

OBSTETRICS & GYNECOLOGY



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obgyn@greenjournal.org.

Date: Nov 19, 2021
To: "Jessica A Peterson" [REDACTED]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-21-2160

RE: Manuscript Number ONG-21-2160

Catastrophic health expenditures with pregnancy and delivery in the United States

Dear Dr. Peterson:

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).

Please be sure to address the Editor comments (see "EDITOR COMMENTS" below) in your point-by-point response.

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 Dec 10, 2021, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1: In this original research, the authors aim to describe the prevalence and risk factors for catastrophic health expenditures in the year of delivery. They also seek to evaluate if there are changes associated with ACA implementation. They report that pregnancy/delivery are associated with increased expenditures and Medicaid is more protective than private insurance.

Abstract:

- A definition of birth parent should be included in the abstract as it is unclear if it's the family unit or the mother
- The inclusion of "changes associated with ACA implementation" should be removed from the objective as these results are not presented in the results section of the abstract
- As the authors present numerous results of characteristics associated with catastrophic health expenditures, this should be included in the methods
- Details of the propensity matching should be briefly expanded in the methods/results
- Line 29: The authors report prediction, however, they only analyze associations. There are no ROC curves to assess prediction

Introduction:

- The definition of catastrophic health care expenditures from the abstract is missing from the definition in lines 61-62.
- I am unclear as to line 63 "context" means; the authors actually aim to compare CHE and describe risk factors. The authors should split lines 62-65 into a primary and secondary objective since this sentence is rather lengthy with multiple goals of the study
- The authors discuss birth parent in the introduction however this is not defined until the methods

Methods:

- Lines 95-96: I am unclear what the "two observations" are derived from. Could there not be more than 2 observations, this is unclear.

- Is date of the birth captured in this dataset? There may be expenditures prior to conception that are included that should not be. This is unclear.
- The authors should explain why the 13% of individuals from the MEPS were included in the case cohort (i.e. pregnancy) although delivery hospitalization data was not available. This creates two cohorts in the tables.
- The authors report that they chose not to match on insurance or employment; however, they do match on race/ethnicity, education. I suspect there is a high level of collinearity in these variables which needs to be addressed here in the propensity section as well as the multivariable logistic regression section.
- The authors use the birth month as a frame of reference for the birth year. However, is someone were to have a birth month of January, data from the prior year of pregnancy would not be included and there would be a large non-pregnant period considered. This is a major limitation and needs to be addressed.

Results:

- Lines 161-162: The authors need to describe why a number o newborns corresponds to 3.98 annual births. This calculation is unclear, but also perhaps unnecessary.
- The authors report that the propensity matching was successful. However, there was a significant difference in marital status, family size (which may be clinically non-significant). Thus, can the authors really report that this match was successful
- Table 2. Race may be correlated with items in Table 2 which are significantly different between the groups. It needs to be justified by employment, insurance status was not considered in the propensity matching and the utility of presenting this unadjusted data for further analysis.
- Lines 179-182 is confusing and unclear
- Line 195: It is unclear why the case n is not 3531 deliveries as opposed to 4056. This is significant 13% attraction that should perhaps be the population cohort to start with. The outcome is derived from a population of 3531, whereas the demographics and matching applies to a larger dataset. This needs to be justified.
- As Table 4 is the true outcomes from the study, I am unclear of the reason to include data based on mode of delivery or newborn hospitalization first. In fact, I'm not sure if delivery type is necessary at all. Table 3's inclusion is very confusing and out of place. Thus, lines 195-209 are not described in the methods or abstract as key results. Why they precede the main results is confusing. In addition, the data presented in the discussion is the new born hospitalization which could simply be mentioned and not within the context of the other findings.
- Line 213: It is expected that birth parents would have more annual office visits (associated with prenatal care) and inpatient stays (which is guaranteed to be at least 1). I'm not sure what this information adds.
- Line 237: the authors use the word "predictor" however there are no tests of prediction only association described
- The authors describe multiple risk factors for CHE: income level, insurance, race, marriage, non-employment. However, many of these are highly likely to be collinear or correlated. In that light instead of a typical multivariable logistic regression, the authors could consider a parsimonious model with the least number of factors included.

Discussion:

- Lines 253: Extended stay was not the only factors association with catastrophic spending. Why do the authors single this one out. All factors should be described here as they are in the abstract.
- The year of delivery depending on the time of delivery could involve a large portion of non-pregnancy related care (i.e. delivery in January) this should be addressed as this could affect insurance churn, expenditures, etc.
- The commentary on the results seems overstated (Lines 312-315)

Reviewer #2:

General: This is a retrospective cohort analysis of MEPS data to examine patterns and determinants of catastrophic health expenditures among birthing people in the US. This is a timely study of an important topic. Unfortunately, the analysis suffers from significant limitations.

Major comments:

1. The analytic approach seems to underrecognize the complex, documented relationships between payer type, income,

race/ethnicity and healthcare spending. I would call the study team to consider a more sophisticated approach to teasing out these complex relationships. The team might consider looking at interactions between race/ethnicity and payer type and income and payer type. Other work suggests that Black and Hispanic people with commercial insurance have HIGHER healthcare expenditures. Similar findings for commercially insured people with lower income. I am concerned that simply stating that Black race and Hispanic ethnicity LOWER the risk of CHE (as is currently done in the abstract) may be misrepresenting important inequities that might exist. These out to be explored in the analysis

2. The examination of temporal trends with ACA policies is underdeveloped. This analysis is conceptually quite distinct from the rest of the paper, and it really isn't explored well in the results - perhaps remove entirely. Alternatively, strengthen the analysis by looking at data points for each year within the pre/during/post ACA periods and conduct a more robust ITS analysis.

3. The Methods section lacks important details. Table 4 outcomes, for example, are never mentioned in the Methods. Temporal trends analysis is sparsely described.

4. The churn data are disjointed from the primary narrative about risk of CHE. Churn seems to be a separate issue. If the authors are interested in exploring how rates of CHE differ across groups exposed to different types of churn, they could do this analysis - but it is currently not included.

Abstract

Line 13-14 - this statement promises examination of changes associated with the ACA, but the abstract does not present any trends data.

"Among birth parents, low-income family was the strongest predictor of 30 catastrophic health expenditures (OR=0.03 for >400% federal poverty level vs. ≤138%)" - Consider "people first" language (e.g., "families living on lower incomes" instead of "low-income parents"). Also, consider making >400% FPL the ref group, so the OR shows higher likelihood among families with lower incomes, to better align with the key messaging.

"Extended newborn care" - recommended defining this briefly in the abstract.

"Medicaid coverage was more protective from 38 high out-of-pocket costs than private insurance, particularly among low-income families." This sentence is supported by the data in the abstract (which does not present data on interactions between income and payer).

The call for expansion of public coverage isn't well-aligned with the findings. The authors might consider calling for changes to insurance benefit design in commercial plans.

Intro

Line 45-46: changes in employment likely contribute to churn as well

Line 58-59: A more accurate literature summary is warranted. There are quite a few emerging studies on OOP spending for pregnancy and childbirth care and financial hardship among peripartum populations (including two studies using NHIS)
<https://pubmed.ncbi.nlm.nih.gov/34140392/>
<https://pubmed.ncbi.nlm.nih.gov/31905056/>
<https://pubmed.ncbi.nlm.nih.gov/34714338/>
<https://www.urban.org/research/publication/changes-new-mothers-health-care-access-and-affordability-under-affordable-care-act>

Methods

Line 107 - please provide rationale for the choice of the Elixhauser Comorbidity Index, vs. other indices (e.g., Bateman, or other indices specifically designed for assessing chronic condition status in obstetric populations)

Line 121 - was matching based on patient characteristics in the month of birth?

Line 124 - insurance coverage and employment status will directly affect OOP spending for healthcare and income - the numerator and denominator for calculating CHE. Employment status is perhaps less of a concern because matching already included income as a variable. Recommend considering at sensitivity analysis with propensity score matched controls including at least insurance coverage, if not also employment status.

Line 134- define income <250% FPL = poverty

Line 148 - please provide rationale for the temporal cut offs. The ACA included multiple policies (Medicaid expansion, marketplace creation, Essential Health Benefits provision for maternity care, Section 2713 on Preventive services) implemented at different times and potentially affecting this study's primary outcome.

Line 144: Did the authors examine for changes in population demographics across the study time period (demographic traits, health status, insurance status)?

Extended newborn stay - not defined in Methods. Also, why define as LOS longer than mother (vs. any stay involving

NICU care?)

Multiple study outcomes are never discussed in the Methods section. Utilization, for example - the authors provide no mention of visits, ED visits, etc in the methods, nor how these outcomes were defined in their dataset. Was ED utilization during admission for childbirth removed from the count of ED visits?

Results

Line 202-203 - this detail might belong in Methods. Also, please elaborate - I thought MEPS included all expenditures and OOP costs at the family level. Are you not able to see newborn OOP costs for ALL newborn hospitalizations? This should be very clearly defined in the Methods, so we know what we are looking at (i.e., are these data fully capturing total spending by a family and accurately calculating CHEs, or is there systematic underestimation, if newborn costs are undercaptured?).

The findings on churn are not well-integrated into the rest of the narrative. The authors could better develop this (perhaps in a separate paper) - presenting OOP spending and CHE risk based on phenotypes of coverage. Currently, it is hard to conceptually link these data to findings on OOP costs/CHE based on coverage status in birth month (I believe this is how coverage was defined - unclear in Methods).

Table 3 - why is the total OOP cost and the proportion with "expenses >10% income" LOWER in the cesarean group? This seems quite odd, when the visit expenditures is so much higher. Does this reflect demographic differences in people delivering by CS vs. vaginal birth (e.g. more Medicaid, lower OOP costs?). Consider reporting this entire table by payer type, since OOP costs and premiums in Medicaid are so much lower. These two populations are so vastly different, that reporting the "average" is really distorting the story.

Table 4: mean ED visits and inpatient stays are defined as counts ("n"), but the number reported appears to be a proportion? These outcomes should be discussed in Methods.

Table 5. This analysis should really account for payer type (consider stratification vs. interaction terms). The current analysis has failed to account for the known complex relationships between payer type, income, and race/ethnicity, and healthcare spending. Insurance coverage - consider setting Medicaid as the ref.

Figure 2 - this really should be reported by payer type. Uninsured will have no premium spending, but potentially higher OOP spending (OOP spending will be higher for services used, but total spending may not be that high if folks avoid care due to cost). Medicaid will have extremely low OOP spending, but any amount of spending accounts for higher proportion of income. Commercially insured folks will have very high OOP spending, but higher income, on the whole. Reporting these data stratified by income group is important for the commercially insured (20% of low-income people have commercial insurance - the "commercially insured" is quite diverse, so it is critical to understand heterogeneity of treatment effects among this population)

Discussion

Line 256-257 - I don't believe any interactions were explored, so not sure on what data the authors are basing this assertion.

Line 275-276: This is really overstating the findings from the analyses conducted. A more robust analytic approach is required for this kind of assertion.

Line 278-290: overly simplistic discussion of a complex issue. Overstating findings in 280-281, as the relationship between employment, insurance, and spending does not appear to have been interrogated in the analysis.

Line 278-290: overly simplistic discussion of a complex issue. Overstating findings in 280-281, as the relationship between employment, insurance, and spending does not appear to have been interrogated in the analysis.

Line 292-297: The authors could present a more sophisticated discussion of the body of literature on financial toxicity, including subjective hardship reported by patients. Important studies are overlooked (Witte et al.'s systematic review on measures of financial toxicity is one example)

Line 314-318: Consider implications for commercial insurance benefit design

STATISTICAL EDITOR COMMENTS:

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

lines 29, 237, 254: Should say association, not predictor.

line 29-30 and Table 4: This would be easier for the reader to follow if the referent were > 400% FPL, since then the lower

income groups would have higher odds of catastrophic expenses. In present format, seems inverted comparison.

Tables 1, 3, fig 1: Should omit the extrapolation to entire US population. The database was representative, but did not have the precision associated with a much larger sample. After all, ~ 4k cases were matched with ~ 8K controls, not anywhere near the 10 million in the entire US population.

Table 5: Should include a footnote citing the matching variables in the propensity analysis.

EDITOR COMMENTS:

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- * Include clinical trial registration numbers, PROSPERO registration numbers, or URLs at the end of the abstract (if applicable).
- * Name the IRB or Ethics Committee institution in the Methods section (if applicable).
- * Add any information about the specific location of the study (ie, city, state, or country), if necessary for context.

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Use "Black" and "White" (capitalized) when used to refer to racial categories. The nonspecific category of "Other" is a convenience grouping/label that should be avoided, unless it was a prespecified formal category in a database or research instrument. If you use "Other" in your study, please add detail to the manuscript to describe which patients were included in that category.

5. All studies should follow the principles set forth in the Helsinki Declaration of 1975, as revised in 2013, and manuscripts should be approved by the necessary authority before submission. Applicable original research studies should be reviewed by an institutional review board (IRB) or ethics committee. This review should be documented in your cover letter as well in the Methods section of the body text, with an explanation if the study was considered exempt. If your research is based on a publicly available data set approved by your IRB for exemption, please provide documentation of this in your cover letter by submitting the URL of the IRB website outlining the exempt data sets or a letter from a representative of the IRB. In addition, insert a sentence in the Methods section stating that the study was approved or exempt from approval. In all cases, the complete name of the IRB should be provided in the manuscript.

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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, RECORD, CHEERS, SQUIRE 2.0, or CHERRIES guidelines, as appropriate.

7. 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 data definitions at <https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-obstetrics-data-definitions> and the gynecology data definitions at <https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-gynecology-data-definitions>. If use of the reVITALize definitions is problematic, please discuss this in your point-by-point response to this letter.

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17. Figures

Figure 1: Please check or explain exclusion boxes in the middle. I do not get the same n values after removing exclusions.

Figures 1-2: Please upload as individual figure files on Editorial Manager.

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Jason D. Wright, MD
Editor-in-Chief

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