OBSTETRICS & GYNECOLOGY

NOTICE: This document contains correspondence generated during peer review and subsequent revisions but before transmittal to production for composition and copyediting:

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

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

Personal or nonessential information may be redacted at the editor's discretion.

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

Date: Jan 24, 2020
To: "Alyssa Rollow Hersh" [redacted]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-19-2270

RE: Manuscript Number ONG-19-2270

Maternal and infant hospitalization costs associated with induction of labor at term in California, 2007-2011

Dear Dr. Hersh:

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 Feb 14, 2020, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1: The authors present a large data base study examining the maternal and neonatal hospital costs of women undergoing induction of labor and women who had spontaneous. The question is important because of several large studies indicating that induction of labor decreases the likelihood of cesarean delivery and thus improves maternal outcomes without compromising neonatal outcomes. They found that older, more educated white women underwent induction of labor and that maternal hospital costs are more for patients undergoing induction of labor regardless of mode of delivery.

The paper is well-written and addresses the important issue of individual hospital costs.

The last author of this paper has done extensive work regarding morbidity and costs of induction of labor and was critical in the reframing of the comparison group for induction of labor morbidity arguing for ongoing pregnancy and not spontaneous labor as the comparator. Similarly, in this paper, one could argue that hospital costs are not the only cost consideration and that induction of labor costs need to be compared to the costs of ongoing pregnancy and then subsequent increase in cesarean delivery and maternal morbidity up to 41 weeks. Please comment on this in your discussion.

The discussion must include your findings of disparities in induction of labor and postulate both on its meaning but also the importance of reducing disparities in whatever approach a hospital or system takes with regards to implementation of induction and decreasing neonatal/maternal morbidity and costs.

Tables 5-7 can be excluded and just described in the text.

Reviewer #2: This is an important study examining the impact of the induction of labor at term. The results show us the tremendous financial cost of labor induction as opposed to spontaneous labor. I have the following comments:

1. This study would be more useful if it looked at elective induction of labor at or beyond 39 weeks. Although expensive, no one is going to refute the wisdom of inducing women with a medical indication for induction in the early term and term gestation. The issue before us today is whether or not elective induction of labor at term (not early term) is appropriate based on improved outcomes. For many of us, this is still an unresolved issue especially given the expense and resources involved. This study doesn't really directly answer the question as the cohort is too broad.

2. The introduction focuses on elective induction at term but fails to explain how this study which is both elective and indicated induction at early term and term gestation answer the question.

3. What is the source of the cost data for the analysis.

4. What happens to the analysis if the cost to charge ratio is different than 0.58, different payor mixes can drop or increase this significantly.

5. There is a confusing paragraph in the discussion (fourth) where infant costs are discussed and the statement is made that the cost findings of the study are in alignment with outcome findings from other studies. How?

6. The cesarean rate in this cohort is lower than the national average. How would a higher cesarean rate impact these results?

7. This data set goes back to 2007, before the push to eliminate elective delivery less than 39 weeks. How would the data from a more recent cohort look?

Reviewer #3: Hersh, et al have submitted a retrospective cohort study which utilized a large state-wide data set in order to determine if there is an association between induction of labor and increased hospital costs.

The abstract and introduction are well-written and concise. The introduction establishes the timeliness and relevance of the study given the results of the ARRIVE trial.

Questions related to the other sections:

Methods:
-Lines 139-143. The authors explain that they "examined women and infants with outliers for costs to determine exclusion criteria, leading to exclusion of women with total hospitalization costs that were unrealistic ($<100) and outliers for the population (greater than $600,000)." They also "excluded infants with the lowest costs (<$7) and outliers for the population (greater than $1,000,000). What criteria were used to establish these cutoffs? It's logical to exclude these outliers but the cutoffs appear arbitrary as described. Less than $100 is, indeed, unrealistic but why isn't <$150 or <$500, etc. Why would a hospital cost of $590,000 be considered realistic but not $600,000? The same questions apply to using the values of<$7 and >$1,000,000 for infants.

Results:
-Line 182 likely needs a reference to Table 2.

Discussion:
-The discussion related to the results in Tables 5 and 6 should be expanded to address the clinical reality that women who are diagnosed with preeclampsia or GDM in spontaneous labor (not requiring an IOL) typically have a different clinical course than those who require induction of labor which may (likely?) explain the differences in hospital costs in these sub-populations (i.e. a patient with preeclampsia with severe features requiring an IOL with MgSO4 likely has a very different course than one who has elevated BP's intrapartum during spontaneous labor . In this instance, it may not be the IOL that is increasing the hospitalization costs, but the timing of the diagnosis with respect to the onset of labor. Of course, this study is not designed to determine this, but this section of the paper would benefit from an expanded discussion of these findings. The same should be addressed for those with GDM--almost double the number of patients in table 7 (50,604 vs 30,375) had GDM with "no induction of labor". Is this not likely due to the fact that the "no IOL" group likely includes a larger proportion of patients with diet controlled GDM who awaited spontaneous labor vs. the IOL group which likely included a larger proportion of patients requiring medication and for whom IOL was indicated? Again, adding patients with preeclampsia and GDM introduces other potential confounders that may affect the observations and this should be addressed if these subgroups are to be included.

STATISTICAL EDITOR COMMENTS:

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

Table 1: The study was not a RCT and the cohorts differ in many baseline characteristics. It would be important to

distinguish the IOL which had a medical indication vs those that did not. Those with a medical indication may have skewed the LOS, or other costs of hospitalization (e.g., DM or pre-eclampsia). Some attempt should be made to account for those differences (and the severity) , otherwise it is unclear how much the difference in costs is attributable to IOL alone. As such, one cannot determine how much of this difference might be altered by a policy change.

Tables 2, 3: Should show (could be as on-line material) how many women were in each subset by GA, mode of delivery and whether or not had IOL.

Tables 4, 5, 6, 7, 8, 9: Show show number of women or infants in each subset.

Fig 1: About 20% of women were excluded, due to missing data for costs. Did those women differ from the cohort analyzed in any way which would have skewed the results or made the conclusions non-representative of the entire group?

Did hospital costs vary according to geographic area in the State and was the rate of IOL vs non-IOL associated with area of the State? Need to assess whether geographic area, SES, hospital costs and rates of IOL were related.

EDITOR'S COMMENTS:

We no longer require that authors adhere to the Green Journal format with the first submission of their papers. However, any revisions must do so. I strongly encourage you to read the instructions for authors (the general bits as well as those specific to the feature-type you are submitting). The instructions provide guidance regarding formatting, word and reference limits, authorship issues, and other things. Adherence to these requirements with your revision will avoid delays during the revision process, as well as avoid re-revisions on your part in order to comply with the formatting. For instance, we do not include a “Condensation, Implications and Contributions” section.

The overarching purpose of your paper--to compare the costs of induced labor compared to those not undergoing induced labor at term--is an important question. Clearly, the ARRIVE trial may have be a reason for doing this analysis. In order to help inform thinking about implementation (or not) of the recommendations stemming from the ARRIVE trial, it is necessary to clearly define the populations one is comparing. No one is going to argue that medically indicated deliveries prior to the onset of labor should be avoided, so all of these should be removed from the analysis. It isn't sufficient to just look at preeclampsia and diabetes. These are not contributing excess costs that might derive from non-medically indicated inductions at >=39 weeks. Similarly, the costs of all cesarean deliveries at term should not be compared to the costs of cesareans at term that follow inductions. Only the costs of cesareans performed in labor--spontaneous or induced--should be compared. Women with scheduled cesarean deliveries often are admitted in the morning and discharged on day 2--whereas women sectioned in labor (spontaneous or induced) have the labor duration that extends the overall LOS and are at higher risk of infection, fatigue, etc. Lastly, it is not surprising that women who enter labor spontaneously incur lower hospital costs than those who are induced. But as you know we can't control when or which women enter spontaneous labor, so it seems like the costs you really should be comparing are the costs incurred by women undergoing labor induction at a given gestational age to the subsequent costs incurred by women who could have been induced but weren't , regardless of whether those women entered spontaneous labor, were induced, or underwent cesarean in the absence of labor.

Line 58: The objective of the abstract should be a simple “To” statement without background information.

Line 74: Did you include women who had cesarean births without IOL who had scheduled cesarean deliveries or only those who had cesareans during labor? It seems that you should only compare the costs w/ cesarean birth between women who labored, and not include the ones who were scheduled.

Line 81: You are assessing both maternal and infant costs in your study, but in your conclusion here you mention “women’ only. It’s not clear if that is inclusive of the costs for their infants. This is true throughout your abstract. Please make it clear what is included in the costs for the women—inclusive or not of infant costS? As a side note, it may be illuminating to report the costs for the women and their infants separately, and then combine them.

Line 145: Include unit (years) for age.

Line 153: I agree completely with your reviewers that you need to do your best to exclude medically indicated inductions or report them separately from the elective inductions of labor. If you have these codes for diabetes and preeclampsia, you likely have other codes available that would indicate a medical reason for IOL, such as those for prelabor rupture of the membranes, fetal growth restriction, lupus, post dates, etc.

Line 160: do you mean “contributes to such disparities AS labor length….”?

Line 182: Please make it crystal clear whether you are talking about only maternal costs or combined maternal and infant

costs throughout. You can set this up here by making a statement such as " We will report median hospitalization costs for the women, infants and combined costs" or the like.

Line 183: While P values are a central part of inference testing in statistics, when cited alone, often the strength of the conclusion can be misunderstood. Whenever possible, the preferred citation should be in terms of an effect size, such as odds ratio or relative risk or the mean difference of a variable between two groups, expressed with appropriate confidence intervals. When such syntax is used, the P value has only secondary importance and often can be omitted or noted as footnotes in a Table format. Putting the results in the form of an effect size makes the result of the statistical test more clinically relevant and gives better context than citing P values alone.
This is true for the abstract as well as the manuscript, tables and figures.

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

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

Line 185: Per my note in the abstract section, it seems you should only compare costs for labored cesarean births This needs to be clarified in methods as well.

Line 193: Does the sentence starting with "Furthermore" relate only to women who delivered by cesarean or is this overall? Same for line 200.

Line 212-215: You state on 213 that the infant costs were "not significantly different in all scenarios" but then on 215, you state the costs for vaginally delivered infants "were significantly different". Is there a typo somewhere or am I missing something?

I hope in your discussion you mention that these infant costs, while statistically different, are financially not really much different (Differences of $100-150) in the 2 groups you report. Also important the LOS data for infants at term are in the vast majority of cases driven by maternal LOS and this should be noted in discussion.

Lines 221-225: Same issues as for lines 212-215: you say on line 221 that these costs were "insignificant in many settings" but then go on to highlight two areas for which there were significant differences. Not sure what you are getting at here.

Line 238: again, muddied information. Is this just maternal costs? The $2billion additional cost figure needs to be adjusted to remove the indicated IOL's. This should ONLY include the elective IOLs.

Lines 243-245: I believe in the ARRIVE trial the total LOS was not different in those induced vs no induced, due to lower CS rates. The LOS is longer in the L&D area, but shorter in the post partum stay area. This should be acknowledged.

EDITORIAL OFFICE COMMENTS:

1. The Editors of Obstetrics & Gynecology are seeking to increase transparency around its peer-review process, in line with efforts to do so in international biomedical peer review publishing. If your article is accepted, we will be posting this revision letter as supplemental digital content to the published article online. Additionally, unless you choose to opt out, we will also be including your point-by-point response to the revision letter. If you opt out of including your response, only the revision letter will be posted. Please reply to this letter with one of two responses:
A. OPT-IN: Yes, please publish my point-by-point response letter.
B. OPT-OUT: No, please do not publish my point-by-point response letter.

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

Please check with your coauthors to confirm that the disclosures listed in their eCTA forms are correctly disclosed on the manuscript's title page.

3. 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. Please submit a completed STROBE checklist with your revision.

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

5. Standard obstetric and gynecology data definitions have been developed through the reVITALize initiative, which was convened by the American College of Obstetricians and Gynecologists and the members of the Women's Health Registry Alliance. Obstetrics & Gynecology 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.

6. 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.

7. 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).

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

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

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

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

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

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

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

12. Please review the journal's Table Checklist to make sure that your tables conform to journal style. The Table Checklist is available online here: http://edmgr.ovid.com/ong/accounts/table_checklist.pdf.

13. 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. Figure 1 may be resubmitted as-is with your revision.

15. Authors whose manuscripts have been accepted for publication have the option to pay an article processing charge and publish open access. With this choice, articles are made freely available online immediately upon publication. An information sheet is available at http://links.lww.com/LWW-ES/A48. The cost for publishing an article as open access can be found at http://edmgr.ovid.com/acd/accounts/ifauth.htm.

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

16. If you choose to revise your manuscript, please submit your revision through Editorial Manager at http://ong.editorialmanager.com. Your manuscript should be uploaded in a word processing format such as Microsoft Word. Your revision's cover letter should include the following:

* A confirmation that you have read the Instructions for Authors (http://edmgr.ovid.com/ong/accounts/authors.pdf), and
* A point-by-point response to each of the received comments in this letter.

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

Again, your paper will be maintained in active status for 21 days from the date of this letter. If we have not heard from you by Feb 14, 2020, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

Nancy C. Chescheir, MD
Editor-in-Chief

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

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February 17th, 2020

Re: Submission of manuscript, “Maternal and infant hospitalization costs associated with elective induction of labor at term in California, 2007-2011”

The Editors
Obstetrics & Gynecology
409 12th Street, SW
Washington, DC 20024-2188

Dear Editors:

Thank you for your continued interest in this manuscript, “Maternal and infant hospitalization costs associated with elective induction of labor at term in California, 2007-2011,” for publication as original research in *Obstetrics & Gynecology*.

OPT-IN: Yes, please publish my point-by-point response letter.

We have included the STROBE checklist with this submission.

We look forward to your comments and critique of the manuscript. If you have any questions about the manuscript, I will be serving as the corresponding author. Thank you for your consideration.

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.
Signed by: Alyssa Hersh
*The manuscript’s guarantor.

Sincerely,

Alyssa R. Hersh, MPH
Oregon Health & Science University
[redacted]

REVIEWER COMMENTS:

Reviewer #1: The authors present a large data base study examining the maternal and neonatal hospital costs of women undergoing induction of labor and women who had spontaneous. The question is important because of several large studies indicating that induction of labor decreases the likelihood of cesarean delivery and thus improves maternal outcomes without compromising neonatal outcomes. They found that older, more educated white women underwent induction of labor and that maternal hospital costs are more for patients undergoing induction of labor regardless of mode of delivery.

The paper is well-written and addresses the important issue of individual hospital costs.

Thank you for your supportive comment.

The last author of this paper has done extensive work regarding morbidity and costs of induction of labor and was critical in the reframing of the comparison group for induction of labor morbidity arguing for ongoing pregnancy and not spontaneous labor as the comparator. Similarly, in this paper, one could argue that hospital costs are not the only cost consideration and that induction of labor costs need to be compared to the costs of ongoing pregnancy and then subsequent increase in cesarean delivery and maternal morbidity up to 41 weeks. Please comment on this in your discussion.

Thank you for bringing this up. As the costs associated with elective induction of labor have not been published previously, we feel that evaluating the difference in cost between elective induction of labor and expectant management would be a very different study design. Capturing the costs of elective induction of labor in a number of population strata are important and as expectant management involves estimating downstream actions and outcomes, it is outside the scope of the current study.

The discussion must include your findings of disparities in induction of labor and postulate both on its meaning but also the importance of reducing disparities in whatever approach a hospital or system takes with regards to implementation of induction and decreasing neonatal/maternal morbidity and costs.

Thank you for this thoughtful suggestion. We have added text to our discussion regarding the disparities in induction of labor.

New text (lines 698-740): "Our findings suggest that differences exist in the utilization of elective induction of labor, particularly among different maternal races and ethnicities. We found that non-Hispanic white women were more likely to undergo elective induction of labor versus no elective induction of labor compared to all other racial and ethnic groups. These findings are consistent with prior research comparing elective induction with expectant management.17,18 These differences may be due to varying levels of education regarding labor management strategies or disparities in how elective induction of labor is offered to patients by providers. In order to reduce these health disparities, it is important to implement institutional policies regarding counseling for elective induction of labor. That being said, given our study findings show an increase in maternal hospitalization costs with elective induction of labor, by reducing these disparities, this may lead to a further increase in maternal hospitalization costs. Yet, by reducing disparities in elective induction of

labor, this may also result in significantly lower infant hospitalization costs in the setting of a vaginal delivery, which may balance the increase in maternal costs.
Irrespective of these costs, the maternal mortality rate for non-Hispanic black women is 2.5 times the rate for non-Hispanic white women.19 Given a large proportion of these deaths are due to obstetric causes such as hypertension in pregnancy, and elective induction of labor has been associated with a lower risk of developing this disorder, evaluating both the costs and outcomes associated with elective induction of labor is critical when working to decrease these disparities.4,19 As an example, two analyses found elective induction of labor at term was cost effective (i.e. resulted in higher costs and higher quality of life) compared to expectant management when considering both the costs and downstream maternal and neonatal outcomes of induction of labor.8,9."

Tables 5-7 can be excluded and just described in the text.

Thank you for the suggestion. We have moved additional analyses to supplementary materials.

Reviewer #2: This is an important study examining the impact of the induction of labor at term. The results show us the tremendous financial cost of labor induction as opposed to spontaneous labor. I have the following comments:

Thank you for this supportive comment.

1. This study would be more useful if it looked at elective induction of labor at or beyond 39 weeks. Although expensive, no one is going to refute the wisdom of inducing women with a medical indication for induction in the early term and term gestation. The issue before us today is whether or not elective induction of labor at term (not early term) is appropriate based on improved outcomes. For many of us, this is still an unresolved issue especially given the expense and resources involved. This study doesn't really directly answer the question as the cohort is too broad.

Thank you for bringing this up. We agree that it is important to evaluate the costs of elective induction of labor. Therefore, we have changed the analysis to evaluate only elective induction of labor and excluded medically-indicated induction of labor.

2. The introduction focuses on elective induction at term but fails to explain how this study which is both elective and indicated induction at early term and term gestation answer the question.

Thank you for pointing this out. We have changed the analysis to evaluate elective induction of labor.

3. What is the source of the cost data for the analysis.

The source of these data is listed in the first paragraph of the Methods section:

Current text (lines 186-198): "We conducted a retrospective cohort study of singleton, non-anomalous births to women identified through the California Vital Statistics Birth Certificate data linked with the California Patient Discharge Data as well as Vital Statistics Death Certificate Data and Vital Statistics Fetal Death File from 2007 to 2011. Linkage was performed by California Office of Statewide Health Planning and Development Health Care Information Resource Center under the State of California Health and Human Services Agency. The resultant linked datasets include maternal antepartum and postpartum hospital records for the 9 months prior to delivery and 1 year post-delivery as well as all

infant admission and readmissions occurring within the first year of life."

4. What happens to the analysis if the cost to charge ratio is different than 0.58, different payor mixes can drop or increase this significantly.

Thank you for this question. Different payor mixes would affect reimbursement, but would not generally impact either charges or true costs. As the CCR is multiplied by the charges, it is unlikely to change our relative conclusions, although it would modify the absolute costs.

5. There is a confusing paragraph in the discussion (fourth) where infant costs are discussed and the statement is made that the cost findings of the study are in alignment with outcome findings from other studies. How?

Thank you for pointing this out. Since we updated the analysis to include only elective induction of labor, our infant outcomes have changed. We have updated the text to reflect our new findings.

New text (lines 686-697): "Interestingly, we found the opposite effect with infant costs and lengths of stay. Infants whose mothers underwent elective induction of labor had significantly lower hospitalization costs and lengths of stay compared to those who didn't. The recently published Arrive Trial found that infant outcomes were not significantly different based on labor induction, although the trend was toward lower adverse infant outcomes.4 Extrapolating those results to our study, it is possible that the lower costs and lengths of stay could be attributed to lower rates of adverse outcomes. However, as this is observational data, we cannot elucidate what exactly contributed to these decreased costs. Furthermore, while we found significantly lower costs, it is important to note that the absolute differences in median costs observed were mostly less than one hundred dollars, with mean costs differing more substantially."

6. The cesarean rate in this cohort is lower than the national average. How would a higher cesarean rate impact these results?

Thank you for this question. Since we stratified the results by cesarean and vaginal delivery, a higher cesarean rate is unlikely to change the absolute costs.

7. This data set goes back to 2007, before the push to eliminate elective delivery less than 39 weeks. How would the data from a more recent cohort look?

Thank you for this question. It is true that the women managed with induction of labor in 2007 could have been different that women in 2020, and we have added this point to our discussion.

New text (lines 751-755): "Additionally, as medical practice evolves over time, it is important to note that our study was conducted between 2007-2011, and the patients undergoing elective induction of labor during those years may differ from women undergoing elective induction of labor currently. Therefore, the costs associated with elective induction of labor should be re-evaluated as practice patterns change since the costs could differ based on patient population."

Reviewer #3: Hersh, et al have submitted a retrospective cohort study which utilized a large state-wide data set in order to determine if there is an association between induction of labor and increased

hospital costs. The abstract and introduction are well-written and concise. The introduction establishes the timeliness and relevance of the study given the results of the ARRIVE trial.

Thank you for this positive comment.

Questions related to the other sections:

Methods:
-Lines 139-143. The authors explain that they "examined women and infants with outliers for costs to determine exclusion criteria, leading to exclusion of women with total hospitalization costs that were unrealistic ($<100) and outliers for the population (greater than $600,000)." They also "excluded infants with the lowest costs (<$7) and outliers for the population (greater than $1,000,000). What criteria were used to establish these cutoffs? It's logical to exclude these outliers but the cutoffs appear arbitrary as described. Less than $100 is, indeed, unrealistic but why isn't <$150 or <$500, etc. Why would a hospital cost of $590,000 be considered realistic but not $600,000? The same questions apply to using the values of<$7 and >$1,000,000 for infants.

Thank you for this question. We agree that we need to more explicitly explain our inclusion and exclusion criteria. We have modified the text to the following:

New text (lines 220-225): "We also examined women and infants with outliers for costs to determine exclusion criteria, leading to exclusion of women with total hospitalization costs less than $100 and upper outliers for the population (greater than $600,000). We excluded infants with the lowest costs (<$7) and upper outliers for the population (greater than $1,000,000). These cut-offs were determined by examining the data for the lowest and highest costs and excluding outliers."

Results:
-Line 182 likely needs a reference to Table 2.

We believe you are asking us to reference the women's demographics, so have added a reference to Table 1 at the end of the paragraph in line 299. Please let us know if the reviewer meant a different reference.

Discussion:
-The discussion related to the results in Tables 5 and 6 should be expanded to address the clinical reality that women who are diagnosed with preeclampsia or GDM in spontaneous labor (not requiring an IOL) typically have a different clinical course than those who require induction of labor which may (likely?) explain the differences in hospital costs in these sub-populations (i.e. a patient with preeclampsia with severe features requiring an IOL with MgSO4 likely has a very different course than one who has elevated BP's intrapartum during spontaneous labor. In this instance, it may not be the IOL that is increasing the hospitalization costs, but the timing of the diagnosis with respect to the onset of labor. Of course, this study is not designed to determine this, but this section of the paper would benefit from an expanded discussion of these findings. The same should be addressed for those with GDM--almost double the number of patients in table 7 (50,604 vs 30,375) had GDM with "no induction of labor". Is this not likely due to the fact that the "no IOL" group likely includes a larger proportion of patients with diet controlled GDM who awaited spontaneous labor vs. the IOL group which likely included a larger proportion of patients requiring medication and for whom IOL was indicated? Again, adding patients with preeclampsia and GDM introduces other potential confounders that may affect the

observations and this should be addressed if these subgroups are to be included.

Thank you for your detailed comment. We have modified the analysis to assess elective induction of labor and removed analyses assessing induction of labor among women with various comorbidities.

STATISTICAL EDITOR COMMENTS:

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

Table 1: The study was not a RCT and the cohorts differ in many baseline characteristics. It would be important to distinguish the IOL which had a medical indication vs those that did not. Those with a medical indication may have skewed the LOS, or other costs of hospitalization (e.g., DM or pre-eclampsia). Some attempt should be made to account for those differences (and the severity) , otherwise it is unclear how much the difference in costs is attributable to IOL alone. As such, one cannot determine how much of this difference might be altered by a policy change.

Thank you for bringing this up. We have performed a new analysis assessing the costs of elective induction of labor and excluded those with a medical indication for induction of labor.

Tables 2, 3: Should show (could be as on-line material) how many women were in each subset by GA, mode of delivery and whether or not had IOL.

Thank you for this comment. We have added the number of women in each subset in Supplemental Table 5.

Tables 4, 5, 6, 7, 8, 9: Show number of women or infants in each subset.

Thank you for this comment. We have added the number of women in each subset in Supplemental Table 5.

Fig 1: About 20% of women were excluded, due to missing data for costs. Did those women differ from the cohort analyzed in any way which would have skewed the results or made the conclusions non-representative of the entire group?

Thank you for this question, which we should have addressed in our Methods. We assessed for differences in demographic characteristics and found that women excluded from our analysis were significantly different than included women. We have added text to the limitations addressing this.

New text (lines 744-747): "women and infants excluded from this study due to missing data were significantly different than those included, and we cannot estimate whether the inclusion of these women would significantly impact our results"

Did hospital costs vary according to geographic area in the State and was the rate of IOL vs non-IOL associated with area of the State? Need to assess whether geographic area, SES, hospital costs and rates of IOL were related.

Thank you for this thoughtful question. We have added an analysis assessing the differences in cost

based on geographic location.

EDITOR'S COMMENTS:

We no longer require that authors adhere to the Green Journal format with the first submission of their papers. However, any revisions must do so. I strongly encourage you to read the instructions for authors (the general bits as well as those specific to the feature-type you are submitting). The instructions provide guidance regarding formatting, word and reference limits, authorship issues, and other things. Adherence to these requirements with your revision will avoid delays during the revision process, as well as avoid re-revisions on your part in order to comply with the formatting. For instance, we do not include a "Condensation, Implications and Contributions" section.

Thank you for pointing this out. We have reviewed the formatting requirements and removed the "Condensation, Implications and Contributions" section.

The overarching purpose of your paper--to compare the costs of induced labor compared to those not undergoing induced labor at term--is an important question. Clearly, the ARRIVE trial may have be a reason for doing this analysis. In order to help inform thinking about implementation (or not) of the recommendations stemming from the ARRIVE trial, it is necessary to clearly define the populations one is comparing. No one is going to argue that medically indicated deliveries prior to the onset of labor should be avoided, so all of these should be removed from the analysis. It isn't sufficient to just look at preeclampsia and diabetes. These are not contributing excess costs that might derive from non-medically indicated inductions at >=39 weeks. Similarly, the costs of all cesarean deliveries at term should not be compared to the costs of cesareans at term that follow inductions. Only the costs of cesareans performed in labor--spontaneous or induced--should be compared.

Thank you for this comment. We have modified the analysis to evaluate the costs associated with elective induction of labor compared with no induction of labor, and have excluded medically-indicated inductions as well as planned cesarean deliveries.

Women with scheduled cesarean deliveries often are admitted in the morning and discharged on day 2--whereas women sectioned in labor (spontaneous or induced) have the labor duration that extends the overall LOS and are at higher risk of infection, fatigue, etc. Lastly, it is not surprising that women who enter labor spontaneously incur lower hospital costs than those who are induced. But as you know we can't control when or which women enter spontaneous labor, so it seems like the costs you really should be comparing are the costs incurred by women undergoing labor induction at a given gestational age to the subsequent costs incurred by women who could have been induced but weren't , regardless of whether those women entered spontaneous labor, were induced, or underwent cesarean in the absence of labor.

Thank you for this comment. The comparison of induction of labor versus expectant management is an entirely different analysis requires many more assumptions about management than the study we designed to examine the costs of induction of labor. Such cost studies are relatively rare in the literature and we believe are necessary in order for the combination of clinical data such as the Arrive Trial with appropriate utilization data in order to understand what such an impact would be. But before one can do such an analysis, they have to have the cost data from this paper. Then, researchers, managers, guideline creators, and policy creators can examine their individual

population, the cesarean rates they experience, the rates of subsequent induction at various gestational ages, and combine with these cost data to conduct appropriate cost-effectiveness analyses.

Line 58: The objective of the abstract should be a simple "To" statement without background information.

Thank you for this suggestion. We have modified the text accordingly.

Lines 68-69: "Objective: To compare hospitalization costs of pregnancies managed by elective induction of labor to those with spontaneous labor in a large cohort of pregnant women."

Line 74: Did you include women who had cesarean births without IOL who had scheduled cesarean deliveries or only those who had cesareans during labor? It seems that you should only compare the costs w/ cesarean birth between women who labored, and not include the ones who were scheduled.

Thank you for this question. We have removed all women with planned cesarean deliveries.

Line 81: You are assessing both maternal and infant costs in your study, but in your conclusion here you mention "women' only. It's not clear if that is inclusive of the costs for their infants. This is true throughout your abstract. Please make it clear what is included in the costs for the women—inclusive or not of infant costS? As a side note, it may be illuminating to report the costs for the women and their infants separately, and then combine them.

Thank you for this important comment. We have edited the discussion to be clear regarding if we are referring to women or their infants.

Line 145: Include unit (years) for age.

Thank you for this suggestion. We have added "years" to age descriptions.

Line 153: I agree completely with your reviewers that you need to do your best to exclude medically indicated inductions or report them separately from the elective inductions of labor. If you have these codes for diabetes and preeclampsia, you likely have other codes available that would indicate a medical reason for IOL, such as those for prelabor rupture of the membranes, fetal growth restriction, lupus, post dates, etc.

Thank you for this suggestion. We have excluded medically-indicated inductions of labor from the analysis, with all relevant ICD-9 codes included below:

Supplemental Table 1. ICD-9 codes used for the identification of co-morbid conditions

Variable	**ICD-9 codes**
Medically-indicated induction of labor	
Human Immunodeficiency virus	042
Diseases of biliary tract	576.8
Placenta Previa	641.01, 641.11
Antepartum hemorrhage	641.81, 641.91

Essential hypertension	642.01, 742.02
Renal hypertension	642.11, 642.12
Old pre-existing hypertension	642.21, 642.22
Transient hypertension of pregnancy	642.31, 642.32
Pre-eclampsia	642.41, 642.42, 642.51, 642.52
Eclampsia	642.61, 642.62, 642.71, 642.72
Unspecified hypertension	642.91, 642.92
Post-term pregnancy	645.11
Unspecified renal disease in pregnancy	646.21, 646.22
Liver/biliary tract disorder	646.71
Diabetes mellitus	648.01
Congenital Cardiovascular disorder of mother	648.51, 648.52
Other cardiovascular disease of mother	648.61, 648.62
Abnormal glucose tolerance	648.81, 648.82
Coagulation defect	649.32
Multiple pregnancy	651.01, 651.11, 651.21, 651.51, 651.61, 651.71, 651.81, 651.91
Malpresentations	652.01, 652.61
Fetal abnormalities	655.01, 655.11, 655.31, 655.41, 655.51, 655.61, 655.81
Fetal-maternal hemorrhage	656.01
Intrauterine death	656.41
Poor fetal growth	656.51
Polyhydramnios	657.01
Oligohydramnios	658.01
Premature rupture of membranes	658.11
Cord prolapse	663.01
Vasa Previa	662.51
Pre-labor rupture of uterus	665.01
Asymptomatic HIV infection	V08
Delivery of single stillborn	V27.1

Line 160: do you mean “contributes to such disparities AS labor length….”?

Thank you for this suggestion. We have modified the text to be clearer.

New text (lines 251-252): “Because parity contributes to disparities in labor length and outcomes, all analyses were stratified by parity…”

Line 182: Please make it crystal clear whether you are talking about only maternal costs or combined maternal and infant costs throughout. You can set this up here by making a statement such as “ We will report median hospitalization costs for the women, infants and combined costs” or the like.

Thank you for pointing this out. We have endeavored to modify the text accordingly in effort to make these issues clear.

Line 183: While P values are a central part of inference testing in statistics, when cited alone, often the strength of the conclusion can be misunderstood. Whenever possible, the preferred citation should be in terms of an effect size, such as odds ratio or relative risk or the mean difference of a variable between two groups, expressed with appropriate confidence intervals. When such syntax is used, the P value has only secondary importance and often can be omitted or noted as footnotes in a Table format. Putting the results in the form of an effect size makes the result of the statistical test more clinically relevant and gives better context than citing P values alone.
This is true for the abstract as well as the manuscript, tables and figures.
Please provide absolute values for variables, in addition to assessment of statistical significance.
We ask that you provide crude OR's followed by adjusted OR's for all relevant variables.

Thank you for this suggestion. Since we used Chi-squared and Kruskal-Wallis tests for statistical significance, these are typically reported only as p-values. We did not use odds ratios in this study.

Line 185: Per my note in the abstract section, it seems you should only compare costs for labored cesarean births This needs to be clarified in methods as well.

Thank you for this comment. We have adjusted the analysis to exclude planned cesarean deliveries.

Line 193: Does the sentence starting with "Furthermore" relate only to women who delivered by cesarean or is this overall? Same for line 200.

Thank you for this question. We have modified the text to be clear about the population we are referring to.

New text (lines 328-329): "Furthermore, length of stay was significantly higher among all nulliparous women undergoing elective induction of labor than women that did not undergo induction of labor ($p<0.01$)."

New text (lines 334): "Length of stay was significantly higher as well among multiparous women ($p<0.01$)."

Line 212-215: You state on 213 that the infant costs were "not significantly different in all scenarios" but then on 215, you state the costs for vaginally delivered infants "were significantly different". Is there a typo somewhere or am I missing something?

Thank you for pointing this out. We have since updated the analysis and the corresponding text.

I hope in your discussion you mention that these infant costs, while statistically different, are financially not really much different (Differences of $100-150) in the 2 groups you report. Also important the LOS data for infants at term are in the vast majority of cases driven by maternal LOS and this should be noted in discussion.

Thank you for these suggestions. We have edited the Discussion in response.

New text (lines 693-697): "Furthermore, while we found significantly lower costs, it is important to note that the absolute differences in median costs observed were mostly less than one hundred dollars, with mean costs differing more substantially. Lastly, as maternal and infant costs and length of stay are impacted by one another, it is unknown to what degree each is driving the other."

Lines 221-225: Same issues as for lines 212-215: you say on line 221 that these costs were "insignificant in many settings" but then go on to highlight two areas for which there were significant differences. Not sure what you are getting at here.

Thank you for pointing out this discrepancy. We have adjusted our discussion now that our results have changed so this no longer applies.

Line 238: again, muddied information. Is this just maternal costs? The $2 billion additional cost figure needs to be adjusted to remove the indicated IOL's. This should ONLY include the elective IOLs.

Thank you for pointing this out. With the changed focus on elective induction of labor, we have edited this figure to represent the potential financial impact of elective induction of labor.

New text (lines 433-436): "While the difference seen was at least $900 per woman, when considering that 15% of pregnancies ended in elective induction of labor in this study, this would be a large cost for our health care system if applied to all women in the United States."

Lines 243-245: I believe in the ARRIVE trial the total LOS was not different in those induced vs no induced, due to lower CS rates. The LOS is longer in the L&D area, but shorter in the post partum stay area. This should be acknowledged.

Thank you for this suggestion. We have added this point to the discussion.

New text (lines 657-681): "A secondary analysis of the Arrive Trial found that elective induction of labor was associated with longer time spent in labor & delivery and additional medications, but lower postpartum stays compared with pregnancies that are not managed with an induction of labor."

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5. Standard obstetric and gynecology data definitions have been developed through the reVITALize initiative, which was convened by the American College of Obstetricians and Gynecologists and the members of the Women's Health Registry Alliance. Obstetrics & Gynecology 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.

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

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