to detect as statistically significant with only 50 subjects (pre) and 40 subjects (post), as this difference may seem relevant to many care providers and patients. Would it be more forthcoming to present this finding and discuss the reasons why it might be?

The 25% of patients that you refer to on POD#3 includes women who were either slightly satisfied, slightly dissatisfied, dissatisfied, or very dissatisfied. We are underpowered to detect clinically significant differences in satisfaction. We derived the greatest clinical meaning from the finding that overall satisfaction and pain scores are the same pre and post-intervention. These important concerns were added as limitations to the discussion: "While the percentage of women who were satisfied or very satisfied "overall" was equivalent before and after the intervention, 25% of women post-intervention compared with 12% of women pre-intervention were either slightly satisfied, slightly dissatisfied, dissatisfied or very dissatisfied with pain control on post-operative day 3 (p=0.16). Though this is statistically unchanged, the survey may not be adequately powered to detect a clinically significant difference in this measure. This difference in satisfaction on post-operative day 3 is mitigated by the finding that pain scores, overall satisfaction, and overall dissatisfaction were unchanged before and after the intervention. Additional study is warranted to further characterize satisfaction in the context of this Ql intervention, and to formally assess the impact of the intervention on care providers."

We also ran an analysis separating out women who were "very satisfied", "satisfied" or "slightly satisfied" as well as patients who were "dissatisfied" and have included the results below. We added the following to the results: "The vast majority of patients were "satisfied" or "very satisfied" with "overall" pain control before and after the intervention (88% vs 90% p=1), and the percentage of patients reporting that they were "dissatisfied" with "overall" pain control was unchanged (0 vs 2.5% p=0.44)."

Outcome	Pre-intervention	Post- intervention	p value
	rie-intervention		p value
Satisfaction, N (%)			
Overall very satisfied	29 (58.00%)	16 (40.00%)	0.0897
POD1 very satisfied	31 (62.00%)	20 (50.00%)	0.2536
POD3 very satisfied	30 (60.00%)	17 (42.50%)	0.0986

		Post-	
Outcome	Pre-intervention	intervention	p value
Satisfaction, N (%)			
Overall satisfied	15 (30.00%)	20 (50.00%)	0.0531
POD1 satisfied	16 (32.00%)	15 (37.50%)	0.5853
POD3 satisfied	14 (28.00%)	13 (32.50%)	0.6434

Outcome	Pre-intervention	Post- intervention	p value
Satisfaction, N (%)			
Overall slightly satisfied	1 (2.00%)	2 (5.00%)	0.5829
POD1 slightly satisfied	0	0	
POD3 slightly satisfied	3 (6.00%)	2 (5.00%)	1

		Post-	
Outcome	Pre-intervention	intervention	p value
Satisfaction, N (%)			
Overall dissatisfied	0	1 (2.50%)	0.4444
POD1 dissatisfied	1 (2.00%)	1 (2.50%)	1
POD3 dissatisfied	1 (2.00%)	3 (7.50%)	0.3192

5) Given the questions above, I wonder whether the conclusions should be tempered a bit. For the patients who experienced dissatisfaction, was it the wait time in receiving additional pain medication? At many institutions, pain scores are used to guide nurses in offering additional pain medications. Is the thought here that taking away this type of mechanism and adding additional steps (some might say obstacles) will reduce the use of narcotics. The protocol could still work well if refractory pain could be treated promptly, but if reaching a covering resident or provider is difficult or receiving an electronic order is delayed, patients with refractory pain could be left in pain for quite some time (for what purpose). It would be helpful to understand a bit more about the protocol in place for how nurses assess and respond to patients' pain so that the generalizability of this QI program can be considered. For example, if patients are found to have 8/10 pain, are the nurses asking the patient if they want narcotics, or are they waiting for the patient to ask for narcotics?

As suggested, additional information about the nursing role in the intervention was added to the methods section: "Nurses were asked to offer opioids if a patient's pain was not well controlled as assessed by the nurse or the patient. Pain scores were assessed by nursing using a 10-point numerical

pain scale, before and after all pain management interventions, and before and after any painproducing events per standard hospital protocol."

We didn't receive any feedback from nursing that providers were delayed in responding to pages, or that patients were delayed in receiving medications, and this is something that we asked about consistently on weekly rounds. There is no specific number on the pain scale for which nurses are instructed to offer opioids. Nurses were asked to use their judgement and to suggest opioids if a patient's pain was assessed to be "not well controlled" either in their perception or the patient's perception. Given that pain scores are unchanged, and that "overall" satisfaction is unchanged, we felt that it is still appropriate to conclude that opioids do not need to be routinely ordered after cesarean. However, we are happy to change this in the manuscript if the editor prefers. Additionally, we have added to the discussion session the need for additional study looking at the impact of this intervention of care providers.

STATISTICAL EDITOR COMMENTS:

The Statistical Editor makes the following points that need to be addressed: lines 114-115, Table 2: Should clearly identify the primary outcome (% patients using and opioids inhosp).

This has been clarified.

lines 115-120: Since these were identified as secondary outcomes, the tables, abstract (lines 19-25), results (lines 146-153) and discussion (lines 181-184), the format and emphasis should be first on the primary outcome, then on the secondary ones.

Thank you. These comments were incorporated into the manuscript as suggested.

EDITOR COMMENTS:

1. Thank you for your submission to Obstetrics & Gynecology. In addition to the comments from the reviewers above, you are being sent a notated PDF that contains the Editor's specific comments. Please review and consider the comments in this file prior to submitting your revised manuscript. These comments should be included in your point-by-point response cover letter.

We appreciate Dr. Chescheir's very helpful review of the manuscript and suggestions. We address each of her comments below.

The notated PDF is uploaded to this submission's record in Editorial Manager. If you cannot locate the file, contact Randi Zung and she will send it by email - <u>rzung@greenjournal.org.</u>

- can you add that it didn't change pain scores? or would that be too many words? Could you say something like "It is possible to eliminate routinely ordering oral opioids after cesarean delivery and reduce post operative opioid consumption without increasing patients' pain scores. "

This has been changed as recommended: "It is possible to eliminate routine ordering of oral opioids after cesarean and reduce post-operative opioid consumption without increasing patients' pain scores."

- All of the 1-3 items, as written, describe the tertiary care center, not the intervention.

This has been changed as recommended: "At a tertiary care center, we implemented a quality improvement intervention which consisted of (1) eliminating the routine ordering of oral opioids following cesarean delivery, (2) implementing guidelines for the ordering of a short course of opioids when opioids were deemed necessary, and (3) coupling opioid prescribing at discharge to patterns of opioid use in-hospital combined with shared decision making...

- Can you please clarify your patient population? All women had neuraxial anesthesia. Were these all cesarean other than those who had GA? only unlabored? Only primary CS? Also, your group has published on shared decision making which is part of component 3. Did they all get that as well (pre and post)

All women in the faculty practice undergoing cesarean section for any indication were included, in the absence of contraindications. This was clarified in the methods of the abstract: "At a tertiary care center, we implemented a quality improvement intervention among faculty practice patients undergoing cesarean delivery which consisted of..."

Patients prior to the intervention did not receive shared decision-making as part of their discharge prescription practice, only patients after intervention implementation received shared decision making. Members of our group published on the routine use of shared decision making at our partner institution Massachusetts General Hospital, but not at Brigham and Women's prior to this intervention.

- Please state your primary and secondary outcomes.

These have been stated in the abstract as follows: "The primary outcome was the percentage of women who used any opioids post-operatively in-hospital. Secondary outcomes included the percentage of women discharged with a prescription for opioids, the quantity of opioids used in-hospital, pain scores, satisfaction, opioid-related side effects and opioid prescriptions ordered in the six weeks following delivery."

- How many got breakthrough oral opioids? Were other pain treatments offered like lidocaine patches, gabapentin, etc?

In our study, there was no distinction between baseline opioids and opioids for breakthrough pain. Any patient whose pain was not controlled with the standard regimen of neuraxial anesthesia, acetaminophen and NSAIDs was offered opioids, and post-intervention, 45% of women required them. Other pain treatments like gabapentin and lidocaine patches are not routinely used at our institution unless a patient has a preexisting pain condition.

- worth mentioning potential side effects of opioid use which can delay recovery from cesarean: nausea, decreased gut motility, drowsiness....etc.

This has been added to the introduction as suggested.

- The 3500 patients referenced are all academic faculty patients or is that the total delivery # and the Brigham, and the faculty attend their own Plus the residents' practice?

The 3500 patients are those attended by the academic faculty with resident involvement. There are additional deliveries at the Brigham by the private providers.

- this is redundant from line 71. Keep it somewhere but not both places. This was consolidated, as recommended.

- The Journal style does not include the use of the virgule (/) except in numeric expressions. Please edit here and in all instances. **These have been edited.**

These have been edited.

Who developed the intervention? Since its likely that the new prescribing pattern would result in change for nursing, were they included in the planning? What about pharmacy?

The intervention was developed by physicians with input and buy-in from nursing administration as well as post-partum nurses. Pharmacy was not a part of the QI intervention, but that it is an important point and good idea for future collaboration.

- Is this a Study or QI?

This was a QI intervention. The language throughout the paper has been changed to consistently reflect this.

- was it reported to them individually or just tracked? Did you have an EMR order set? Who manages the post op pain in your hospital: OB or anesthesia?

Compliance was not reported to house staff individually. It was just tracked. There is an order set in our hospital's EMR (EPIC) that is routinely used for patients post-cesarean. This order set, in addition to additional orders written for opioids, are managed by OB.

- was classical CS an exclusion?

No, women with classical CS were included. This information has been added to the methods.

- "surveyed" implies a standardized series of questions. Were these written or oral surveys? Who administered them?

Surveys were administered by staff of this QI project. The following information has been added to the methods section: "Included patients were verbally asked to complete a brief written survey, recalling their level of satisfaction with pain relief on post-operative day one, post-operative day three (the day of survey administration), and overall, using a 6-point Likert scale including the options "very satisfied, satisfied, slightly satisfied, slightly dissatisfied, dissatisfied, and very dissatisfied." They were asked to quantify their experience with specific opioid-related side effects as "a lot," "some," or "none."

- what do you mean "were surveyed prospectively"? the only survey you described was post-delivery. The language was clarified and the term "prospectively" removed.

- wow! 25%? Boston must be a tough place to be!!

This was clarified as follows: "Approximately half of patients were publicly insured, and 25% carried a psychiatric diagnosis, of which the majority consisted of anxiety and depression with bipolar disorder, post-traumatic stress disorder (PTSD) and "other" comprising a small proportion of patients."

- Please limit p values to 3 decimals. For data presented in the text, please provide the raw numbers as well as data such as percentages, effect size (OR, RR, etc) as appropriate and 95% Cl's.

These changes have been made in the text, as suggested.

- We do no allow authors to describe variables or outcomes in terms that imply a difference (such us of the terms "trend" or "tendency" or "marginally different") unless there is a statistical difference. Please edit here and throughout.

This language has been edited throughout.

- Can you get data from these same time periods from your patient satisfaction surveys to see if there were any differences in satisfaction on your delivered patients? At least one of your reviewers asked an important question about potential burden on the nursing staff to call for the 45% of patients who needed oral opioids?

Yes, a sample of patients was surveyed with regards to satisfaction both before and after the intervention. We have added the following to the discussion: "Additional study is warranted to further characterize satisfaction in the context of this QI intervention, and to formally assess the impact of the intervention on care providers and their workload."

- Where appropriate, please provide effect size measures and CI's. These have been included.

2. Throughout your submission, you use cause and effect language. Since your study is not a RCT, this language is not appropriate. Please rephrase your text so that you are framing everything as an association.

For example, your Conclusion should say something like: "Eliminating the routine ordering of oral opioids after cesarean delivery is associated with a significant decrease in opioid consumption...". This language has been revised throughout the paper.

3. 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:

1. OPT-IN: Yes, please publish my response letter and subsequent email correspondence related to author queries.

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

OPT-IN: Yes, please publish my response letter and subsequent email correspondence related to author queries.

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

If you are the lead author, please include this statement in your cover letter. If the lead author is a

different person, please ask him/her to submit the signed transparency declaration to you. This document may be uploaded with your submission in Editorial Manager. This statement has been added to the beginning of this letter.

5. Standard obstetric and gynecology data definitions have been developed through the reVITALize initiative, which was convened by the American College of Obstetricians and Gynecologists and the members of the Women's Health Registry Alliance. Obstetrics & Gynecology will be transitioning as much as possible to use of the reVITALize definitions, and we encourage authors to familiarize themselves with them. The obstetric data definitions are available at http://links.lww.com/AOG/A515, and the gynecology data definitions are available at http://links.lww.com/AOG/A515, The relevant definitions have been reviewed.

6. Because of space limitations, it is important that your revised manuscript adhere to the following length restrictions by manuscript type: Clinical Practice and Quality articles should not exceed 22 typed, double-spaced pages (5,500 words). Stated page limits include all numbered pages in a manuscript (i.e., title page, précis, abstract, text, references, tables, boxes, figure legends, and appendixes).

Please limit your Introduction to 250 words and your Discussion to 750 words. **The introduction and discussion both meet these word limits.**

7. Titles in Obstetrics & Gynecology are limited to 100 characters (including spaces). Do not structure the title as a declarative statement or a question. Introductory phrases such as "A study of..." or "Comprehensive investigations into..." or "A discussion of..." should be avoided in titles. Abbreviations, jargon, trade names, formulas, and obsolete terminology also should not be used in the title. Titles should include "A Randomized Controlled Trial," "A Meta-Analysis," or "A Systematic Review," as appropriate, in a subtitle. Otherwise, do not specify the type of manuscript in the title. **The title meets these specifications**.

8. Specific rules govern the use of acknowledgments in the journal. Please edit your acknowledgments or provide more information in accordance with the following guidelines: **There are no acknowledgements in this manuscript.**

* 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 signature on the journal's author agreement 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).

9. Provide a précis on the second page, for use in the Table of Contents. 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 (i.e.,

the bottom line). The précis should be similar to the abstract's conclusion. Do not use commercial names, abbreviations, or acronyms in the précis. Please avoid phrases like "This paper presents" or "This case presents."

This has been included.

10. 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: Clinical Practice and Quality, 300 words. Please provide a word count. **The abstract has been reviewed with these comments in mind, and a word count added.**

11. 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.

This has been reviewed and incorporated where applicable.

12. 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.

This has been corrected.

13. Please review the journal's Table Checklist to make sure that your tables conform to journal style. The Table Checklist is available online here: <u>http://edmgr.ovid.com/ong/accounts/table_checklist.pdf</u>. **This has been reviewed.**

14. The American College of Obstetricians and Gynecologists' (College) documents are frequently updated. These documents may be withdrawn and replaced with newer, revised versions. If you cite College documents in your manuscript, be sure the reference you are citing is still current and available. If the reference you are citing has been updated (i.e., replaced by a newer version), please ensure that the new version supports whatever statement you are making in your manuscript and then update your reference list accordingly. If the reference you are citing has been withdrawn with no clear replacement, please contact the editorial office for assistance (obgyn@greenjournal.org). In most cases, if a College document has been withdrawn, it should not be referenced in your manuscript (exceptions could include manuscripts that address items of historical interest). All College documents (eg, Committee Opinions and Practice Bulletins) may be found via the Resources and Publications page at http://www.acog.org/Resources-And-Publications.

The ACOG reference cited is current and available.

15. Figures

Figure 1: This may be re-submitted as-is.

Figure 2: Is this figure available at a higher resolution?

A higher resolution figure has been re-submitted along with this manuscript.

16. 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, that each author has given approval to the final form of the revision, and that the agreement form signed by each author and submitted with the initial version remains valid.

Again, your paper will be maintained in active status for 21 days from the date of this letter. If we have not heard from you by Sep 27, 2018, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

Nancy C. Chescheir, MD Editor-in-Chief Dear Randi,

Thank you very much for the email. The requested changes have been made in track changes and the revised manuscript attached to this email. The responses are also noted below.

1. General: The Editor has made edits to the manuscript using track changes. Please review them to make sure they are correct. **The edits have been reviewed and are correct.**

2. Line 55: Page 13 says 90%. Which is correct? The exact number is 90.6 but I rounded to 91%. This has also been changed on page 13 for consistency.

3. Line 62: Do you have any information to add to this paragraph? **No, there is no funding source.**

4. Line 89: This is a new section we're adding to Clinical Practice and Quality articles that are being considered for the January 2019 issue and beyond. Do you have any information to add? **No information to add.**

5. Line 230: The abstract says 91%. This was corrected to 91% to be consistent with the abstract. The number was rounded up from 90.6

6. Line 369: Please add an in-text citation for Table 2. Tables should be cited in order at first mention. **This has been included in line 196 of the Results.**

From: Randi Zung <RZung@greenjournal.org>
Sent: Thursday, October 04, 2018 3:14 PM
To: Holland, Erica, M.D.
Subject: Your Revised Manuscript 18-1502R1

External Email - Use Caution

Dear Dr. Holland:

Your revised manuscript is being reviewed by the Editors. Before a final decision can be made, we need you to address the following queries. Please make the requested changes to the latest version of your manuscript that is attached to this email. **Please track your changes and leave the ones made by the Editorial Office.** Please also note your responses to the author queries in your email message back to me.

1. General: The Editor has made edits to the manuscript using track changes. Please review them to make sure they are correct.

2. Line 55: Page 13 says 90%. Which is correct?

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4. Line 89: This is a new section we're adding to Clinical Practice and Quality articles that are being considered for the January 2019 issue and beyond. Do you have any information to add?

5. Line 230: The abstract says 91%.

6. Line 369: Please add an in-text citation for Table 2. Tables should be cited in order at first mention.

To facilitate the review process, we would appreciate receiving a response by October 9.

Best, Randi Zung

Randi Zung (Ms.)

Editorial Administrator | *Obstetrics & Gynecology* The American College of Obstetricians and Gynecologists 409 12th Street, SW Washington, DC 20024-2188 T: 202-314-2341 | F: 202-479-0830 http://www.greenjournal.org

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Hi Stephanie,

I have reviewed the images and they look correct. I do not have any changes.

Thank you.

Erica

From: Stephanie Casway <SCasway@greenjournal.org>
Sent: Wednesday, October 10, 2018 9:21 AM
To: Holland, Erica, M.D.
Subject: O&G Figure Revision: 18-1502

External Email - Use Caution

Good Morning Dr. Holland,

Your figures and legend have been edited, and PDFs of the figures and legend are attached for your review. Please review the figures CAREFULLY for any mistakes.

PLEASE NOTE: Any changes to the figures must be made now. Changes at later stages are expensive and time-consuming and may result in the delay of your article's publication.

To avoid a delay, I would be grateful to receive a reply no later than Friday, 10/12. Thank you for your help.

Best wishes,

Stephanie Casway, MA Production Editor *Obstetrics & Gynecology* American College of Obstetricians and Gynecologists 409 12th St, SW Washington, DC 20024 Ph: (202) 314-2339 Fax: (202) 479-0830 <u>scasway@greenjournal.org</u>

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