OBSTETRICS & GYNECOLOGY

NOTICE: This document contains comments from the reviewers and editors generated during peer review of the initial manuscript submission and sent to the author via email.

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

Date: Jul 18, 2019
To: "Alexander M Friedman" [redacted]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-19-1154

RE: Manuscript Number ONG-19-1154

Postpartum Readmissions among Women with Diabetes

Dear Dr. Friedman:

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 Aug 08, 2019, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1:

1. Title/Precis. These accurately reflect the content of the manuscript.

2. Abstract. The abstract is concise and clearly summarizes the paper.
a. Would include something about the source of the data (ICD-9 codes), to convey a better sense of the limitations of the dataset.
b. Suggest including data about the secondary outcomes (indications for admission) rather than simply writing that they were all significant.
c. Might add "particularly pregestational diabetes" to the conclusion (aRR for GDM <1.2).

3. Introduction. Well-written, concise.
In lines 115-119, the knowledge gap is probably in the overall maternal morbidity and readmission risk associated with these complications. Might be more specific about your study objective (how you sought to achieve it), e.g. by including the type or name of dataset.

4. Methods.
a. More information about the NRD might be helpful. Are all hospitals in a given state required to report to the NRD? In lines 125-128, please clarify what you meant about "weights that allow calculation of national estimates."
b. Lines 140-142. Physicians providing care to women with diabetes should know what type they have. Might omit the "unspecified" group from analysis, because counseling probably shouldn't be based on study results.
c. Lines 147-149. Why weren't all analyses restricted to women with diabetes at delivery?

5. Results.
a. Lines 201-205 and table 1. Here and elsewhere, suggest reporting the demographic data in table 1 (including hospital and insurance characteristics) separately from medical and obstetrical complication data like hypertension and cesarean delivery. The cesarean delivery rate is striking (68% in women with T1DM), and the rate of pregnancy hypertension is also quite high. Might include something about this in the text.
b. Lines 206-210. Approximately 4% of women with pregestational diabetes and 2% of those with gestational diabetes required readmission. This type of data can be very useful for counseling (or simply conveying information to readers). Would include more data in this format. Readmission risks in pregestational and gestational diabetics with and without co-morbidities (e.g. hypertension, cesarean delivery) would help put RR and aRR data into perspective.
c. Lines 218-221. Suggest presenting mean and SD and including p-values, rather than means alone.
d. Table 4 nicely shows the increase in morbidities associated with diabetes. Are women with gestational diabetes at

significantly lower risk than women with pregestational diabetes?

6. Discussion.
a. Suggest including some summary data in the discussion. This is often done in the first paragraph, to synthesize the findings for the reader. Simply reporting that women with DM are at increased risk is anticipated. The absolute risk of postpartum hospitalization of 4% for pregestational DM and 2% for GDM is a nice take-home and helps with perspective. A few additional summary percentages might be helpful. Differences between pregestational and gestational DM carry through in the analyses, so this might be discussed. The high C/S rates and high rates of associated morbidities in women readmitted are interesting as well, because if women with DM and other risk factors are at particular risk, anticipatory guidance and closer follow-up might be planned.
b. Lines 265-268. Comments about poor control are reasonable, but this topic wasn't addressed in the study (is not supported by the findings) and is not referenced.
c. Suggest adding limitation of using ICD-9 coding for co-morbidities - potentially missing morbidities that not able to be addressed. This is relevant because the relative risks with pregestational diabetes decreased by more than half after adjustment. Would also address magnitude of risk, considering that the aRR for GDM was only 1.16 (statistically significance does not equate to clinical relevance).

Reviewer #2: The paper was well written and the data is robust. It will be nice to see how much of a role class 3 obesity plays into the findings, since class 3 obesity and diabetes are twins. This paper will help draw attention to the need for adequate follow up after delivery. At this time the concept of antenatal surveillance is well grounded with NST, BPP and glucose monitoring being a key part of this. Post natal surveillance going beyond the 75g glucose test at the 6 weeks postpartum visit would also be very beneficial for patients with gestational diabetes.

Reviewer #3: While at first glance, this paper was yet another mining of an administrative database, resulting in somewhat low adjusted relative risk ratios for the primary outcome that were that were almost all <2, closer reading identifies pockets of morbidity that are very significant and the discussion appropriately points to the need for more targeted patient-based studies obtain more granular information on how to address these problems.

Clarify the exclusion of women with severe morbidity during the delivery admission (l.186-189). Were they not part of the study? The risk for readmission among women with severe morbidity during the delivery hospitalization should be described, as well as readmission rates for women with DVTs. This would be highly useful information for a very concerning subset of women as they are discharged from the delivery admission.

Although this study is descriptive only, consider a comment about the rates of admission for wound complications being highest in when with Type 2 diabetes and lowest in women with gestational diabetes. In addition, the almost 3x higher incidence of type 2 diabetes in the oldest group of women, ages 40-54, noted in the demographics table, is noteworthy and that age group has consistently some of the highest readmission risks of all; comment on this.

For those unfamiliar with the NRD, explain how many states were represented by the study or what percentage of annual US deliveries during the 5 year study period were included.

Reviewer #4: In this manuscript, the authors utilize a large national database of all hospital discharges. This database is a good source for this type of information in looking at postpartum readmission rates. The data are limited by typical limitations of these types of administrative databases that rely upon ICD9/10 codes for characteristics that are recorded by innumerable different hospital coders. The authors found that essentially all types of diabetes put a woman at increased risk for postpartum readmission and severe maternal morbidity during that readmission. I have a few questions/comments for the authors.

1. The Precis should likely start with the primary outcome of hospital readmission, not the secondary outcome of severe maternal morbidity.

2. Abstract Results line 74- the n=13,312 can be deleted.

3. The authors list several limitations. An important one not mentioned is the inability to characterize the glucose control for the diabetic women not just during pregnancy but also during the PP hospitalization and postpartum period.

4. The titles of Tables 2 and 4 are identical but show very different items. I might suggest the title of Table 4 be changed to "...readmission with specific morbidities" or something like that.

5. Utilizing these findings to highlight the importance of early PP followup in diabetics is good.

6. Reference # 9 and reference #22 are the same ACOG Committee Opinion.

7. Table 2 should have a footnote describing the variables in the adjusted analysis and methods used.

STATISTICAL EDITOR COMMENTS:

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

Related to Table 1 and the Results section: The length of stay and costs were cited as mean values. Both are often highly skewed, so median (range or IQR) would be a more appropriate metric, unless the Authors can show that their data distributions were normal, thus justifying use of mean.

Tables 2, 3, 4: RR and aRR are useful metrics, but lack information re: the absolute number of women who had PP readmission. Some of the absolute proportions are cited in Abstract and Results, the reader should get a fuller understanding of the scope of how readmission rates were affected by DM status, as well as the subsets of demographic and clinical characteristics. Some of this can be assessed in the Tables (esp for the statistically significant associations), while a complete enumeration could be cited as on-line material.

Furthermore, although this is a large study, some of the subsets (esp for unspecified DM, No charge payor status, many of the Missing entries, some of the rarer medical conditions (eg, SLE or thromboembolism categories) have relatively small counts, so the adjustment model may be over fitted. Need to specify in footnotes to Tables which variables were retained in the final models and justify their use vs the counts of adverse events.

Additionally, given the large number of comparisons in each Table, with no adjustment for multiple hypothesis testing, some of the associations may be spurious. For example, many of the 95% CIs for RR and aRR have boundaries close to 1.00. A stricter threshold (eg, 99% CIs or even more restrictive), will not negate the stronger associations, but will give a more concise narrative that is more likely reproducible.

EDITOR COMMENTS:

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

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

- Your precis isn't clear that you are specifically talking about SMM during the readmission. Could you edit to reflect this please?

- 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.

- This would be "of whom" not "of which".

- Could you phrase lines 74-77 to indicate that its WOMEN with diabetes, not diabetes itself you are talking about? "Diabetes" doesn't have agency

- Delete this highlighted sentence as it is redundant with the 2nd sentence.

- You also were looking at rates of SMM during this readmission.. Since you highlight that in your precis, it should appear in your abstract and your list of objectives. Alternatively, you could remove it from the precis.

- perhaps classified as "non diabetic" rather than "no diabetes"?

- Please include a box with the components for the SMM criteria by CDC either in your paper if you have room or in Supplemental Digital Content.

- Could you clarify please? "Additionally" throws me--is this just more information or does it refer back to those with DVT in delivery hospitalization? . Do you mean women with prior DVT (not during delivery hospitalization" were included or excluded in your model?

- This is a bit counter intuitive (That Type 2 would be more associated with wound complications than Type 1) Presumably, this is due to higher risk of obesity in the Type 2 patients vs Type 1 patients. Can you control for that?

- One of the big pushes at UNC where I work, and I think it stems from a national mandate of some sort, is to make sure that women w/ diabetes who don't already have a primary care doc (or specialist if needed) are connected to one prior to discharge in order to have a clean connection with someone to pick up this care post partum. Since you are looking at 60 day window, that would extend beyond the time when many women just see their OB GYN in the pp period. I wonder if that is worth mentioning as one important step?

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

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

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

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

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

5. Please submit a completed STROBE checklist.

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.

6. 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.

7. 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.

8. 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).

9. Provide a short title of no more than 45 characters (40 characters for case reports), including spaces, for use as a running foot.

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

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

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

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

13. Line 123-124: Do you have a citation to support your statement that this is one of the largest national administrative discharge databases?

14. 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.

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

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

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

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

Again, your paper will be maintained in active status for 21 days from the date of this letter. If we have not heard from you by Aug 08, 2019, 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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