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: Mar 13, 2020
To: "Luciana Mullman" lmullman16@icloud.com
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-20-221

RE: Manuscript Number ONG-20-221

Improved Outcomes with an Enhanced Recovery Approach to Cesarean Delivery

Dear Dr. Mullman:

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 Apr 03, 2020, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1:

1) Title: The Title is reflective of the study performed.

2) Precis: The Precis is well stated.

3) Abstract: The Abstract is a reasonable summary of the full manuscript.

4) Introduction: You state in Line 59 that the C/S rate in the United States is estimated to be 32% of all births. When you calculate out the estimated C/S rate for Saint Barnabas Medical Center it seems to be closer to 36%. I would recommend commenting on why that may be the case. Furthermore, it is interesting that when you look at the Post-Intervention numbers it seems that the C/S rate at Saint Barnabas is closer to 38%, which may warrant further explanation. Additionally, you mention in Line 69 that the multidisciplinary effort was to create an ERAS pathway for all cesarean patients at your center, however in the methods you only describe the pathway for those with anticipated or scheduled cesareans.

5) Methods: IRB approval is referenced in Lines 131-132. Your paper would benefit from describing the two circumstances by which patients end up having a C/S - either anticipated/scheduled or unscheduled/emergent. Your methods clearly review the Preop / Intraop / Postop care and management for those undergoing scheduled C/S, however there is no mention about how patients who ultimately end up needing a C/S on an urgent/emergent basis due to complications during the L&D experience enter the ERAS protocol. In my experience, it is typically this cadre of patients who end up experiencing more pain than those patients who arrive well rested for their scheduled C/S. Do they simply enter the ERAS protocol at the Intraoperative time point? In Line 100 you discuss identifying anemia in the early third trimester and that those patients were referred to our "blood management program for hemoglobin optimization." Please describe what that entailed as in Table 1 it seems this occurs at 37 weeks, so wondering what is recommended between 26-28 weeks and that 37 week referral. Also, I think it would be helpful to address if there were any other issues that may have come up related to some of the Postoperative care. For example, with removing the urinary catheters prior to transfer to the postpartum floor, have you experienced any issues w/ increased urinary retention or lack of identifying postoperative abdominal bleeding given that lack of monitoring. If it was indicated to keep the urinary catheter in place (i.e. for patients with severe Preeclampsia for which monitoring of urine output is critical of if concern for additional blood loss) were those patients maintained in the study? What was the patient's reaction about the requirement of a TAP block for postpartum pain management? Were patients allowed to decline this intervention? Was there any delay in the operating rooms and subsequent scheduled cases due to difficulty achieving completion of the TAP blocks? Clarifying this section more would improve the reader's experience. Did the requirement for physician assessment prior to any opioid

order mean that the resident/attending had to physically see the patient or was speaking to the RN over the phone sufficient for assessment? If a physician assessment was necessary, were there any barriers to this happening. Did this requirement cause any undue stress on either the physicians or the RNs involved?

6) Results: Were there any significant differences in the scheduled C/S vs. non-scheduled C/S groups? Given that the number of C/S's performed Pre-intervention (approximately 36% of deliveries) and Post-intervention (approximately 38% of deliveries), I have surmised that you have included both of these groups (planned vs. unplanned) into your assessment, if not then please specify this. Providing more specifics will add depth and clarity to your paper.

7) Discussion: Elaborating on the points mentioned up above under the Methods section here in the Discussion as well would add further depth and understanding to your study.

8) References: The Reference List appears complete.

9) Tables & Figures: Figures 1 and 2 nicely demonstrate the pre/post effect of your intervention on average length of stay and postpartum opioid use. Table 1 could include a more descriptive explanation such that colleagues could use your ERAS protocol as a Tool Kit to apply at their institutions.

Reviewer #2: The study is overall well written and addresses an important topic. The results are interesting and I believe that it will be highly cited in the future.

I have several concerns:
1. According to the Methods section, there is a pre-op component of the enhanced recovery after surgery (ERAS) plan - how can this be applied in cases of unplanned CS (almost 35% of both cohorts)? Can the authors present a sub-analysis for the unplanned/planned CS groups?

2. In the post-ERAS period - Were all components of the ERAS given to all women (for example - did all women had TAP block?). Please mention in results and if not, provide %.

3. No data were presented regarding potential confounders between the groups (maternal BMI, number of prior CS, indications for CS, estimated blood loss, need for blood products transfusion) that may affect the outcomes (length of stay, costs). A table with baseline characteristics of the groups may be useful.

4. I believe that average length of stay is not as important as the median. Please add data.

5. What were the criteria for discharge home after CS? Did the protocol (pre and post ERAS) necessitate to fulfill all criteria in order to be discharged?

Reviewer #3: Mullman and colleagues present findings from a prospective quality improvement (QI) study designed to evaluate the impact of an enhanced recovery after surgery (ERAS) program for women undergoing cesarean delivery. The authors used a pre- and post-intervention approach for their analysis. Their intervention was broken into 3 major components: preoperative strategy, 2) intraoperative management, and 3) post-operative care. The authors noted that the ERAS program resulted in lesser use of opioid use, shorter length of stay, less cost, and less use of morphine. The issue of us of ERAS in the setting of cesarean delivery is an important consideration, however, the present study is limited information is provided regarding the study cohort demographics. Some of the interventions are also vaguely described in the paper. A point-by-point critique of the paper follows:

1) It would be helpful to define the pre and post interval in the Abstract of the paper. How was the interval selected such that there was imbalance in the pre- and post-intervention sample sizes and time epoch (pre-intervention interval was 12 months and 2109 women, and post-interval was for 8 months and 1463 women.

2) The authors evaluate length of stay in their analysis and note decreased length of stay with the implementation of ERAS. Was length of stay inclusive of pre-operative time or only post-operative time? This is important to clarify in the revised paper. It would seem to be appropriate to evaluate only the post-operative time as this would be the only portion of length of stay that might be impacted by ERAS. The manuscript should be revised to more clearly state the definition of length of stay.

3) Were there any changes in the postpartum care of women or newborns during the study interval? Were there any unit interventions to enhance early discharge time or changes in neonatal evaluation, circumcisions, etc that may have confounded the length of stay. Any parallel interventions or the lack of any, should be specified in the revised paper.

4) The authors describe on lines 91-101, the authors describe how women having scheduled cesarean delivery were prepared for surgery with educational efforts including pre-operative management. How many of the women in the cohort (pre and post time epochs) had scheduled cesarean deliveries vs non-scheduled cesarean? How were women having non-scheduled cesarean managed? Was there a consistent approach? This should be clarified in the revised paper.

5) There are limited specific regarding how each of the interventions were undertaken. For instance, minimization of intravenous opioids in favor of neuraxial opioids, active body warming with warm circulated air, multimodal prophylactic anti emetics, balanced fluid administration are ill defined interventions. The paper would benefit for increased precision in the description of these specific interventions, and others as part of the ERAS implementation.

6) The author report that transversus abdominis plane blocks were used. How was this done and by who? Was this done in all cases post-intervention? As this is not a commonly used procedure during cesarean delivery, it would be of value to provide additional specific regarding how this procedure was done, or provide a reference for the reader.

7) No demographic information is provided for the study cohort (pre vs post implementation groups). It would be helpful to the reader to have some comparison of demographic characteristics to ensure the groups were comparable.

8) No information is provided in the paper regarding compliance with each of the interventions suggested by their ERAS. This information would be helpful to add to the revised paper.

9) Why were the 110 women excluded for admission > 2 days before cesarean delivery? This would advocate for evaluating length of stay following delivery rather than entire admission time.

STATISTICAL EDITOR COMMENTS:

The Statistical Editor makes the following points that need to be addressed:

lines 119-121, Figs 1, 2: Since the ERAS pathway was implemented on 17 Dec 2018, the Authors need to clarify the x-axes. It appears that there are 11 points to the left of the vertical red line, one on the line and 8 points to the right of the red line. Therefore, it appears that monthly means are reported for Jan-Nov before the line, Dec is on the line and Jan-Aug are represented after the line. If so, then Dec was actually a transitional month. How exactly were the pre and post ERAS periods allocated? Was the implementation entirely accomplished on Dec 17 or was it more gradually implemented? Did providers have some changes in practices prior to the implementation? It appears that there was a slight decrease in average LOS prior to the Dec 17 date. If the transition was actually implemented more gradually than at one day in Dec, then should modify the pre and post periods to reflect times before any implementation and after full implementation.

lines 141-146: LOS is often skewed and average (mean) and SD are often not the most appropriate representation of LOS. Since a non-parametric test was used to compare LOS, then I assume the distributions were non-normal. Then, the LOS should be cited as median(range) in text and figure of monthly rates, not as mean(SD). Likewise for costs, which are also often skewed. If those were non-normally distributed, should cite as median(range) and that test should also be non-paremetric. What was the 30-day readmission rate pre and post? If those rates were small, then there may have been insufficient power to generalize any NS comparison.

Suggest a concise Table to show the stats comparisons pre and post.

EDITOR'S 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 things. Adherence to these requirements with your revision will avoid delays during the revision process, as well as avoid re-revisions on your part in order to comply with the formatting.

PRESENTATION OF STATS INFORMATION: THIS APPLIES TO YOUR ENTIRE SUBMISSION (Abstract, Manuscript, Tables, etc)
P Values vs Effect Size and Confidence Intervals: While P values are a central part of inference testing in statistics, when cited alone, often the strength of the conclusion can be misunderstood. Whenever possible, the preferred citation should be in terms of an effect size, such as odds ratio or relative risk or the mean difference of a variable between two groups, expressed with appropriate confidence intervals. When such syntax is used, the P value has only secondary importance

and often can be omitted or noted as footnotes in a Table format. Putting the results in the form of an effect size makes the result of the statistical test more clinically relevant and gives better context than citing P values alone.

This is true for the abstract as well as the manuscript, tables and figures.

Please provide absolute values for variables, in addition to assessment of statistical significance.

We ask that you provide crude OR's followed by adjusted OR's for all relevant variables.

27: Please avoid causal language throughout your manuscript. Your study can identify and quantify associations, but not causation. Language should be changed in the precis, abstract, and manuscript, if causal language is used in those sites. For instance, in the process you note that "Implementation…reduces length of stay" which is an example of causal language. There are multiple other examples of this throughout your manuscript. You could write this instead as" implementing an enhanced recovery after surgery program for Cesarean delivery is associated with reduce length of stay…"

30: he objective of the abstract should be a simple "To" statement without background information. Just say "to examine the results of a quality improvement project…"

30: It is an idiosyncratic fact that at the Journal we tend to avoid the use of the word impact to imply the result of a change, preferring to limit "impact" to mean a physical blow.

34: I'm not clear what a consensus pathway is. As touch this sentence doesn't make sense to me.

37: please note here and elsewhere in your paper that your study was contacted from day one to date to nap between those dates. As written it would exclude the dates given.

84: do not begin a sentence with a. Either spell out or edit your sensitive or the need to start with a number.

44: instead of saying"our program…" just say something like" there are significant benefit of an ERAS pathway…".

53: I really like your description of ERAS pathways.

71: please clearly state hypothesis, primary and secondary outcomes. Then report your results and organize your discussion addressing your primary and then your secondary outcomes.

80: was there a standard order sent prior to this time for the postoperative pain regimen or was this left to the individual physician's discretion?

87: how did you identify the literature used to inform your team discussions?

91: Beginning in this section and ongoing through your methods section common you need to address the issue raised by several over your reviewers, with which I agree, regarding the patients with an unscheduled cesarean birth. Your discussion starting at 91 and going through 101 at the very least relate to scheduled cesarean births.

It will be necessary in a revision to not only provide the results from your overalls cesarean birth cohorts pre-and post, but also broken down by patients who delivered via scheduled versus unscheduled cesarean delivery. As well, the length of stay for the unscheduled cesarean birth cohort needs to be compared from the time of surgery to discharge not for total length of stay given that the patients' intrapartum LOS might be highly variable and unrelated to the ERAS protocol.

107: in your discussion it will be necessary for you to describe the evidence-based that you use for the TAP blocks. The green journal and others have published data that' suggest not effective in reducing postoperative pain compared to not using the TAP block. As such these do not seem like they are evidence-based and that warrants a conversation in your discussion.

139: please break this sentence into two parts as written it seems rather disjointed. We do not allow our Thursday describe variables are outcomes in terms that imply a difference parentheses such as the use of terms of "trend" or "tendency" or "Slight decrease." when there was no statistical difference. Please edit here and throughout indicate that there is no difference.

152: make sure you discuss your primary followed by your secondary outcomes.

153: this is an example of causal language.

154: This is known as a primacy claim: yours is the first, "unique" biggest, best study of its kind. In order to make such a claim, please provide the data bases you have searched (PubMED, Google Scholar, EMBASE for example) and the search terms used. IF not done, please edit it out of the paper.

157: please provide a relevant data

Discussion: one of your reviewers wanted you to address your very delivery rate. I don't believe that that is relevant or necessary for your paper.

168: what is a medical leader ship society?

177: it seems reasonable to comment on the fact that decreasing variability in practice as an independent step seems to be a reasonable approach to quality improvement in the area of standardized medical care.

181: this is the second time you mentioned a"dedicated ERAS coordinator". Could you tell us a little bit more about this position? In your hospital who pays for this, what is his or her background, and to whom do they report?

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. As of December 17, 2018, Obstetrics & Gynecology has implemented an "electronic Copyright Transfer Agreement" (eCTA) and will no longer be collecting author agreement forms. When you are ready to revise your manuscript, you will be prompted in Editorial Manager (EM) to click on "Revise Submission." Doing so will launch the resubmission process, and you will be walked through the various questions that comprise the eCTA. Each of your coauthors will receive an email from the system requesting that they review and electronically sign the eCTA.

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. Please submit a completed STROBE checklist with your revision.

Responsible reporting of research studies, which includes a complete, transparent, accurate and timely account of what was done and what was found during a research study, is an integral part of good research and publication practice and not an optional extra. Obstetrics & Gynecology supports initiatives aimed at improving the reporting of health research, and we ask authors to follow specific guidelines for reporting randomized controlled trials (ie, CONSORT), observational studies (ie, STROBE), meta-analyses and systematic reviews of randomized controlled trials (ie, PRISMA), harms in systematic reviews (ie, PRISMA for harms), studies of diagnostic accuracy (ie, STARD), meta-analyses and systematic reviews of observational studies (ie, MOOSE), economic evaluations of health interventions (ie, CHEERS), quality improvement in health care studies (ie, SQUIRE 2.0), and studies reporting results of Internet e-surveys (CHERRIES). Include the appropriate checklist for your manuscript type upon submission. Please write or insert the page numbers where each item appears in the margin of the checklist. Further information and links to the checklists are available at http://ong.editorialmanager.com. In your cover letter, be sure to indicate that you have followed the CONSORT, MOOSE, PRISMA, PRISMA for harms, STARD, STROBE, CHEERS, SQUIRE 2.0, or CHERRIES guidelines, as appropriate.

4. Standard obstetric and gynecology data definitions have been developed through the reVITALize initiative, which was convened by the American College of Obstetricians and Gynecologists and the members of the Women's Health Registry Alliance. Obstetrics & Gynecology has adopted the use of the reVITALize definitions. Please access the obstetric and gynecology data definitions at https://www.acog.org/About-ACOG/ACOG-Departments/Patient-Safety-and-Quality-Improvement/reVITALize. If use of the reVITALize definitions is problematic, please discuss this in your point-by-point response to this letter.

5. 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.

6. 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).

7. Provide a short title of no more than 45 characters, including spaces, for use as a running foot.

8. The most common deficiency in revised manuscripts involves the abstract. Be sure there are no inconsistencies between the Abstract and the manuscript, and that the Abstract has a clear conclusion statement based on the results found in the paper. Make sure that the abstract does not contain information that does not appear in the body text. If you submit a revision, please check the abstract carefully.

In addition, the abstract length should follow journal guidelines. The word limits for different article types are as follows: Original Research articles, 300 words. Please provide a word count.

9. Only standard abbreviations and acronyms are allowed. A selected list is available online at http://edmgr.ovid.com/ong/accounts/abbreviations.pdf. Abbreviations and acronyms cannot be used in the title or précis. Abbreviations and acronyms must be spelled out the first time they are used in the abstract and again in the body of the manuscript.

10. The journal does not use the virgule symbol (/) in sentences with words. Please rephrase your text to avoid using "and/or," or similar constructions throughout the text. You may retain this symbol if you are using it to express data or a measurement.

11. In your Abstract, manuscript Results sections, and tables, the preferred citation should be in terms of an effect size, such as odds ratio or relative risk or the mean difference of a variable between two groups, expressed with appropriate confidence intervals. When such syntax is used, the P value has only secondary importance and often can be omitted or noted as footnotes in a Table format. Putting the results in the form of an effect size makes the result of the statistical test more clinically relevant and gives better context than citing P values alone.

If appropriate, please include number needed to treat for benefits (NNTb) or harm (NNTh). When comparing two procedures, please express the outcome of the comparison in U.S. dollar amounts.

Please standardize the presentation of your data throughout the manuscript submission. For P values, do not exceed three decimal places (for example, "P = .001"). For percentages, do not exceed one decimal place (for example, 11.1%").

12. 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.

13. Figures 1–2: Please upload as figure files on Editorial Manager.

14.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 http://edmgr.ovid.com/acd/accounts/ifauth.htm.

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.

15. 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 21 days from the date of this letter. If we have not heard from you by Apr 03, 2020, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

Nancy C. Chescheir, MD
Editor-in-Chief

2018 IMPACT FACTOR: 4.965
2018 IMPACT FACTOR RANKING: 7th out of 83 ob/gyn journals

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Dr. Chescheir,

We would like to thank you for the thoughtful commentary from yourself and reviewers, as well as the opportunity to address these comments. We believe the updated analysis and manuscript representative a significant increase in the quality of our study. In particular, we have adjusted our length of stay definition to reflect the time from cesarean to discharge, and subsequently included all cesarean cases. Additionally, the clarification of the benefit of our program to both scheduled and emergent cases, as well as the subset analyses of these groups, has provided greater insight into the benefits of the program. Below we provide point by point responses to the provided reviewer comments (tracked changes). We have also included both a clean and tracked changes version of our manuscript, have included the relevant STROBE checklist, and also acknowledge that we have read the instructions for authors.

Sincerely,

Luciana Mullman MPH, CSSGB

Administrative Director- Clinical Excellence and Effectiveness

Saint Barnabas Medical Center

REVIEWER COMMENTS:

Reviewer #1:

1) Title: The Title is reflective of the study performed.

2) Precis: The Precis is well stated.

3) Abstract: The Abstract is a reasonable summary of the full manuscript.

4) Introduction: You state in Line 59 that the C/S rate in the United States is estimated to be 32% of all births. When you calculate out the estimated C/S rate for Saint Barnabas Medical Center it seems to be closer to 36%. I would recommend commenting on why that may be the case. Furthermore, it is interesting that when you look at the Post-Intervention numbers it seems that the C/S rate at Saint Barnabas is closer to 38%, which may warrant further explanation. Additionally, you mention in Line 69 that the multidisciplinary effort was to create an ERAS pathway for all cesarean patients at your center, however in the methods you only describe the pathway for those with anticipated or scheduled cesareans.

We have provided additional commentary in the discussion regarding the cesarean rate at our institution, and our continued focus on initiatives which can reduce our rate. The cesarean rate in the state of NJ has historically been higher than that of the United States, nearing 36%, and we have referenced this within the discussion.

The manuscript does not present the cesarean rate for our institution pre or post intervention, and only presents the number of cesarean cases and not the total number of births. The introduction had previously provided a historical estimate of birth and cesareans, but we have adjusted the text of this section in order to avoid any potential confusion as this text did not have a specific reference period.

We have clarified in the methods that the all cesarean cases are enrolled in the pathway, but only the scheduled cases received the preoperative components.

5) Methods: IRB approval is referenced in Lines 131-132. Your paper would benefit from describing the two circumstances by which patients end up having a C/S - either anticipated/scheduled or unscheduled/emergent. Your methods clearly review the Preop / Intraop / Postop care and management for those undergoing scheduled C/S, however there is no mention about how patients who ultimately end up needing a C/S on an urgent/emergent basis due to complications during the L&D experience enter the ERAS protocol. In my experience, it is typically this cadre of patients who end up experiencing more pain than those patients who arrive well rested for their scheduled C/S. Do they simply enter the ERAS protocol at the Intraoperative time point? In Line 100 you discuss identifying

anemia in the early third trimester and that those patients were referred to our "blood management program for hemoglobin optimization." Please describe what that entailed as in Table 1 it seems this

occurs at 37 weeks, so wondering what is recommended between 26-28 weeks and that 37 week referral. Also, I think it would be helpful to address if there were any other issues that may have come up related to some of the Postoperative care. For example, with removing the urinary catheters prior to transfer to the postpartum floor, have you experienced any issues w/ increased urinary retention or lack of identifying postoperative abdominal bleeding given that lack of monitoring. If it was indicated to keep the urinary catheter in place (i.e. for patients with severe Preeclampsia for which monitoring of urine output is critical of if concern for additional blood loss) were those patients maintained in the study? What was the patient's reaction about the requirement of a TAP block for postpartum pain management? Were patients allowed to decline this intervention? Was there any delay in the operating rooms and subsequent scheduled cases due to difficulty achieving

completion of the TAP blocks? Clarifying this section more would improve the reader's experience. Did the requirement for physician assessment prior to any opioid order mean that the resident/attending had to physically see the patient or was speaking to the RN over the phone sufficient for assessment? If a physician assessment was necessary, were there any barriers to this happening. Did this requirement cause any undue stress on either the physicians or the RNs involved?

We agree that the differentiation of scheduled/emergent cases and how they enter into our protocol was not well defined. We have updated the manuscript to ensure clarity in that all patients are included in our protocol, but emergent cases by definition do not benefit from the preoperative components, but are managed according to the intraoperative and postoperative ERAS aspects. We have additionally included sub analyses of all outcomes based on scheduled/emergent cesarean.

We have corrected Table 1 in regards to hemoglobin optimization. This had previously been listed at 37 weeks, but should have been listed as 27 weeks.

All patients who had a cesarean section within the study period were included on study, and we have incorporated additional details on compliance to specific aspects of the ERAS protocol to the discussion section. Patients were not excluded based on their need for longer term urinary catheter use, and we have adjusted the methods to indicate they were kept in as necessary to avoid any complications.

To date we have had no objections from patients regarding the usage of TAP blocks, and none have refused them prior to cesarean. On average TAP blocks are typically completed within 5 minutes at the end of the case and have not caused any unnecessary delays. We have additionally expanded upon their usage in the discussion.

The ob/gyn resident are called by nursing staff if multimodal pain management is not effective enough for the patient patient and there is a need for opioid use. In most cases the residents prefer to assess the patient at bedside before ordering any opioids, but may give a one-time verbal order to the nurse over the phone when necessary. We have adjusted the wording in the manuscript description as it relates to this ordering to clarify the process.

6) Results: Were there any significant differences in the scheduled C/S vs. non-scheduled C/S groups? Given that the number of C/S's performed Pre-intervention (approximately 36% of deliveries) and Post-intervention (approximately 38% of deliveries), I have surmised that you have included both of these groups (planned vs. unplanned) into your assessment, if not then please specify this. Providing more specifics will add depth and clarity to your paper.

We agree that the question of differences in outcomes is an important one and have additionally included sub-analyses of all outcomes based on scheduled non/scheduled cesarean. Overall, the sub-analysis results were similar to those of the overall analysis for all outcomes, with no differences in terms of significance or conclusions. We have also attempted to clarify throughout the manuscript that we have included both scheduled and emergent cases.

7) Discussion: Elaborating on the points mentioned up above under the Methods section here in the Discussion as well would add further depth and understanding to your study.

We agree, and have incorporated additional information in the discussion section based on the above and other reviewer commentary.

8) References: The Reference List appears complete.

9) Tables & Figures: Figures 1 and 2 nicely demonstrate the pre/post effect of your intervention on average length of stay and postpartum opioid use. Table 1 could include a more descriptive explanation such that colleagues could use your ERAS protocol as a Tool Kit to apply at their institutions.

We agree and have expanded on the details provided in Table 1.

Reviewer #2: The study is overall well written and addresses an important topic. The results are interesting and I believe that it will be highly cited in the future.

I have several concerns:

1. According to the Methods section, there is a pre-op component of the enhanced recovery after surgery (ERAS) plan - how can this be applied in cases of unplanned CS (almost 35% of both cohorts)? Can the authors present a sub-analysis for the unplanned

/planned CS groups?

As you note, the pre-op aspect of the ERAS plan does not provide benefit to patients with unscheduled cesareans, and we have clarified this within the manuscript. Our goal was to evaluate the overall benefit in all cesarean cases as all aspects during and after the cesarean are beneficial for all patients. We have

additionally provided sub-analyses for all outcomes based on scheduled/emergent cesarean and our outcomes remain consistent within each sub-group.

2. In the post-ERAS period - Were all components of the ERAS given to all women (for example - did all women had TAP block?). Please mention in results and if not, provide %.

Standardized order sets were developed for the ERAS protocol to ensure that the standing orders were the same for all patients who had a cesarean. Our ERAS coordinator works to review patient charts and ensure that the order sets are being followed. Overall we have noted good compliance with all aspects of the protocol, with approximately 98% of patients receiving TAP blocks as ordered. We have updated the manuscript to include additional details on the ERAS coordinator and compliance.

3. No data were presented regarding potential confounders between the groups (maternal BMI, number of prior CS, indications for CS, estimated blood loss, need for blood products transfusion) that may affect the outcomes (length of stay, costs). A table with baseline characteristics of the groups may be useful.

Our data was sourced from an administrative database which did not contain additional demographic information beyond age and race. We acknowledge that this lack of additional data limits the generalizability of our conclusions and have included these limitations in our discussion.

4. I believe that average length of stay is not as important as the median. Please add data.

We agree that the average length of stay is not a perfect representation, particularly in the situation where length of stay can be skewed for some patients. We have additionally noted within the text what the median length of stay was, although given that most patients are inpatient for a limited time, the median remained the same across the two periods. This further supports the presentation of the average length of stay as it provides an indication of the change which isn't evident in the median. Additionally, many institutions remain focused on average length of stay in evaluating their performance, which supports the presentation of average length of stay in conjunction with the median.

5. What were the criteria for discharge home after CS? Did the protocol (pre and post ERAS) necessitate to fulfill all criteria in order to be discharged?

The discharge criteria remained unchanged across the study period and contained standard criteria including was being able to tolerate oral food and medication intake, passing flatus, with good pain control, and ability to ambulate. We have provided additional details in the methods section as well.

Reviewer #3: Mullman and colleagues present findings from a prospective quality improvement (QI) study designed to evaluate the impact of an enhanced recovery after surgery (ERAS) program for women undergoing cesarean delivery. The authors used a pre- and post-intervention approach for their analysis. Their intervention was broken into 3 major components: preoperative strategy, 2) intraoperative management, and 3) post-operative care. The authors noted that the ERAS program resulted in lesser use of opioid use, shorter length of stay, less cost, and less use of morphine. The issue of us of ERAS in the setting of cesarean delivery is an important consideration, however, the present study is limited information is provided regarding the study cohort demographics. Some of the interventions are also vaguely described in the paper. A point-by-point critique of the paper follows:

1) It would be helpful to define the pre and post interval in the Abstract of the paper. How was the interval selected such that there was imbalance in the pre- and post-intervention sample sizes and time epoch (pre-intervention interval was 12 months and 2109 women, and post-interval was for 8 months and 1463 women.

We have included the specific pre/post implementation periods in the abstract as recommended. The pre-implementation period was selected in order to provide a full calendar year worth of data prior to implementation, and the post implementation period was selected based on the period of available data at the time of analysis. We have additionally included these details in the methods section.

2) The authors evaluate length of stay in their analysis and note decreased length of stay with the implementation of ERAS. Was length of stay inclusive of pre-operative time or only post-operative time? This is important to clarify in the revised paper. It would seem to be appropriate to evaluate only the post-operative time as this would be the only portion of length of stay that might be impacted by ERAS. The manuscript should be revised to more clearly state the definition of length of stay.

We agree with the reviewers point and have updated the analysis and manuscript accordingly. The analysis now includes all cesarean patients, and the length of stay is defined as the time from cesarean to discharge.

3) Were there any changes in the postpartum care of women or newborns during the study interval? Were there any unit interventions to enhance early discharge time or changes in neonatal evaluation, circumcisions, etc that may have confounded the length of stay. Any parallel interventions or the lack of any, should be specified in the revised paper.

There were no parallel interventions in place over the study period with respect to patient care, and we have included this detail in the discussion.

4) The authors describe on lines 91-101, the authors describe how women having scheduled cesarean delivery were prepared for surgery with educational efforts including pre-operative management. How many of the women in the cohort (pre and post time epochs) had scheduled cesarean deliveries vs non-scheduled cesarean? How were women having non-scheduled cesarean managed? Was there a consistent approach? This should be clarified in the revised paper.

We agree with the reviewers point and have edited our manuscript and analysis accordingly. In the pre and post implementation periods cesarean was scheduled in 67% and 63% of cases, respectively, and these details are included in the results section. We have additionally included subset analyses of all outcomes based on non/scheduled cesarean section, and note no differences in the results. Many of the ERAS pathway components focus on the cesarean section itself and management of the patient afterwards, and as such the pathway as developed provides considerable benefit to both scheduled and non-scheduled patients. We have additionally clarified this point within the text.

5) There are limited specific regarding how each of the interventions were undertaken. For instance, minimization of intravenous opioids in favor of neuraxial opioids, active body warming with warm circulated air, multimodal prophylactic anti emetics, balanced fluid administration are ill defined interventions. The paper would benefit for increased precision in the description of these specific interventions, and others as part of the ERAS implementation.

We have included additional information in the methods and table which outlines the ERAS program in an effort to increase the clarity of the program description.

6) The author report that transversus abdominis plane blocks were used. How was this done and by who? Was this done in all cases post-intervention? As this is not a commonly used procedure during cesarean delivery, it would be of value to provide additional specific regarding how this procedure was done, or provide a reference for the reader.

The TAP blocks were done by anesthesiologists at the end of each cesarean, and compliance to the order set which included the use of the TAP blocks has been near 98% across the study period. We have elaborated on their usage in the methods section. We have additionally elaborated in our discussion regarding the usage of TAP blocks within this population and provided additional references for their use.

7) No demographic information is provided for the study cohort (pre vs post implementation groups). It would be helpful to the reader to have some comparison of demographic characteristics to ensure the groups were comparable.

Our data was sourced from an administrative database which did not contain additional demographic information beyond age and race. We acknowledge that this lack of additional data limits the generalizability of our conclusions and have included these limitations in our discussion.

8) No information is provided in the paper regarding compliance with each of the interventions suggested by their ERAS. This information would be helpful to add to the revised paper.

We agree that the issue of compliance was not well covered and we have included additional details on the role of our ERAS coordinator and observed compliance over the study period to the discussion.

9) Why were the 110 women excluded for admission > 2 days before cesarean delivery? This would advocate for evaluating length of stay following delivery rather than entire admission time.

We agree with the reviewer's position and have edited the manuscript and analysis accordingly. We have included all cesarean section deliveries in our updated analysis, and have assessed length of stay as the time from cesarean section to discharge, and have also restricted opioid usage to the same time interval.

STATISTICAL EDITOR COMMENTS:

The Statistical Editor makes the following points that need to be addressed:

lines 119-121, Figs 1, 2: Since the ERAS pathway was implemented on 17 Dec 2018, the Authors need to clarify the x-axes. It appears that there are 11 points to the left of the vertical red line, one on the line and 8 points to the right of the red line. Therefore, it appears that monthly means are reported for Jan-Nov before the line, Dec is on the line and Jan-Aug are represented after the line. If so, then Dec was actually a transitional month. How exactly were the pre and post ERAS periods allocated? Was the implementation entirely accomplished on Dec 17 or was it more gradually implemented? Did providers have some changes in practices prior to the implementation? It appears that there was a slight decrease in average LOS prior to the Dec 17 date. If the transition was actually implemented more gradually than at one day in Dec, then should modify the pre and post periods to reflect times before any implementation and after full implementation.

We agree with the reviewer and have adjusted the graphics accordingly, including clarification in the figure caption regarding the presentation. We have separated the month of December, when the program implementation took place, into two points, one for pre and post-implementation. The standardized order set went into place on December 17th, and as such all cesarean cases after that point were managed according to the order set. Providers were informed of the new order sets, and the program itself was developed as a collaborative which included OB/GYN staff. Given potential variability in provider practice, it is possible that some providers adopted aspects prior to the official implementation. We have included additional details on the role of our ERAS coordinator and compliance to the individual items in our order set to the manuscript.

lines 141-146: LOS is often skewed and average (mean) and SD are often not the most appropriate representation of LOS. Since a non-parametric test was used to compare LOS, then I assume the distributions were non-normal. Then, the LOS should be cited as median(range) in text and figure of monthly rates, not as mean(SD). Likewise for costs, which are also often skewed. If those were non-normally distributed, should cite as median(range) and that test should also be non-paremetric. What was the 30-day readmission rate pre and post? If those rates were small, then there may have been insufficient power to generalize any NS comparison.

We agree that the mean length of stay can be difficult to interpret in cases with large skewed values. We have additionally included the median (range) length of stay in the results as well. Given that most patients are inpatient for only a short time, the median remains unchanged across the pre/post implementation period, supporting the presentation of the average length of stay as well. Additionally, many institutions continue to focus on average length of stay as an evaluation metric for performance which we believe also supports its presentation in combination with the median value. Of note, all tests of significance were done using a non-parametric approach as noted.

For costs, we agree that the median (range) are appropriate and have updated the results accordingly.

In the updated results, the 30 day readmission rates were 1.4% (n = 31) and 1.7% (n=26) respectively in the pre/post periods, and we have included these details in the results.

Suggest a concise Table to show the stats comparisons pre and post.

We have included an additional table with results, including the subset analyses by scheduled/emergent cesarean requested by additional reviewers.

EDITOR'S 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 things. Adherence to these requirements with your revision will avoid delays during the revision process, as well as avoid re-revisions on your part in order to comply with the formatting.

PRESENTATION OF STATS INFORMATION: THIS APPLIES TO YOUR ENTIRE SUBMISSION (Abstract, Manuscript, Tables, etc)

P Values vs Effect Size and Confidence Intervals: While P values are a central part of inference testing in statistics, when cited alone, often the strength of the conclusion can be misunderstood. Whenever possible, the preferred citation should be in terms of an effect size, such as odds ratio or relative risk or the mean difference of a variable between two groups, expressed with appropriate confidence intervals. When such syntax is used, the P value has only secondary importance and often can be omitted or noted as footnotes in a Table format. Putting the results in the form of an effect size makes the result of the statistical test more clinically relevant and gives better context than citing P values alone.

This is true for the abstract as well as the manuscript, tables and figures.

Please provide absolute values for variables, in addition to assessment of statistical significance.

We ask that you provide crude OR's followed by adjusted OR's for all relevant variables.

27: Please avoid causal language throughout your manuscript. Your study can identify and quantify associations, but not causation. Language should be changed in the precis, abstract, and manuscript, if causal language is used in those sites. For instance, in the process you note that "Implementation…reduces length of stay" which is an example of causal language. There are multiple other examples of this throughout your manuscript. You could write this instead as" implementing an enhanced recovery after surgery program for Cesarean delivery is associated with reduce length of stay…"

We have adjusted the wording throughout in order to avoid causal language.

30: he objective of the abstract should be a simple "To" statement without background information. Just say "to examine the results of a quality improvement project…"

We have adjusted the wording as noted.

30: It is an idiosyncratic fact that at the Journal we tend to avoid the use of the word impact to imply the result of a change, preferring to limit "impact" to mean a physical blow.

We have adjusted the wording as noted.

34: I'm not clear what a consensus pathway is. As touch this sentence doesn't make sense to me.

We have adjusted the wording to clarify. The intention was to indicate that this was an agreed upon (consensus) pathway, but we agree this was not clear in the abstract.

37: please note here and elsewhere in your paper that your study was contacted from day one to date to nap between those dates. As written it would exclude the dates given.

We have updated the text to clarify that the study period was inclusive of the initial and final dates.

84: do not begin a sentence with a. Either spell out or edit your sensitive or the need to start with a number.

We have adjusted the wording as noted.

44: instead of saying"our program…" just say something like" there are significant benefit of an ERAS pathway…".

We have adjusted the wording accordingly.

53: I really like your description of ERAS pathways.

Thank you!

71: please clearly state hypothesis, primary and secondary outcomes. Then report your results and organize your discussion addressing your primary and then your secondary outcomes.

We have adjusted the text accordingly.

80: was there a standard order sent prior to this time for the postoperative pain regimen or was this left to the individual physician's discretion?

Prior to the ERAS protocol, pain management was left to the physician's discretion. We have included this in the text as well.

87: how did you identify the literature used to inform your team discussions?

Publications from the ERAS society as well as other governing medical societies was reviewed. We have included these details as well.

91: Beginning in this section and ongoing through your methods section common you need to address the issue raised by several over your reviewers, with which I agree, regarding the patients with an unscheduled cesarean birth. Your discussion starting at 91 and going through 101 at the very least relate to scheduled cesarean births.

It will be necessary in a revision to not only provide the results from your overalls cesarean birth cohorts pre-and post, but also broken down by patients who delivered via scheduled versus unscheduled cesarean delivery. As well, the length of stay for the unscheduled cesarean birth cohort needs to be compared from the time of surgery to discharge not for total length of stay given that the patients' intrapartum LOS might be highly variable and unrelated to the ERAS protocol.

We agree with the reviewer's comment regarding the importance of the potential difference in outcomes between un/scheduled cesareans. Additionally, we have adjusted our definition of length of time to be the time from cesarean till discharge. We have included additional subset analyses which address this point, and all of the earlier results remain consistent within our subsets. Additionally, we have adjusted the methods section to further clarify the inclusion of all patients (scheduled/emergent) as well as iterate which aspects of the ERAS pathway provide benefit to each group of patients.

107: in your discussion it will be necessary for you to describe the evidence-based that you use for the TAP blocks. The green journal and others have published data that' suggest not effective in reducing postoperative pain compared to not using the TAP block. As such these do not seem like they are evidence-based and that warrants a conversation in your discussion.

We have elaborated on the usage of TAP blocks in our discussion. Several studies have noted a beneficial effect for post-operative pain management and reducing opioid consumption in the cesarean population (Buluc 2019, Baker 2018, Jadon 2018, Fusco 2015, Abdallah 2012). We have also commented on other studies which have shown no effect in the cesarean population (McKeen 2014) or other gynecological surgery (Hachem 2015, Kane 2012). We believe our results further support their usage within a multimodal pain management strategy in reducing opioid consumption and total MME when opioids are needed.

139: please break this sentence into two parts as written it seems rather disjointed. We do not allow our Thursday describe variables are outcomes in terms that imply a difference parentheses such as the use of terms of "trend" or "tendency" or "Slight decrease." when there was no statistical difference. Please edit here and throughout indicate that there is no difference.

We have adjusted the text to reflect no difference across the pre/post period.

152: make sure you discuss your primary followed by your secondary outcomes.

We have reordered this section to discuss the primary outcome first, followed by the secondary outcomes.

153: this is an example of causal language.

We have adjusted the text accordingly.

154: This is known as a primacy claim: yours is the first, "unique" biggest, best study of its kind. In order to make such a claim, please provide the data bases you have searched (PubMED, Google Scholar, EMBASE for example) and the search terms used. IF not done, please edit it out of the paper.

We have adjusted the text accordingly.

157: please provide a relevant data

We have removed all references to patient satisfaction from the manuscript as they were not a primary of secondary aim, and were also not well evaluated or presented in the manuscript.

Discussion: one of your reviewers wanted you to address your very delivery rate. I don't believe that that is relevant or necessary for your paper.

noted

168: what is a medical leader ship society?

We intended to refer to governing medical societies such as: American College of Obstetricians and Gynecologists (ACOG), Society of Maternal Fetal Medicine (SMFM). We have adjusted the text to "governing medical societies" to clarify.

177: it seems reasonable to comment on the fact that decreasing variability in practice as an independent step seems to be a reasonable approach to quality improvement in the area of standardized medical care.

We agree and have included additional text.

181: this is the second time you mentioned a"dedicated ERAS coordinator". Could you tell us a little bit more about this position? In your hospital who pays for this, what is his or her background, and to whom do they report?

This is a full time hospital employee that reports to Administrative Director of Clinical Excellence and Effectiveness. Their main function is to track pathway compliance and report out to team any issues. Our coordinator has experience within the hospital setting and we believe an individual with a clinical background is a key support program for any ERAS program. We have included additional details in the respective section as well.

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.

We support your efforts to provide transparent review and elect to OPT-IN

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

2. As of December 17, 2018, Obstetrics & Gynecology has implemented an "electronic Copyright Transfer Agreement" (eCTA) and will no longer be collecting author agreement forms. When you are ready to revise your manuscript, you will be prompted in Editorial Manager (EM) to click on "Revise

Submission." Doing so will launch the resubmission process, and you will be walked through the various questions that comprise the eCTA. Each of your coauthors will receive an email from the system requesting that they review and electronically sign the eCTA.

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. Please submit a completed STROBE checklist with your revision.

Responsible reporting of research studies, which includes a complete, transparent, accurate and timely account of what was done and what was found during a research study, is an integral part of good research and publication practice and not an optional extra. Obstetrics & Gynecology supports initiatives aimed at improving the reporting of health research, and we ask authors to follow specific guidelines for reporting randomized controlled trials (ie, CONSORT), observational studies (ie, STROBE), meta-analyses and systematic reviews of randomized controlled trials (ie, PRISMA), harms in systematic reviews (ie, PRISMA for harms), studies of diagnostic accuracy (ie, STARD), meta-analyses and systematic reviews of observational studies (ie, MOOSE), economic evaluations of health interventions (ie, CHEERS), quality improvement in health care studies (ie, SQUIRE 2.0), and studies reporting results of Internet e-surveys (CHERRIES). Include the appropriate checklist for your

manuscript type upon submission. Please write or insert the page numbers where each item appears in the margin of the checklist. Further information and links to the checklists are available at http://ong.editorialmanager.com. In your cover letter, be sure to indicate that you have followed the CONSORT, MOOSE, PRISMA, PRISMA for harms, STARD, STROBE, CHEERS, SQUIRE 2.0, or CHERRIES guidelines, as appropriate.

4. Standard obstetric and gynecology data definitions have been developed through the reVITALize initiative, which was convened by the American College of Obstetricians and Gynecologists and the members of the Women's Health Registry Alliance. Obstetrics & Gynecology has adopted the use of the reVITALize definitions. Please access the obstetric and gynecology data definitions at https://www.acog.org/About-ACOG/ACOG-Departments/Patient-Safety-and-Quality-Improvement/reVITALize. If use of the reVITALize definitions is problematic, please discuss this in your point-by-point response to this letter.

5. 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.

6. 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).

7. Provide a short title of no more than 45 characters, including spaces, for use as a running foot.

8. The most common deficiency in revised manuscripts involves the abstract. Be sure there are no inconsistencies between the Abstract and the manuscript, and that the Abstract has a clear conclusion statement based on the results found in the paper. Make sure that the abstract does not contain information that does not appear in the body text. If you submit a revision, please check the abstract carefully.

In addition, the abstract length should follow journal guidelines. The word limits for different article types are as follows: Original Research articles, 300 words. Please provide a word count.

9. Only standard abbreviations and acronyms are allowed. A selected list is available online at http://edmgr.ovid.com/ong/accounts/abbreviations.pdf. Abbreviations and acronyms cannot be used in the title or précis. Abbreviations and acronyms must be spelled out the first time they are used in the abstract and again in the body of the manuscript.

10. The journal does not use the virgule symbol (/) in sentences with words. Please rephrase your text to avoid using "and/or," or similar constructions throughout the text. You may retain this symbol if you are using it to express data or a measurement.

11. In your Abstract, manuscript Results sections, and tables, the preferred citation should be in terms of an effect size, such as odds ratio or relative risk or the mean difference of a variable between two groups, expressed with appropriate confidence intervals. When such syntax is used, the P value has only secondary importance and often can be omitted or noted as footnotes in a Table format. Putting the results in the form of an effect size makes the result of the statistical test more clinically relevant and gives better context than citing P values alone.

If appropriate, please include number needed to treat for benefits (NNTb) or harm (NNTh). When comparing two procedures, please express the outcome of the comparison in U.S. dollar amounts.

Please standardize the presentation of your data throughout the manuscript submission. For P values, do not exceed three decimal places (for example, "P = .001"). For percentages, do not exceed one decimal place (for example, 11.1%").

12. 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.

13. Figures 1–2: Please upload as figure files on Editorial Manager.

14.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 http://edmgr.ovid.com/acd/accounts/ifauth.htm.

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.

15. 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.

Date: May 13, 2020
To: "Luciana Mullman" [redacted]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-20-221R1

RE: Manuscript Number ONG-20-221R1

Improved Outcomes with an Enhanced Recovery Approach to Cesarean Delivery

Dear Ms. Mullman:

Your revised manuscript has been reviewed by the handling Editor. Before a final decision can be made, we need you to address the following comments. Please make the requested changes to the latest version of your manuscript that is uploaded to your Author account in Editorial Manager (5-13-20v2). Please contact me by email if you cannot locate this file.

Please track your changes and leave the ones made by the Editorial Office. Your next version should be uploaded to Editorial Manager with a point-by-point reply letter to the comments below.

Your next version will be due by May 29.

1. General: The Manuscript Editor and Dr. Chescheir have made edits to the manuscript using track changes. Please review them to make sure they are correct.

2. Lynice Holmes will need to complete our electronic Copyright Transfer Agreement, which was sent to them by email through Editorial Manager. Once the form is complete, please add their disclosures to the “Financial Disclosure” section.

3. Line 41: This is a little vague. What do you mean to “assess changes in all patients”? What kind of changes?

4. Line 45: Please clarify if this is opioids while in the hospital or on discharge.

5. Line 48: As it is more relevant, please report the total LOS post CS here in the abstract; you can report the total LOS in the paper.

6. Line 49: This is causal language. Perhaps more clearly written to avoid this as “Compared to the pre-implementation group, those in the post-implementation period had a shorter post-cesarean length of stay (xxxxxx), lower direct costs by $349 (p< 0.0010 and no change in the 30-day readmission rate (1.4% vs 1.7%, p=0.562).

7. Line 82: This sentence was added here to make sure the Methods mentions the type of study you conducted.

8. Line 92: What milestones?

9. Line 97: Is this actually the name “ERAS Society”?

10. Line 97: I think SMFM and ACOG, as well as others, would resist the notion that they “Govern”.

11. Line 98: Please change “cesarean patients” throughout. We don’t talk about “vaginal patients.” You can either use cesarean births or cesarean deliveries, or “patients who underwent cesarean birth” (or cesarean delivery).

12. Line 102: You have mixed tenses throughout this paragraph. If the pathway has not changed, please put everything into present tense; if the pathway has changed, past tense is appropriate.

13. Line 111: Is this all women or only those who were known to be having a planned Cesarean birth at 28 weeks or so?

14. Line 134: Since I’ve asked you to define these criteria earlier, no need to repeat. You can say they didn’t change.

15. Line 142: Please state how you defined your primary outcome. It seems like it was a binary Yes or No.

16. Line 156: Please report the primary and major secondary outcomes for your total populations pre and post and then for pre/post for scheduled and intrapartum cesarean births.

17. Line 159: Do not begin a sentence with a numeral. Either spell out or edit your sentence to avoid the need to start w/ a number.

18. Line 165: P Values vs Effect Size and Confidence Intervals
While P values are a central part of inference testing in statistics, when cited alone, often the strength of the conclusion can be misunderstood. Whenever possible, the preferred citation should be in terms of an effect size, such as odds ratio or relative risk or the mean difference of a variable between two groups, expressed with appropriate confidence intervals. When such syntax is used, the P value has only secondary importance and often can be omitted or noted as footnotes in a Table format. Putting the results in the form of an effect size makes the result of the statistical test more clinically relevant and gives better context than citing P values alone.

This is true for the abstract as well as the manuscript, tables and figures. Please correct throughout

Please provide absolute values for variables, in addition to assessment of statistical significance.

We ask that you provide crude OR's followed by adjusted OR's for all relevant variables.

19. Line 186: I've asked you above to include the data broken about by all cesareans, then by scheduled and intrapartum deliveries.

20. Line 186: This statement belongs in a separate discussion of strengths and limitations of your study, which should be just before your concluding paragraph. "Our results are strongly supported by our robust sample size of 2,171 patients in the pre-implementation and 1,508 in the post-implementation period."

21. Line 192: Then how can you say this, which you do above: was associated with an overall reduction in the percentage of patients requiring opioids at any time."

22. Line 203: I am unclear how you can make this statement—please provide data. The ERAS pathway is a unit—you didn't measure anything about the individual components of it. As such, you can't really break out one part of it and say you think that one part made a significant contribution. That would require allocating people to your full ERAS protocol and compare them to a group with ERAS minus TAPS, for instance and measure results.

23. Lines 206-211: These lines were deleted as they are not relevant to your study.

24. Line 225: ACOG is moving toward discontinuing the use of "provider." Please replace "provider" throughout your paper with either a specific term that defines the group to which are referring (for example, "physicians," "nurses," etc.), or use "health care professional" if a specific term is not applicable.

25. Line 242: This is sentence is repetitive from earlier. Please it delete here.

26. Line 245: You've provided no data about babies. Please delete reference to baby outcome.

27. Table 1: All patients or those with planned CS?

28. Table 1: May we make this a shaded box? "Preoperative," "Intraoperative," and "Postoperative" would appear in boldface, with the bullet points listed under each. If you agree, please change "Table 1" to "Box 1" both here in and in the body text, and renumber Table 2 to Table 1.

Best,
Randi Zung for Dr. Chescheir

_____

Dr. Chescheir,

We would like to thank you again for your consideration of our manuscript. We believe the additional comments and clarifications have greatly improved this work, and appreciate your thoughtful edits. Below we provide point by point responses to the specific comments (tracked changes), and have also included both a clean and tracked changes version of our manuscript.

Sincerely,

Luciana Mullman MPH, CSSGB

Administrative Director- Clinical Excellence and Effectiveness

Saint Barnabas Medical Center

Reviewer Responses:

1. General: The Manuscript Editor and Dr. Chescheir have made edits to the manuscript using track changes. Please review them to make sure they are correct.

We have reviewed the comments and edits and made additional changes or responded directly to the comments listed as appropriate. All original comments were retained, and text was struck through where appropriate to indicate deletions but retain the original comments.

2. Lynice Holmes will need to complete our electronic Copyright Transfer Agreement, which was sent to them by email through Editorial Manager. Once the form is complete, please add their disclosures to the "Financial Disclosure" section.

Lynice has completed the agreements, and no additional disclosures were noted.

3. Line 41: This is a little vague. What do you mean to "assess changes in all patients"? What kind of changes?

We have included the specific outcomes assessed to clarify

4. Line 45: Please clarify if this is opioids while in the hospital or on discharge.

Clarified as inpatient and post cesarean

5. Line 48: As it is more relevant, please report the total LOS post CS here in the abstract; you can report the total LOS in the paper.

Throughout the manuscript LOS is assessed as time from cesarean to discharge, and only presented in this way. We have clarified here to reflect this.

6. Line 49: This is causal language. Perhaps more clearly written to avoid this as "Compared to the pre-implementation group, those in the post-implementation period had a shorter post-cesarean length of stay (xxxxxx), lower direct costs by $349 ($p< 0.0010$ and no change in the 30-day readmission rate (1.4% vs 1.7%, $p=0.562$).

We had adjusted the section as advised.

7. Line 82: This sentence was added here to make sure the Methods mentions the type of study you conducted.

Understood

8. Line 92: What milestones?

Clarified here based on information provided later and removed in the later section as advised.

9. Line 97: Is this actually the name “ERAS Society”?

That is the correct name. Additional details can be found at https://erassociety.org/about/history/

10. Line 97: I think SMFM and ACOG, as well as others, would resist the notion that they “Govern”.

Agreed

11. Line 98: Please change “cesarean patients” throughout. We don’t talk about “vaginal patients.” You can either use cesarean births or cesarean deliveries, or “patients who underwent cesarean birth” (or cesarean delivery).

Corrected here and throughout

12. Line 102: You have mixed tenses throughout this paragraph. If the pathway has not changed, please put everything into present tense; if the pathway has changed, past tense is appropriate.

This paragraph and the subsequent ones which describe the pre/intra/post-operative components have been adjusted to present tense.

13. Line 111: Is this all women or only those who were known to be having a planned Cesarean birth at 28 weeks or so?

This applies to all women regardless of planned Cesarean and has been clarified here as well as in Box 1.

14. Line 134: Since I’ve asked you to define these criteria earlier, no need to repeat. You can say they didn’t change.

Adjusted here as noted in 8. above.

15. Line 142: Please state how you defined your primary outcome. It seems like it was a binary Yes or No.

Clarified the outcome definition as binary for any opioid usage and continuous for overall opioid usage in terms of MME

16. Line 156: Please report the primary and major secondary outcomes for your total populations pre and post and then for pre/post for scheduled and intrapartum cesarean births.

We have included the primary and major secondary outcomes separately among scheduled and emergent cases within the results section.

17. Line 159: Do not begin a sentence with a numeral. Either spell out or edit your sentence to avoid the need to start w/ a number.

Adjusted accordingly

18. Line 165: P Values vs Effect Size and Confidence Intervals
While P values are a central part of inference testing in statistics, when cited alone, often the strength of the conclusion can be misunderstood. Whenever possible, the preferred citation should be in terms of an effect size, such as odds ratio or relative risk or the mean difference of a variable between two groups, expressed with appropriate confidence intervals. When such syntax is used, the P value has only secondary importance and often can be omitted or noted as footnotes in a Table format. Putting the results in the form of an effect size makes the result of the statistical test more clinically relevant and gives better context than citing P values alone.

This is true for the abstract as well as the manuscript, tables and figures. Please correct throughout

Please provide absolute values for variables, in addition to assessment of statistical significance.

We ask that you provide crude OR's followed by adjusted OR's for all relevant variables.

When describing opioid usage, we have additionally included the odds ratio and 95% confidence interval.

19. Line 186: I've asked you above to include the data broken about by all cesareans, then by scheduled and intrapartum deliveries.

We have included the additional breakdown as requested within the results section.

20. Line 186: This statement belongs in a separate discussion of strengths and limitations of your study, which should be just before your concluding paragraph. "Our results are strongly supported by our robust sample size of 2,171 patients in the pre-implementation and 1,508 in the post-implementation period."

We have moved this statement as well as the other paragraph which acknowledged our limitations in conclusions to the final paragraph in the manuscript as noted.

21. Line 192: Then how can you say this, which you do above: was associated with an overall reduction in the percentage of patients requiring opioids at any time."

Corrected earlier to reflect inpatient opioid usage.

22. Line 203: I am unclear how you can make this statement—please provide data. The ERAS pathway is a unit—you didn't measure anything about the individual components of it. As such, you can't really break out one part of it and say you think that one part made a significant

contribution. That would require allocating people to your full ERAS protocol and compare them to a group with ERAS minus TAPS, for instance and measure results.

We have removed this section and reworded within the framework of our results being in line with other studies regarding the usage of TAP blocks.

23. Lines 206-211: These lines were deleted as they are not relevant to your study.

Understood.

24. Line 225: ACOG is moving toward discontinuing the use of "provider." Please replace "provider" throughout your paper with either a specific term that defines the group to which are referring (for example, "physicians," "nurses," etc.), or use "health care professional" if a specific term is not applicable.

This has been corrected here and elsewhere.

25. Line 242: This is sentence is repetitive from earlier. Please it delete here.

Deleted.

26. Line 245: You've provided no data about babies. Please delete reference to baby outcome.

Deleted.

27. Table 1: All patients or those with planned CS?

Clarified as all patients.

28. Table 1: May we make this a shaded box? "Preoperative," "Intraoperative," and "Postoperative" would appear in boldface, with the bullet points listed under each. If you agree, please change "Table 1" to "Box 1" both here in and in the body text, and renumber Table 2 to Table 1.

You may. We have changed here and elsewhere to reflect Box 1 and Table 1