

OBSTETRICS & GYNECOLOGY



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

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

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

Date: Apr 18, 2019
To: "Sarah Rae Easter" [REDACTED]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-19-427

RE: Manuscript Number ONG-19-427

The Potential Impact of Regionalized Maternity Care on United States Hospitals

Dear Dr. Easter:

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 May 09, 2019, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1:

This cross sectional observational study looked at lineage analysis of American Hospital Association (AHA) survey and State Inpatient Database (SID) data from 7 representative states. Characteristics and procedure codes were used to assign a level of maternity care for each hospital. Patient ICD 9 codes and demographics were identified to compare appropriate minimum level of care. The primary outcome was to look at the inappropriate lower level of care delivered to further guide feasibility of obstetric regionalization of care.

The authors do an excellent job using a large geographically diverse data base to further quantify the need and focus on specific approaches to triage. Using ICD 9 codes before the formal change to ICD 10 was very smart and minimized coding bias.

Abstract:

1. The objectives are concise and clearly outlined.
2. Line 51 The wording of only 37% of high risk patients delivered at level I/II is confusing. It is not clear what the denominator is. Was the 37% of the prior described 2.6% at high risk? Also the word "only" implies this was the preferred level of care and the number should be higher. I would suggest leaving it out or making it clear where the mismatch is occurring.

Introduction:

3. This is an excellent review of the literature and the purpose of the study. Nothing to add

Materials and methods:

4. Lines 95-97 Why specifically were these states chosen vs. including all or more of the 22 listed in 2014? Was it logistical or incomplete data? The definition of rural and nearest level 3 or 4 hospitals may be significantly different and underrepresented in this study ie Western states Washington and Oregon vs. the more populous states listed on the East coast.

5. Line 98 What were the validated methodologies?

Results:

6. Line 141-144 What was the distribution of deliveries by state and level of care?

Table 1

7. It is unclear what the purpose of preterm chronic HTN means. By definition if it is chronic or < 20 weeks it would be similar and therefore designated as level 2. For many of the chronic medical diagnosis it would be more important to know if they were still in the institutional level of care at term.

Table 2

8. Annual transfers are not clear in which direction. Clearly level 1 is transferring out however between the other levels it is not clear if the transfer is accepting or the actual transferee.

9. Some of the listed level 1 hospitals are listed as having surgery, ICU, SICU and cardiac ICU which is listed as a level 2 or 3 in the appendix. Please explain the designation. It also appears none of level 1 or 2 institutions have NICUs. Was there any information about neonatal transfers vs. maternal transfers?

10. The breakdown by state is very helpful. Is there further breakdown by state and number of deliveries and inappropriate level of care?

11. Line 169 Which states had the greatest variation 1.26-4.21% in inappropriate level of care? This would be important along with further evaluation of barriers and distance to regional higher levels of care.

12. Line 175-180 The inappropriate rates of care seem to rise for preterm pre eclampsia with severe features vs without 14% vs 18% and placenta previa without and with prior surgery 18-37%. This does not make sense. Further description by state and overall may give useful information for further investigation. The rate of inappropriate care for cardiovascular disease 68% needs to be defined as to whether it was diagnosed in the prenatal time period vs. intrapartum. These patients may have received the diagnosis due to intrapartum events that lead to a work up and diagnosis for the first time.

Figure 1.

13. Combining level 3 and 4 for appropriate level of care cover significant overlap of acuity of care which cross covers many comorbidities. This is a clinically useful comparison.

Discussion:

14. Line 189 The identification of a potential cohort in this study of 6,042 patients with either previa and prior uterine surgery or cardiac disease needs to be analyzed further. Is there a way to determine if these were known prenatally or only at the time of delivery? If it is the later the focus ought to be on accurate diagnosis vs. awareness and mobilization of resources for triage.

15. Line 210-213 The limitation and references for the assumption of level of care are well described and acknowledged.

16. Line 223-226 I would argue the use of ICD 9 codes and severity of disease based upon the appendix for level IV care may actually be underestimated. Working at a DSH hospital this is a constant problem from coders collecting accurate severity of illness not underestimation of disease.

Reviewer #2: In the manuscript under review, the authors report cohort study using linked American Hospital Association survey data and state inpatient database data for 7 states to assign a level of maternal care to each hospital and a minimal required LOC to each subject based on their comorbidities and then look at (as their outcome) delivery at an inappropriately low LoMC. Strengths of the current study include a large number of study patients in the analysis from a rich dataset. The study question that is being asked is original and clinically applicable and very timely. What is missing from this analysis is actual clinical outcomes and morbidities associated with delivery at the hospital that is assumed to be the wrong level of care.

Specific comments include:

1) It would be helpful to include a figure describing the different levels of care with characteristics of the levels much like what is noted in the ACOG document (such as that seen in the article: Levels of Maternal Care Verification Pilot: Translating Guidance Into Practice, Zahn et al Obstetrics & Gynecology Volume 132(6), December 2018, p 1401-1406)

2) Did the authors think to include birth centers (they are noted in the ACOG LOC document)

3) The results section of the abstract is a bit confusing. It is clear that a small fraction of women 2.36% of the 845,545 warranted delivery in a level III or IV hospital (perhaps the "n" would be helpful), but who are the 37.84% of the high risk

patients? Is this 37% of the 2.36%, and who are the 2.41% (of what group)? This could be further clarified

4) The authors in the appendix look at multiple conditions to assign what complication warrants what level of care (the premise of the paper) and reference the ACOG document. Acog does not have a table but does under each level give examples (see below from the ACOG document), I am not sure the minimal level assigned is concordant with these recommendations. For example ACOG sites preeclampsia without severe features of as someone who needs at least level 1 and they are sited as level II care minimal. Additionally chronic kidney disease, epilepsy may not warrant level III (see below), an interesting research question would be how these women do at a different level of care than recommended. Although the authors note why they chose to do this, it is important to note (perhaps in the limitations) that not all women with these comorbidities need a higher level of care.

See ACOG examples from the document:

Examples of women who need at least level I care include women with term twin gestation; women attempting trial of labor after cesarean delivery; women expecting an uncomplicated cesarean delivery; and women with preeclampsia without severe features at term.

Examples of women who need at least level II care include women with severe preeclampsia and women with placenta previa with no prior uterine surgery

Examples of women who need at least level III care include those women with extreme risk of massive hemorrhage at delivery, such as those with suspected placenta accreta or placenta previa with prior uterine surgery; women with suspected placenta percreta; women with adult respiratory distress syndrome; and women with rapidly evolving disease, such as planned expectant management of severe preeclampsia at less than 34 weeks of gestation.

Examples of women who would need level IV care (at least at the time of delivery) include pregnant women with severe maternal cardiac conditions, severe pulmonary hypertension, or liver failure; pregnant women in need of neurosurgery or cardiac surgery; or pregnant women in unstable condition and in need of an organ transplant.

Why were the categories chosen similar/different please justify

5) Although I understand that the primary outcome was delivery at the wrong level of care, I believe to warrant publication it would be helpful (and useful) to have other clinical outcomes that demonstrate why delivering at the wrong level of care helped/hurt the women in the study. Utilizing the available datasets I believe that this would be possible and would take this paper to the next level in terms of impact. This is critical for publication.

Reviewer #3: The authors sought to examine the current patterns of care for women at high risk for delivery related morbidity to explore regionalization of maternity services. The authors linked data from the State Inpatient Database and the AHA Survey for 7 representative states. They assigned a level of maternal care to each hospital and then assigned a patient to a minimum level of care based on the comorbidities captured in the SID.

Overall, I found the topic compelling and relevant for this clinical journal. There are some areas where the manuscript could be strengthened:

1. Throughout the results section - and to some degree in the abstract's results section - the authors aren't as clear as they need to be about which group they are discussing. The results section needs to utilize tables better to present their results and then use the text to summarize take home messages vs. trying to reiterate everything. It can become confusing at times to follow the message.

2. Ultimately, the authors' analysis isn't nationally representative - so the title and perhaps some of the conclusions need to be modified to reflect that point. It is only reflective of seven states.

3. As noted earlier, the results section would benefit greatly from a revision that allows some of the findings to move to a table. It was difficult to follow the authors train of thought and couldn't tell where they were getting some numbers and what they represented. Ideally, the results section should summarize key take home messages from each table and walk the reader through the results - but it shouldn't just be this dense reference to numbers. It would be helpful if many of these estimates were presented in the tables, so that the tables were more useful.

4. The authors mention at the end of the methods section that "a p-value of < 0.05 was considered statistically significant". But I only see p-values presented in Table 2, and these appear to be general associations - either from a chi-square test or an ANOVA. Because it was difficult at times to follow the results presented, it was also confusing to know whether the relationship discussed were significant based on statistical testing or just based on size.

STATISTICAL EDITOR'S COMMENTS:

1. Table 2: The column totals vary from n = 46 to n = 259, with smaller samples for many hospital bedsize, area or State. There is no justification for citing proportions to nearest .01%. Should round to nearest integer value in the n(%) format.
2. Table 3: Similar issue for this Table. The precision should be reported as no more than nearest 0.1 %.
3. General: The report does a good job of describing the proportion of women who were delivered at hospitals inappropriate to their need for specialized care. However, the report could be much improved by analysis of the average and range of distances or time from the hospital where care was given to the hospital appropriate for the needed level of care. That would give more meaning to the scope of the proposed adherence to matching maternal comorbidity needs vs hospital level of care.
4. Are there any data re: the maternal/neonatal outcomes of the women who needed level III or greater care, but who delivered at a lower level hospital compared to a similar cohort who delivered at level III or IV?

Associate Editor's Comments:

Your manuscript would be greatly strengthened by the inclusion of maternal and neonatal outcomes.

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:

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

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.

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.

3. 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.

4. In order for an administrative database study to be considered for publication in Obstetrics & Gynecology, the database used must be shown to be reliable and validated. In your response, please tell us who entered the data and how the accuracy of the database was validated. This same information should be included in the Materials and Methods section of the manuscript.

5. 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, references, 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. 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.

10. 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.

11. 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.

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. 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>.

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/ifaauth.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.

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 May 09, 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

In compliance with data protection regulations, you may request that we remove your personal registration details at any time. (Use the following URL: <https://www.editorialmanager.com/ong/login.asp?a=r>) Please contact the publication office if you have any questions.

Dwight Rouse MD
Associate Editor
Obstetrics and Gynecology

May 9, 2019

Dear Dr. Rouse,

It is with great enthusiasm that we resubmit our manuscript entitled “The Potential Impact of Regionalized Maternity Care on United States Hospitals”. This manuscript is a detailed description of our work presented at the 2018 Society for Obstetric Anesthesia and Perinatology in Miami, Florida. We would be open to sharing this revision letter and subsequent email correspondence related to author queries as outlined in the response below.

The objective of the manuscript is to better understand delivery patterns for women at risk of severe maternal morbidity to inform the implementation of the levels of maternal care. We chose delivery at an inappropriate level of maternal care hospital as our primary outcome of interest as opposed to an analysis of adverse maternal outcomes. We acknowledge that the goal of regionalization is to improve maternal outcomes and not simply deliver women at an appropriate level of care. We also recognize that maternal outcomes as a function of level of maternal care is of great interest to the Reviewers and readers of the Journal. We have refrained from reporting maternal outcomes in the initial paper and in this revision because of our limited understanding of disease severity and current referral patterns in this administrative dataset. The revised manuscript includes a more complete discussion of this limitation, concerns about residual confounding, and our decision to exclude maternal outcomes in the present analysis. We would be open to analyzing outcomes should you deem this essential for publication. However, we are concerned about the potential for false associations to dampen enthusiasm towards ongoing efforts to define levels of maternal care.

This study was deemed exempt by the Partners Human Research Committee. As the lead author I affirm that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned have been explained. Each author substantially contributed to both the design and analysis of the data as well as manuscript development and review. We all approve this submission and have attested to our roles in this project as documented in the Author Agreement. We, the authors, report no conflict of interest and disclose financial support on the title page of the manuscript. We look forward to your response to our manuscript and welcome your feedback.

Sincerely,



Sarah Rae Easter MD

Response to Reviewer Comments

REVIEWER #1

This cross sectional observational study looked at lineage analysis of American Hospital Association (AHA) survey and State Inpatient Database (SID) data from 7 representative states. Characteristics and procedure codes were used to assign a level of maternity care for each hospital. Patient ICD 9 codes and demographics were identified to compare appropriate minimum level of care. The primary outcome was to look at the inappropriate lower level of care delivered to further guide feasibility of obstetric regionalization of care.

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Abstract:

1. The objectives are concise and clearly outlined.
2. Line 51 The wording of only 43% of high risk patients delivered at level I/II is confusing. It is not clear what the denominator is. Was the 43% of the prior described 2.6% at high risk? Also the word "only" implies this was the preferred level of care and the number should be higher. I would suggest leaving it out or making it clear where the mismatch is occurring.

This number refers to the 43% of the 19,988 high-risk patients warranting level III or IV care who delivered at level I or II centers. The abstract has been updated to include the denominator and the preferred level of care and to remove the word "only" as suggested by the Reviewer.

Introduction:

3. This is an excellent review of the literature and the purpose of the study. Nothing to add

Materials and methods:

4. Lines 95-97 Why specifically were these states chosen vs. including all or more of the 22 listed in 2014? Was it logistical or incomplete data? The definition of rural and nearest level 3 or 4 hospitals may be significantly different and underrepresented in this study ie Western states Washington and Oregon vs. the more populous states listed on the East coast.

Inclusion of all 22 states with available data was cost prohibitive due to the expense of the SID. We attempted to include states of significant geographic diversity to provide a nationally representative sample to within the constraints of funding limitations. The manuscript has been updated to reflect our attempt to include states of varying geography in terms of proximity to each hospital to address the concerns of the Reviewer on lines 95-97.

5. Line 98 What were the validated methodologies?

The validated methodology for identifying deliveries was that described by Kuklina and colleagues referenced at the end of the sentence. This is now explicitly stated in the methods for clarity (line 99).

Results:

6. Line 141-144 What was the distribution of deliveries by state and level of care?

The distribution of deliveries by level of care is included in Figure 1 which has now been referenced in the first sentence of the Results section. The distribution of actual deliveries has been added to the Results as well. The distribution of deliveries by state is now included as a Supplemental Table.

Table 1

7. It is unclear what the purpose of preterm chronic HTN means. By definition if it is chronic or < 20 weeks it would be similar and therefore designated as level 2. For many of the chronic medical diagnosis it would be more important to know if they were still in the institutional level of care at term.

Preterm chronic hypertension refers to chronic hypertension requiring delivery at preterm gestation. A footnote has been added to Table 1 to clarify the preterm designation with respect to all hypertensive diagnoses.

Table 2

8. Annual transfers are not clear in which direction. Clearly level 1 is transferring out however between the other levels it is not clear if the transfer is accepting or the actual transferee.

The transfers referenced in Table 2 are transfers into the hospital. Table 2 has been edited to clarify this variable.

9. Some of the listed level 1 hospitals are listed as having surgery, ICU, SICU and cardiac ICU which is listed as a level 2 or 3 in the appendix. Please explain the designation. It also appears none of level 1 or 2 institutions have NICUs. Was there any information about neonatal transfers vs. maternal transfers?

In order to meet criteria to be a certain level hospital the hospital is required to meet all criteria set forth in the appendix. For example, if a hospital has general surgery services but lacks an MRI they are designated as a level I hospital. This clarification has been added to the methods on lines 122-123.

Unfortunately, the datasets lack a clear designation of neonatal data and therefore information on neonatal transfers. Maternal transfer volume into the hospital has been added to Table 2.

10. The breakdown by state is very helpful Is there further breakdown by state and number of deliveries and inappropriate level of care?

The breakdown by state as requested by the Reviewer has been included as a Supplemental Table.

11. Line 169 Which states had the greatest variation 1.26-4.21% in inappropriate level of care? This would be important along with further evaluation of barriers and distance to regional higher levels of care.

Please see response above regarding state level variation. We agree that the evaluation of geography and distance to level of care is important to understanding barriers to regionalization. We are regrettably currently limited in our geocoding abilities with the current dataset. A better understanding of the role of geography as a barrier to regionalization is an important area of future research. This has been stated as an area for future research on lines 250-253 of the Discussion.

12. Line 175-180 The inappropriate rates of care seem to rise for preterm pre eclampsia with severe features vs without 14% vs 18% and placenta previa without and with prior surgery 18-37%. This does not make sense. Further description by state and overall may give useful information for further investigation. The rate of inappropriate care for cardiovascular disease 68% needs to be defined as to whether it was diagnosed in the prenatal time period vs. intrapartum. These patients may have received the diagnosis due to intrapartum events that lead to a work up and diagnosis for the first time.

The rise in rates of inappropriate level of care for placenta previa without and with prior surgery and preterm preeclampsia without and with severe features likely reflects the recommendation for a higher level of care with increasing comorbidity. For example, women with an uncomplicated previa could be appropriately delivered at level II or above centers whereas women with previa with prior uterine surgery require level III or above centers. The more strict criteria for appropriate level of care with increasing maternal complexity likely account for this rising percentage. This explanation has been provided in the Results section lines 187-188.

The dataset unfortunately lacks granularity on whether cardiovascular disease was diagnosed intrapartum or known prenatally as present on admission modifiers are inconsistently used. To address this issue we defined cardiovascular disease using diagnostic codes that are limited to chronic diseases such as congenital heart disease, chronic ischemic heart disease, valvular disease, and chronic congestive heart failure. Codes describing acute cardiovascular conditions such as acute myocardial infarction or acute decompensated heart failure are not included. These codes are included in

Appendix I and the description of this process has been added to the methods on lines 117-119.

Figure 1.

13. Combining level 3 and 4 for appropriate level of care cover significant overlap of acuity of care which cross covers many comorbidities. This is a clinically useful comparison.

The possibility of providing risk-appropriate care for some level IV conditions at level III hospitals has now been acknowledged on lines 160-162 of the Results section.

Discussion:

14. Line 189 The identification of a potential cohort in this study of 6,042 patients with either previa and prior uterine surgery or cardiac disease needs to be analyzed further. Is there a way to determine if these were known prenatally or only at the time of delivery? If it is the latter the focus ought to be on accurate diagnosis vs. awareness and mobilization of resources for triage.

ICD-9 codes lack a reliable diagnosis code for antenatally diagnosed placenta accreta which can be a challenging diagnosis to make in clinical practice. We therefore used placenta previa with prior uterine surgery as the only requirement for delivery at a level III center requirement to try to capture diagnoses more likely to be known prior to delivery. In a similar manner, we limited our definition of cardiac disease to ICD-9 codes associated with chronic disease conditions as opposed to those with acute onset with the potential to arise during the intrapartum process. The inclusion of only chronic cardiovascular disease has previously been updated in the Methods section.

15. Line 210-213 The limitation and references for the assumption of level of care are well described and acknowledged.

16. Line 223-226 I would argue the use of ICD 9 codes and severity of disease based upon the appendix for level IV care may actually be underestimated. Working at a DSH hospital this is a constant problem from coders collecting accurate severity of illness not underestimation of disease.

We agree that we are limited by our lack of granularity regarding the severity of disease and could actually be underestimating disease severity as well. The Discussion has been updated to account for the possibility of both overestimation and underestimation of disease severity on lines 237-241.

REVIEWER #2

In the manuscript under review, the authors report cohort study using linked American Hospital Association survey data and state inpatient database data for 7 states to assign a level of maternal

care to each hospital and a minimal required LOC to each subject based on their comorbidities and then look at (as their outcome) delivery at an inappropriately low LoMC. Strengths of the current study include a large number of study patients in the analysis from a rich dataset. The study question that is being asked is original and clinically applicable and very timely. What is missing from this analysis is actual clinical outcomes and morbidities associated with delivery at the hospital that is assumed to be the wrong level of care.

Specific comments include:

1) It would be helpful to include a figure describing the different levels of care with characteristics of the levels much like what is noted in the ACOG document (such as that seen in the article: Levels of Maternal Care Verification Pilot: Translating Guidance Into Practice, Zahn et al Obstetrics & Gynecology Volume 132(6), December 2018, p 1401-1406)

The Figure referenced by the Reviewer has been adapted to our manuscript and included in the paper as Box 1. This addition is now referenced in the Materials and Methods section.

2) Did the authors think to include birth centers (they are noted in the ACOG LOC document)

Unfortunately the AHA and SID are hospital-based datasets and do not include freestanding birth centers in their datasets. This explanation has been included as a footnote in the newly-created Box 1 and in lines 103-104 of the manuscript.

3) The results section of the abstract is a bit confusing. It is clear that a small fraction of women 2.36% of the 845,545 warranted delivery in a level III or IV hospital (perhaps the "n" would be helpful), but who are the 43% of the high risk patients? Is this 43% of the 2.36%, and who are the 2.41% (of what group)? This could be further clarified

Please see response to Reviewer 1 above for clarifications.

4) The authors in the appendix look at multiple conditions to assign what complication warrants what level of care (the premise of the paper) and reference the ACOG document. Acog does not have a table but does under each level give examples (see below from the ACOG document), I am not sure the minimal level assigned is concordant with these recommendations. For example ACOG sites preeclampsia without severe features of as someone who needs at least level 1 and they are sited as level II care minimal. Additionally chronic kidney disease, epilepsy may not warrant level III (see below), an interesting research question would be how these women do at a different level of care than recommended. Although the authors note why they chose to do this, it is important to note (perhaps in the limitations) that not all women with these comorbidities need a higher level of care.

See ACOG examples from the document:

Examples of women who need at least level I care include women with term twin gestation; women attempting trial of labor after cesarean delivery; women expecting an uncomplicated cesarean delivery; and women with preeclampsia without severe features at term.

Examples of women who need at least level II care include women with severe preeclampsia and women with placenta previa with no prior uterine surgery

Examples of women who need at least level III care include those women with extreme risk of massive hemorrhage at delivery, such as those with suspected placenta accreta or placenta previa with prior uterine surgery; women with suspected placenta percreta; women with adult respiratory distress syndrome; and women with rapidly evolving disease, such as planned expectant management of severe preeclampsia at less than 34 weeks of gestation.

Examples of women who would need level IV care (at least at the time of delivery) include pregnant women with severe maternal cardiac conditions, severe pulmonary hypertension, or liver failure; pregnant women in need of neurosurgery or cardiac surgery; or pregnant women in unstable condition and in need of an organ transplant.

Why were the categories chosen similar/different please justify

Women with preterm preeclampsia without severe features and those with preeclampsia with severe features at term are advised to deliver in level II or above hospitals in the ACOG guidelines and within our dataset. Women with preeclampsia without severe features at term can deliver at any level center. Our definitions are concordant with these guidelines though preeclampsia without severe features was included in error in Table 1. This has been removed from Table 1. It is already correctly absent from Table 3 as these women can deliver at any level of care center.

Level I centers are those designed to care for uncomplicated pregnancies with the ability to detect, stabilize and initiate management of unanticipated problems. We therefore defined any medical comorbidity complicating pregnancy as warranting level II or higher care. This clarification and rationale has been added to the Methods section on lines 102-105.

A distinguishing characteristic between level II and level III centers is the availability of subspecialists to manage increasingly complex maternal medical comorbidities. The medical comorbidities selected for inclusion of level III care or above are those associated with high rates of severe maternal morbidity or mortality in the literature. This has been further described on lines 110-114 of the methods section.

We appreciate the Reviewer's observation on the spectrum of disease and our likely overestimation of the minimum level of care for a given medical comorbidity. This overestimation is reiterated in the limitations as suggested on lines 239-241 of the Discussion.

5) Although I understand that the primary outcome was delivery at the wrong level of care, I believe to warrant publication it would be helpful (and useful) to have other clinical outcomes that demonstrate why delivering at the wrong level of care helped/hurt the women in the study.

Utilizing the available datasets I believe that this would be possible and would take this paper to the next level in terms of impact. This is critical for publication.

Please see response to Associate Editor below.

REVIEWER #3

The authors sought to examine the current patterns of care for women at high risk for delivery related morbidity to explore regionalization of maternity services. The authors linked data from the State Inpatient Database and the AHA Survey for 7 representative states. They assigned a level of maternal care to each hospital and then assigned a patient to a minimum level of care based on the comorbidities captured in the SID.

Overall, I found the topic compelling and relevant for this clinical journal. There are some areas where the manuscript could be strengthened:

1. Throughout the results section - and to some degree in the abstract's results section - the authors aren't as clear as they need to be about which group they are discussing. The results section needs to utilize tables better to present their results and then use the text to summarize take home messages vs. trying to reiterate everything. It can become confusing at times to follow the message.

The Results section currently highlights findings already presented in Tables. To address this Reviewer's concern we deleted some of the percentages reported in the Results section and hope that this aids in ease of reading of the manuscript. We would be happy to clarify further at the discretion of the Editor. Some of the numbers in the Results section have been rounded to show less statistical significance as requested by the Statistical Editor (see below) which we hope aids in the ease of reading of the Results.

2. Ultimately, the authors' analysis isn't nationally representative - so the title and perhaps some of the conclusions need to be modified to reflect that point. It is only reflective of seven states.

The limitations of available datasets in terms of creating a nationally-representative sample have been added to lines 219-221 of the Discussion. We would be happy to modify the title should the Editor find this helpful.

3. As noted earlier, the results section would benefit greatly from a revision that allows some of the findings to move to a table. It was difficult to follow the authors train of thought and couldn't tell where they were getting some numbers and what they represented. Ideally, the results section should summarize key take home messages from each table and walk the reader through the results - but it shouldn't just be this dense reference to numbers. It would be helpful if many of these estimates were presented in the tables, so that the tables were more useful.

Please see response to Reviewer 3, point 1 above.

4. The authors mention at the end of the methods section that "a p-value of < 0.05 was considered statistically significant". But I only see p-values presented in Table 2, and these appear to be general associations - either from a chi-square test or an ANOVA. Because it was difficult at times to follow the results presented, it was also confusing to know whether the relationship discussed were significant based on statistical testing or just based on size.

The goal of the paper is to better understand our national obstetric landscape, therefore the data presented in the manuscript is primarily descriptive. The Methods section has been updated to specify the use of comparative statistics in the concluding paragraph of this section.

STATISTICAL EDITOR'S COMMENTS:

1. Table 2: The column totals vary from $n = 46$ to $n = 259$, with smaller samples for many hospital bedsize, area or State. There is no justification for citing proportions to nearest .01%. Should round to nearest integer value in the $n(\%)$ format.

Percentages have been rounded to the nearest integer as requested.

2. Table 3: Similar issue for this Table. The precision should be reported as no more than nearest 0.1 %.

Percentages have been rounded to the nearest 0.1% as requested.

3. General: The report does a good job of describing the proportion of women who were delivered at hospitals inappropriate to their need for specialized care. However, the report could be much improved by analysis of the average and range of distances or time from the hospital where care was given to the hospital appropriate for the needed level of care. That would give more meaning to the scope of the proposed adherence to matching maternal comorbidity needs vs hospital level of care.

We appreciate the insights of the Statistical Editor regarding the desire for information about distances and time. As discussed in the response to Reviewer 1, we are regrettably currently limited in our geocoding abilities with the current dataset. A better understanding of the role of geography as a barrier to regionalization is an important area of future research. We would be happy to state this as an important direction for future research should the Editor deem it useful.

4. Are there any data re: the maternal/neonatal outcomes of the women who needed level III or greater care, but who delivered at a lower level hospital compared to a similar cohort who delivered at level III or IV?

Please see response to Associate Editor below.

ASSOCIATE EDITOR'S COMMENTS:

Your manuscript would be greatly strengthened by the inclusion of maternal and neonatal outcomes.

We appreciate the request for outcomes from the Associate Editor and Reviewers. We recognize that the goal of regionalization is to improve maternal outcomes—not simply deliver women at an appropriate level of care. This manuscript is an important first step in defining hospital levels of care using available administrative data to better understand the current distribution of basic, specialty and subspecialty levels of maternal care hospitals. We also provide estimates, using population-based data, of the proportion of women who might benefit from care at higher acuity hospitals. We have refrained from analyzing or presenting outcomes in the present analysis because administrative data may not be suitable for such an analysis. We have concerns about residual confounding—particularly as it relates to disease severity and referral patterns.

As an example, clinical intuition would suggest that women with severe cardiac disease prone to decompensation, such as mitral stenosis, will be more likely to be referred to higher level of maternal care centers but also more likely to experience severe maternal morbidity at the time of delivery. Conversely, a patient with mild cardiac disease of trivial physiologic consequence, such as mitral valve prolapse, would be less likely to be referred and less likely to have a severe maternal outcome. These two diseases have the same ICD-9 codes. As currently defined, the former patient would be delivered at an appropriate level of care and have morbidity whereas the latter would be delivered at an inappropriate level of maternal care and have no adverse outcome. Similar arguments could be made for other high-risk conditions such as placenta previa with prior uterine surgery or severe preterm preeclampsia. If regionalized maternal care systems are already in place, one would expect to have women with more severe illness to deliver in level III and level IV hospitals. Without ability to adjust for disease severity, a simple comparison may suggest to some that delivery at an appropriate level of care center actually worsens maternal outcomes.

We are currently unable to control for disease severity and address this residual confounding and lack a complete understanding of referral patterns in this administrative dataset. We therefore made a conscious decision to exclude outcomes from the current analysis to avoid irresponsible reporting of an association we do not yet fully understand. We attempted to address the Editor's comments regarding outcomes and our concerns about disease severity and residual confounding as they relate to outcomes in the concluding paragraphs of the Discussion (lines 246-250). We would be open to analyzing outcomes should the Editor deem it essential for publication. But are concerned about the impact of these potentially false associations on the ongoing efforts to define levels of maternal care currently taking place.

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:

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

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.

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.

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

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

This statement has been included in the original cover letter and the cover letter for the revision.

4. In order for an administrative database study to be considered for publication in Obstetrics & Gynecology, the database used must be shown to be reliable and validated. In your response, please tell us who entered the data and how the accuracy of the database was validated. This same information should be included in the Materials and Methods section of the manuscript.

The details of the two databases used for the study are included in the Materials and Methods section and referenced as references 15 and 16 in the manuscript. We attempted to use validated coding when available and included those references in the Materials and Methods section when available, most notably with reference 18.

5. 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.

The STROBE checklist has been included in the revised materials.

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.

The use of an administrative dataset requires that the disease definitions used are based on ICD-9 coding and the granularity of available data unfortunately precludes the use of the reVITALize definitions as described in the Materials and Methods section.

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, references, tables, boxes, figure legends, and print appendixes) but exclude references.

The revised manuscript adheres to the recommended guidelines as documented in the Title Page.

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).

Some of the aforementioned guidelines are not applicable to the submission as we have no acknowledgments or funding. The presentation of the meeting at the SOAP annual meeting is disclosed on the Title Page and in the Cover Letter.

9. 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.

The abstract has been double checked for accuracy against the manuscript and adheres to the word count guidelines.

10. 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.

r. Commercial names should not be used in the title, précis, or abstract.

Commercial names are not used in the manuscript and the abbreviations used in the abstract are limited to AHA and SID (the commonly known names for the datasets) and LoMC for Levels of Maternal Care to adhere to the abstract word limit. The LoMC abbreviation is not standard but is necessary to adhere to guidelines given the frequency with which this terminology is used. We would be happy to spell this out completely as the Journal sees fit with hopes that we could exceed the Abstract word limit if necessary to do so.

11. 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.

The virgule symbol is absent from the manuscript.

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.

The Table Checklist has been reviewed and Tables adhere to the guidelines. Appendix 2 does include separate subheadings to aid in clarity which we would be happy to remove should the Journal deem it helpful.

13. 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>.

The referenced ACOG documents have been checked to ensure they are updated.

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>.

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