

# OBSTETRICS & GYNECOLOGY



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

**Date:** May 24, 2019  
**To:** "Sawsan As-Sanie" [REDACTED]  
**From:** "The Green Journal" em@greenjournal.org  
**Subject:** Your Submission ONG-19-837

RE: Manuscript Number ONG-19-837

Impact of shared decision making on opioid prescribing following hysterectomy

Dear Dr. As-Sanie:

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 Jun 14, 2019, we will assume you wish to withdraw the manuscript from further consideration.

#### REVIEWER COMMENTS:

Reviewer #1: Great effort to help identify and address the issues around use of narcotics in women after benign hysterectomy.

Specific issues:

##### 1- Methods:

- a. Standardization of discussion around use of non-steroidal anti-inflammatory drugs (NSAID) use and acetaminophen is important. Please provide references to information included in the decision aid and the video discussion about the average and the max prescriptions estimates for narcotics!
- b. Why acetaminophen was not around the clock as well and what is the reference for 3 grams as the max cut off?
- c. What was the primary outcome of the study? Please add to the method section! Did the author had any sample size or power analysis?
- d. Usually implementation of any new protocol require time to reach consistent high levels, did the author planned any evaluation of the percent of patients who did not have the protocol in the beginning of the study?

##### 2- Results:

- a. What did the authors offer to patients with contraindication to taking NSAID or Acetaminophen?
- b. Was there any change in postoperative pain in women undergoing combined procedures, like e.g. apical suspension, vaginal repair etc.?
- c. Table 2: It seems that the refill request were relatively higher after utilizing the new decision aid method? Who are those patients and did the authors identify a group of patients (e.g. combined procedures, apical suspension, etc) that may have been not adequately prescribed narcotics using the current protocol?
- d. Given the differences in the route of hysterectomy in the pre-implantation cohort and the post implementation cohort, did the author adjusted for the type of hysterectomy?
- e. Figure 1: Please review the need for permission of use and add a reference if this was not original work of the authors!
- f. Video: Please consider removing sound tracks from songs in your video! To avoid any copyright issues and to emphasize the educational nature of the video!

##### 3- Discussion:

- a. More discussion is needed on what is "accepted amount of prescription" after hysterectomy for benign disease based on best evidence! This would help clinician in their next steps in managing their patients!
- b. What is the external validity of the data presented in this study! Please discuss!

Reviewer #2: This study attempts to look at opioid use after an intervention (decision aid) as compared to opioid use without the intervention. It is a timely study, and relevant. Comments below indicate areas that require clarification and explanation. One of the more challenging aspects of this article for the reader was the use of "decision aid" vs "intervention." The decision aid was experienced by the patient and used by the provider as an intervention. At times it is difficult to understand what you are measuring when you constantly refer to "use of a decision aid." Also, it would help your reader to better understand how you gathered your data from the pre intervention era as a comparison, and the limitations of that and potential source of bias.

#### Abstract:

1. Line 54- was the opioid naive cohort that was used as comparison during the education the same cohort that the primary outcomes were compared to? This seems somewhat circular and question begging. Can you clarify and justify this approach and how it might cause bias?

2. Line 65- can you say how this was calculated in the abstract?

You refer to the intervention as a decision aid and uniform education. Could you please use one term uniformly?

#### Introduction:

3. Line 97: reduced as compared to what?

#### Methods:

4. Line 112: can you explain what you counted as excluding complications?

5. Line 114: can you explain what you mean by "routine discussion"? Also, does this assume you are discharging patients same day as their surgery? Is this the case for benign hysterectomy for AUB v prolapse?

6. Line 125: again, is this the cohort that you are comparing the intervention group to? Meaning is the arrow that indicates how many narcotics other patients have gotten your pre intervention group?

7. Line 130: please give a citation for the Michigan Law so your reader can refer to it.

8. Line 153: was EMR the exclusive means of determining the information for the demographic/clinical data sheet? who abstracted that data? Was it study personnel?

9. Line 191: did you define average as the amount of opioids used by the pre-intervention group?

10. Line 199: You often refer to patient satisfaction? Did you use a validated tool? Was it by likert scale or "Are you satisfied?" Can you clarify?

#### Results:

11. Line 211: it is confusing the way you use "decision aid" interchangeably with intervention. (see also lines 228-229)

12. Line 212: Was it that the patient "didn't complete the decision aid" or they weren't subject to the intervention?

13. Line 231: typo

14. Line 232: it was not statistically significant. There were nearly twice as many patients requesting refills in the intervention group. That might be clinically significant, so please qualify with "statistically"

15. Line 234-5: the cohort didn't use the decision aid, the providers "used" the decision aid with the patients, who were exposed to the decision aid as the intervention. The cohort that used the decision aid were the trainees that saw the patient in preop after they were taught to use it. They are not being studied...although that would be interesting.

16. Line 239: mixed tense, awkward

17. Line 240: which half are you referring to? Unclear- is this exclusive or inclusive of those that didn't use any pain meds.

18. In lines 238 and beyond, was this data gathered from the phone followups?

19. Line 255: when you say number here do you mean low medium or high? Please clarify

20. Line 256: what about age, bmi, type of insurance, etc. Did you look at these?

21. Line 264: what about vaginal?

Discussion:

22. Line 286- was this really shared decision making? It sounds more like the patients told you how many opioids they wanted. It is odd to have shared decision making appear here.

23. Line 291: can you show how your results compare to the cesarean delivery work? Is there really nothing in the literature to which you can compare your work? A quick pub med review shows a few things that could help your reader more greatly appreciate your work.

24. Line:318-this seems a more accurate description rather than shared decision making.

25. Line 328: can you address how the decision making card may have biased the patients themselves in wanting to choose a number they would think would please the MD? Or do you think there is any limitation in not looking at age as an independent predictor of choice of tabs? Or, did you address your limitations in looking at the stats from those prior to the intervention

Reviewer #3: i applaud your successful efforts to discharge patients early. appears that many are discharged less than 23 hours. table 1

1\*you collected data on bmi(line 158) but i could not find where you used this data in the manuscript . it is noted in appendix 2. there should be specific mention of whether bmi contributes to narcotic requirement in the discussion.

2\* line 129 refers to a michigan law. the law should be specifically cited and or referenced

3\* address why the practitioners/surgeons did not just make a dictum tha only 10-20 narcotic tablets would be prescribed instead of using a visual card or "shared" decision making. those with chronic pain or depression could be adjusted accordingly.

4\* address why lavh was included in the vaginal group instead of laparoscopy group. i would think these patients would be more similar to laparoscopy patients over straight vaginal surgery patients.

5\* can you highlight some of he requirements of the michigan narcotic rx law?

6\* why wasn't acetaminphen the first pain med followed by second line ibuprofen? why werent they both scheduled for 5 days after discharge? Figure 1

7\* many eras protocols suggest gabapentin or decadron. why werent these meds used at least for first 23 hours the figure 1 is excellent and facilitates patient and families to manage post op pain visually.

8. Nelson, G., Altman, AD, Dowdy, SC. et al. Guidelines for postoperative care in gynecologic/oncology surgery: Enhanced Recovery after Surgery (ERAS) Society recommendations--Part II Gynecologic Oncology 140(2016) 323-332 Table 1 p 324

#### STATISTICAL EDITOR'S COMMENTS:

1. Tables 1 and 2: Many of the comparisons involve small counts and there would be little stats power to discern differences. Those NS findings cannot be generalized. (eg, comparing demographic profile pre and post decision aid for lysis of adhesions, treatment of endometriosis, or comparisons of before vs after on refill rates, whether "all" or individual routes.) I am surprised that length of stay was normally distributed (lines 204-206) and reported as mean  $\pm$  SD, since it is so often skewed. For consistency in Tables and text, suggest using laparotomy or abdominal consistently throughout.

2. Table 2, lines 201-202: For comparison of request for refill rates for abdominal and vaginal: should use Fisher's test, not Chi-square. It will not change the inference conclusion, but the p-values differ. Again, there is little power to generalize NS results from the small counts.

3. Table 3: The subsets (esp abdominal) have small samples and it is not possible to cite precision of proportions to nearest 0.1%. Fr uniformity in this chart, should just round all %s to nearest integer. Since the subset samples are small, there is limited power to discern differences and many of the NS findings cannot be generalized, from these data. For example, reasons for d/c opioids have low counts (often < 10 and by necessity for the abdominal group, all smaller still). Same comment re: citing %s to nearest 0.1%, should round to nearest integer %.

4. Table 4, Appendix 2 : Same issue with %s and with limited power for comparison of small counts and therefore generalizing those NS findings.

## 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, 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:

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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.

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3. 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, 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.
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- \* 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. 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.

8. 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.

9. 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.

10. Please review the journal's Table Checklist to make sure that your tables conform to journal style. The Table Checklist is available online here: [http://edmgr.ovid.com/ong/accounts/table\\_checklist.pdf](http://edmgr.ovid.com/ong/accounts/table_checklist.pdf).

11. The Journal's Production Editor had the following to say about the figures in your manuscript:

"Fig 1: The "Back of Decision Aid" part has 3 versions stacked on top of each other and covers some parts of text – is this okay?

Fig 3: Would the author be able to send a higher res image or the original file?"

When you submit your revision, art saved in a digital format should accompany it. If your figure was created in Microsoft Word, Microsoft Excel, or Microsoft PowerPoint formats, please submit your original source file. Image files should not be copied and pasted into Microsoft Word or Microsoft PowerPoint.

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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 Jun 14, 2019, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

The Editors of Obstetrics & Gynecology

2017 IMPACT FACTOR: 4.982

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

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