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: Oct 08, 2020
To: "Nathalie Auger" [redacted]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-20-2422

RE: Manuscript Number ONG-20-2422

Severe maternal morbidity and risk of mortality over three decades

Dear Dr. Auger:

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 14 days from the date of this letter. If we have not heard from you by Oct 22, 2020, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1: This is a retrospective cohort study of women with severe maternal morbidity at the time of pregnancy versus a cohort of women without severe maternal morbidity in pregnancy compared for mortality up to 29 years following the morbidity or pregnancy event. I appreciate the authors' work on this large database and thank the editors for the change to review this interesting manuscript.

Strengths
* This is an extremely large cohort of women with long-term follow up in a healthcare system that allows linking of health outcomes many years earlier to health outcomes years later.
* Proper analysis with censoring using Cox proportional hazard to compare Kaplan-Meier curves of time to exposure to time of death or time of study end.
* The authors accounted for socioeconomic status, which is important in measuring overall mortality.

Limitations
* The logic of this paper indicates that increased mortality up to 29 years after the last delivery is ATTRIBUTABLE to severe maternal morbidity, but I am not sure I agree with this. It would seem much more feasible that women with severe maternal morbidity have poor health, and therefore are at risk for both the maternal morbidity and the earlier mortality. The authors did correct for other health morbidities in this analysis, but not all of these can be accounted for. The paper acknowledges on Line 294 that causality cannot be proven with this, so that is appreciated in the Discussion.
* There is only in-hospital mortality and only those with valid health insurance numbers accounted for in this analysis, so the results cannot be externalized to all population mortality in general, including patients that died out of hospital or migrated out of the province. The authors acknowledge this in the Discussion.
* The authors repeatedly said associated with mortality up to 29 years later, but this is flawed. They don't have analysis year by year (up to the 29th year) that says elevated risks exists that far out. The last time period analyzed is 10-29 years, so the last censorship point before 29 years is 10 years, and the 29th year is affected by less women in the cohort.

Comments/suggestions for authors by section:

Introduction:
* Line 69-70: This sentence does not indicate that a control group is being employed; from reading this sentence you could believe this is a descriptive study that merely wants to examine the risk of mortality after severe pregnancy morbidity, but not compare it to non-morbid pregnancy women.
* Line 69-70: There should be a clearly stated hypothesis.

Methods
* Line 84-89: How were multiple pregnancies, some of which may have been morbid or non-morbid in the same woman, handled? If a woman had even one pregnancy affected by a severe morbidity, I am assuming she was in the cohort analyzed as exposed, but this should be very clear reading the paper. The Results' Lines 195-197 and Discussion's Lines 269-270 then confuse me, as the authors indicate here that perhaps they only counted the order of the pregnancy in analysis, but it is unclear in the Methods how this was handled.
* Line 121-122: Not all relevant comorbidities are accounted for in this analysis, such as hypertension or severe hypertension at baseline, renal diseases, or cardiovascular disease.
* Account for socioeconomic status in the modelling of the results with a composite score including neighborhood, which is excellent.
* The 29th year, or a period close to it, is not truly analyzed here, as the last time period is a broad one (10-29 years), so the authors cannot truly comment or conclude on "up to 29 years", just that follow up for some women lasted up to 29 years.

Discussion
* Line 265: This is a very good point that most suicide mortality occurs out of the hospital. As suicide is a common kind of mortality in women of reproductive age and early menopause, it is fortunate that the authors explored this in the Discussion.
* Line 285-290: This is a good summary of the strengths of the study. I would even add the contribution of correcting for some relevant confounders.
* Line 294-295: This should be better explored here. What other factors were NOT accounted for in this study that could be linked to both maternal severe morbidity and mortality. This should be more clearly delineated than this one vague sentence, as it is a major weakness in the logic of the paper.

Reviewer #2: Thank you for the opportunity to review this manuscript entitled "Severe maternal morbidity and risk of mortality over three decades." This study utilizes data from the Canadian Maintenance and Use of Data for the Study of Hospital Clientele registry, which includes 99% of deliveries in Quebec, to develop a longitudinal cohort of women to assess their hypothesis that there is an association between severe maternal morbidity during pregnancy and long-term mortality risk. This study asks an important clinical and public health question that is only possible to evaluate given the Canadian health care structure and their longitudinal database tracking. The findings are quite interesting and novel, but I have some comments that should be addressed:

1. Title: "The risk of mortality over three decades" is a bit misleading because while the study time period did include 3 decades, not all patients were followed for three decades. Only the patients who delivered in 1989 truly had 29 years of follow-up; those who delivered after that had less and less follow-up time. I would suggest the authors change the wording of this.

2. Abstract:
-Lines 34-35: In the Methods section, the authors only list the severe morbidity variables "cerebrovascular accidents, acute renal failure, and severe preeclampsia." I imagine that this was due to the limited word count and the multiple morbidity exposure variables that they had studied, and therefore they only listed the variables that were found to be significant. However, many readers often only read the abstract and not the full-length of the manuscript. Only listing these three variables in the methods section may confuse readers that these were the only variables assessed. I would recommend that the authors describe the multiple morbidity variables more generally in the abstract in the Methods section.

3. Methods:
-Overall: It would be helpful if the authors could include a line or two about the health care structure in Canada (specifically Quebec) and how well documented health care information is tracked. For readers who are mostly not familiar with the Canadian system, it would help put things in context since the registry was limited to those who had health insurance. Additionally, it would be helpful to add a line about whether in-hospital deaths are common or whether more people in Quebec are likely to die at home. This would provide context for the readers since this registry was limited to in-hospital deaths only.
-Lines 91-99: It may be helpful to list the ICD-10 codes for the morbidity exposure variables in Table S1, like the authors did for the cause of death ICD-10 codes. It would give more transparency as to how the exposure variables were grouped together and how diagnoses were defined.
-Lines 121-122: The authors chose obesity, type 1 or 2 diabetes, alcohol, tobacco or substance use as preexisting comorbidity covariates. However, I would be very interested to see other important preexisting comorbidities such as chronic hypertension, cardiac disease, hematologic conditions such as sickle cell disease, and neurologic conditions that could increase risk for future mortality. If these other conditions are available in the registry, I would encourage looking at these other conditions. If these are not available in the registry, it should be acknowledged in the manuscript and explain why they weren't considered.

4. Discussion:
-If other preexisting comorbidities such as hypertension and cardiac disease can't be added as covariates, I would definitely list that as a limitation.

5. Tables:
-Table 1: While it is understandable that p-values were not provided given the very large sample size, I still think it would be interesting to list the p-values for Table 1 baseline data.
-Table S1: as above in Methods section
-In the Methods, it may be helpful to describe what the definition of "obstetric" cause of death was with the ICD-10 code? Was this a general category for any death that occurred <42 days from delivery or are there specific causes of death that would meet the definition? The HR was 249 (but was this because these were deaths directly related to severe maternal morbidity?)
-May be helpful to add a figure flowsheet of numbers of patients being excluded based on criteria.

Reviewer #3:

1. What is the process for reporting deaths in Quebec? Must all deaths be pronounced in a hospital or can they be pronounced out of hospital as well? This study was limited to in-hospital deaths so there is likely underreporting of deaths if out of hospital are not included.

2. The study included only patients with valid health insurance numbers. Can the authors estimate the percentage of patients excluded for no insurance?

3. Can the authors also estimate the movement of their patient population out of Quebec during the study period? Most likely this was the same for women with and without severe morbidity but is there any data to give the reader an idea of this potential impact?

4. What was the definition of a surgical complication?

5. The authors state that some causes of death were not coded until 2006 but suicide was included from the start. In table 4, the second most common cause of death in the no morbidity group was suicide but there very few in the severe morbidity group. This seems odd. It is possible that limiting deaths to in-hospital missed many deaths by suicide, but more information on this seems needed.

6. Also, homicide and accidents are very common causes of death but not mentioned in the outcomes. Can the authors address this?

7. How was socioeconomic status determined?

8. The text states there were differences in the populations of women with and without morbidity for age, parity, socioeconomic issues and preexisting comorbidity (line 153 and table 1.) There were no statistics addressing these differences and multiple gestations also seemed dramatically different. Please address.

9. For line 161, "after adjusting for confounders," are these the same as noted above in Question 8?

10. How were the data interpreted for women that had multiple severe morbidities? How do the numbers reflect, say a woman that had a severe postpartum hemorrhage from a ruptured uterus that ended up intubated in the ICU? Multiple morbidities all in one woman. How was this addressed in tables 2 and 3?

11. It is very hard to address the nature of the deaths in this study and draw conclusions about causality. Clearly the authors identified associations, but it may be that women at risk for death in the years after a pregnancy would also be at increased risk for death, had they not been pregnant, and the pregnancy was complicated due some unknown underlying predisposition to illness. This is only briefly addressed in the discussion.

STATISTICAL EDITOR COMMENTS:

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

Table 1: Need to statistically compare the two cohorts. Many of the baseline characteristics are statistically different.

Table 2: For some of these subsets, the number of person years is < 100,000. Therefore estimates of mortality rates per 100,000 person years must be rounded to more practical numbers. For example, one cannot estimate mortality rate as 1008.0 when there were only ~ 10,00 person years in the denominator. Further, for some of the subsets with few deaths, ie, < 60, one cannot adjusted for 6 variables in the aHR models. Likely those aHRs are over fitted.

Table 3: Should provide (as on line material, the numerators and denominators for each of the time periods and subsets of morbidity. The issues of potential over fitting are amplified by counts that were too small for many of the subsets.

Table 4: The issue of over fitting the aHR model applies to each of these estimates, particularly since the deaths are allocated among the various follow-up times.

Table 5: Need to include the median follow-up times for each of these row entries. Again, for the entry with n = 26 deaths, adjustment for 5 variables likely results in an over fitted model.

General: More of the women with SMM had preexisting comorbidities (table 1, 8.7 vs 4.9%). If those women were omitted from both the SMM and no SMM groups, were the subsequent mortality rates still different? In other words, to what extent could the increased mortality be associated with preexisting comorbidities, rather than the SMM event itself? Similarly, if analysis removed those with socioeconomic deprivation, what were the respective mortality risks of SMM vs no SMM?

EDITOR 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:
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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. Please submit a completed STROBE checklist.

Responsible reporting of research studies, which includes a complete, transparent, accurate and timely account of what was done and what was found during a research study, is an integral part of good research and publication practice and not an optional extra. Obstetrics & Gynecology supports initiatives aimed at improving the reporting of health research, and we ask authors to follow specific guidelines for reporting randomized controlled trials (ie, CONSORT), observational studies (ie, STROBE), observational studies using ICD-10 data (ie, RECORD), 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, RECORD, CHEERS, SQUIRE 2.0, or CHERRIES guidelines, as appropriate.

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

5. Because of space limitations, it is important that your revised manuscript adhere to the following length restrictions by manuscript type: Original Research reports should not exceed 22 typed, double-spaced pages (5,500 words). Stated page limits include all numbered pages in a manuscript (i.e., title page, précis, abstract, text, references, tables, boxes, figure legends, and print appendixes) but exclude references.

6. Specific rules govern the use of acknowledgments in the journal. Please note the following guidelines:

* All financial support of the study must be acknowledged.

* 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).

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

In addition, the abstract length should follow journal guidelines. The word limit for Original Research articles is 300 words. Please provide a word count.

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

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

10. 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%").

11. 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.

12. Please review examples of our current reference style at http://ong.editorialmanager.com (click on the Home button in the Menu bar and then "Reference Formatting Instructions" document under "Files and Resources). Include the digital object identifier (DOI) with any journal article references and an accessed date with website references. Unpublished data, in-press items, personal communications, letters to the editor, theses, package inserts, submissions, meeting presentations, and abstracts may be included in the text but not in the reference list.

In addition, 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 at the Clinical Guidance page at https://www.acog.org/clinical (click on "Clinical Guidance" at the top).

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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. Do not omit your responses to the Editorial Office or Editors' comments.

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 14 days from the date of this letter. If we have not heard from you by Oct 22, 2020, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

Dwight J. Rouse, MD, MSPH

2019 IMPACT FACTOR: 5.524
2019 IMPACT FACTOR RANKING: 6th out of 82 ob/gyn journals

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Dwight J. Rouse, MD, MSPH
Obstetrics & Gynecology

22 October 2020

Dear Dr. Rouse,

Thank you for inviting us to resubmit our manuscript “Severe maternal morbidity and risk of mortality beyond the postpartum period”. We have revised the article and incorporated the recommendations of the Reviewers and Editors. Please find below a point-by-point response, and attached the manuscript with changes tracked. We confirm that we have read the Instructions for Authors. Each author contributed to the revision and has approved the final version.

We hope you will find the revised manuscript satisfactory and remain available for additional modifications if requested.

Thank you for considering our work for publication in *Obstetrics & Gynecology*. We look forward to hearing from you.

Kind regards,

Nathalie Auger MD

RESPONSE TO REVIEWS

Reviewer #1: This is a retrospective cohort study of women with severe maternal morbidity at the time of pregnancy versus a cohort of women without severe maternal morbidity in pregnancy compared for mortality up to 29 years following the morbidity or pregnancy event. I appreciate the authors' work on this large database and thank the editors for the change to review this interesting manuscript.

Strengths

*** This is an extremely large cohort of women with long-term follow up in a healthcare system that allows linking of health outcomes many years earlier to health outcomes years later.**

*** Proper analysis with censoring using Cox proportional hazard to compare Kaplan-Meier curves of time to exposure to time of death or time of study end.**

*** The authors accounted for socioeconomic status, which is important in measuring overall mortality.**

Limitations

R1.1. The logic of this paper indicates that increased mortality up to 29 years after the last delivery is ATTRIBUTABLE to severe maternal morbidity, but I am not sure I agree with this. It would seem much more feasible that women with severe maternal morbidity have poor health, and therefore are at risk for both the maternal morbidity and the earlier mortality. The authors did correct for other health morbidities in this analysis, but not all of these can be accounted for. The paper acknowledges on Line 294 that causality cannot be proven with this, so that is appreciated in the Discussion.

Response: We agree with the Reviewer and revised the text to ensure that we do not directly attribute the risk of mortality to severe maternal morbidity. In the Discussion, we added that "*We cannot confirm that severe maternal morbidity was the cause of mortality. Women with pregnancy complications may already be predisposed to chronic conditions that are either revealed during pregnancy or manifest at a later date. Further, a failure to completely recover after severe maternal morbidity may later lead to chronic disorders*" (page 15, line 24; page 16, lines 1-4). We also reinforced the message that "*severe maternal morbidity may help identify women at risk of premature mortality*" (page 16, lines 4-5). Closer follow-up of women with severe maternal morbidity may help prevent mortality.

R1.2. There is only in-hospital mortality and only those with valid health insurance numbers accounted for in this analysis, so the results cannot be externalized to all population mortality in general, including patients that died out of hospital or migrated out of the province. The authors acknowledge this in the Discussion.

Response: We clarified in the Methods that "*We could not account for deaths out of hospital*" (page 7, line 17), and added in the limitations that "*The results do not generalize to patients who died out of hospital or migrated out of the province. However, out-of-province migration is not common in Quebec.*[34]" (page 16, lines 5-7). Out-of-province migration is not a major phenomenon as most of the population is French and tends to remain in the province (Girard 2010).

Girard C. La migration interprovinciale au Québec, 2000-2009. Institut de la Statistique du Québec; 2010.

R1.3. The authors repeatedly said associated with mortality up to 29 years later, but this is flawed. They don't have analysis year by year (up to the 29th year) that says elevated risks exists that far out. The last time period analyzed is 10-29 years, so the last censorship point before 29 years is 10 years, and the 29th year is affected by less women in the cohort.

Response: We revised the text to avoid suggesting that severe maternal mortality is associated with mortality up to 29 years later. Instead, we wrote that severe maternal morbidity was associated with the long-term risk of mortality, mortality several years after delivery, or mortality after the postpartum period. The "*time scale was the number of days between the last delivery and death or the study end*" (page 8, line 24; page 9, line 1), thus censoring occurred throughout the study. For example, a woman with 25 years of follow-up was censored at 25 years, rather than 10 years. It is nevertheless true that fewer women contributed to the mortality estimate at later time points.

Comments/suggestions for authors by section:

Introduction:
R1.4. Line 69-70: This sentence does not indicate that a control group is being employed; from reading this sentence you could believe this is a descriptive study that merely wants to examine the risk of mortality after severe pregnancy morbidity, but not compare it to non-morbid pregnancy women.

Response: We added the comparison group as follows: "*We examined the long-term risk of in-hospital mortality after severe maternal morbidity, compared with no morbidity*" (page 5, lines 20-21).

R1.5. Line 69-70: There should be a clearly stated hypothesis.

Response: We added that "*We hypothesized that severe maternal morbidity was associated with a greater long-term risk of mortality relative to no morbidity*" (page 5, lines 21-23).

Methods
R1.6. Line 84-89: How were multiple pregnancies, some of which may have been morbid or non-morbid in the same woman, handled? If a woman had even one pregnancy affected by a severe morbidity, I am assuming she was in the cohort analyzed as exposed, but this should be very clear reading the paper. The Results' Lines 195-197 and Discussion's Lines 269-270 then confuse me, as the authors indicate here that perhaps they only counted the order of the pregnancy in analysis, but it is unclear in the Methods how this was handled.

Response: We clarified that "*The main exposure measure was severe maternal morbidity in the last pregnancy, coded using diagnostic and procedure codes in the International Classification of Diseases (ICD), Canadian Classification of Diagnostic, Therapeutic and Surgical Procedures, and Canadian Classification of Health Interventions. As a secondary exposure measure, we included severe maternal morbidity in previous pregnancies*" (page 6, lines 14-18) and that "*In secondary analyses, we assessed how severe maternal morbidity in previous pregnancies was associated with the risk of mortality. To do so, we separated women who were multiparous (severe maternal morbidity in last pregnancy only, severe maternal morbidity in previous and last pregnancies, severe maternal morbidity in previous pregnancies only, no morbidity) from*

women who were nulliparous (severe maternal morbidity, no morbidity)" (page 9, lines 9-13).

R1.7. Line 121-122: Not all relevant comorbidities are accounted for in this analysis, such as hypertension or severe hypertension at baseline, renal diseases, or cardiovascular disease.

Response: We updated the comorbidity variable to include hypertension and all disorders in the Charlson comorbidity index (Charlson 1987; Quan 2005). Comorbidity now includes women with a previous history of "*myocardial infarction, congestive heart failure, peripheral vascular disease, cerebrovascular disease, dementia, chronic pulmonary disease, rheumatic disease, peptic ulcer disease, liver disease, hemiplegia or paraplegia, renal disease, malignancies other than skin cancer, metastatic solid tumor, HIV disease, hypertension, obesity, type 1 or 2 diabetes, alcohol, tobacco or substance use*" (page 8, lines 9-13). We added two supporting references (Charlson 1987; Quan 2005), reran all analyses, and updated the results throughout the manuscript.

Charlson ME, Pompei P, Ales KL, MacKenzie CR. A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. J Chronic Dis. 1987;40(5):373–83.

Quan H, Sundararajan V, Halfon P, et al. Coding algorithms for defining comorbidities in ICD-9-CM and ICD-10 administrative data. Med Care 2005;43(11):1130–9.

R1.8. Account for socioeconomic status in the modelling of the results with a composite score including neighborhood, which is excellent.

Response: Thank you.

R1.9. The 29th year, or a period close to it, is not truly analyzed here, as the last time period is a broad one (10-29 years), so the authors cannot truly comment or conclude on "up to 29 years", just that follow up for some women lasted up to 29 years.

Response: We revised the text to indicate that severe maternal morbidity was associated with the long-term risk of mortality, mortality several years after delivery, and mortality in the postpartum period. Please see R1.3 for related material.

Discussion

R1.10. Line 265: This is a very good point that most suicide mortality occurs out of the hospital. As suicide is a common kind of mortality in women of reproductive age and early menopause, it is fortunate that the authors explored this in the Discussion.

Response: Thank you.

R1.11. Line 285-290: This is a good summary of the strengths of the study. I would even add the contribution of correcting for some relevant confounders.

Response: We added this point as follows: "*We analyzed a large cohort containing data on several relevant confounders and the majority (>99%) of deliveries in Quebec*" (page 15, lines 14-15).

R1.12. Line 294-295: This should be better explored here. What other factors were NOT accounted for in this study that could be linked to both maternal severe morbidity and mortality. This should be more clearly delineated than this one vague sentence, as it is a major weakness in the logic of the paper.

Response: We clarified the text as follows: "*The methods in our study were not causative analyses. We cannot confirm that severe maternal morbidity was the cause of mortality. Women with pregnancy complications may already be predisposed to chronic conditions that are either revealed during pregnancy or manifest at a later date. Further, a failure to completely recover after severe maternal morbidity may later lead to chronic disorders. Nonetheless, the findings suggest that severe maternal morbidity may help identify women at risk of premature mortality*" (page 15, line 24; page 16, lines 1-5).

Reviewer #2: Thank you for the opportunity to review this manuscript entitled "Severe maternal morbidity and risk of mortality over three decades." This study utilizes data from the Canadian Maintenance and Use of Data for the Study of Hospital Clientele registry, which includes 99% of deliveries in Quebec, to develop a longitudinal cohort of women to assess their hypothesis that there is an association between severe maternal morbidity during pregnancy and long-term mortality risk. This study asks an important clinical and public health question that is only possible to evaluate given the Canadian health care structure and their longitudinal database tracking. The findings are quite interesting and novel, but I have some comments that should be addressed:

R2.1. Title: "The risk of mortality over three decades" is a bit misleading because while the study time period did include 3 decades, not all patients were followed for three decades. Only the patients who delivered in 1989 truly had 29 years of follow-up; those who delivered after that had less and less follow-up time. I would suggest the authors change the wording of this.

Response: We changed the title to "*Severe maternal morbidity and risk of mortality beyond the postpartum period*" (page 1, line 1).

R2.2. Abstract:
-Lines 34-35: In the Methods section, the authors only list the severe morbidity variables "cerebrovascular accidents, acute renal failure, and severe preeclampsia." I imagine that this was due to the limited word count and the multiple morbidity exposure variables that they had studied, and therefore they only listed the variables that were found to be significant. However, many readers often only read the

abstract and not the full-length of the manuscript. Only listing these three variables in the methods section may confuse readers that these were the only variables assessed. I would recommend that the authors describe the multiple morbidity variables more generally in the abstract in the Methods section.

Response: We confirm that we listed all severe morbidities in the Methods as follows: "*Components of severe maternal morbidity included severe preeclampsia or eclampsia, severe hemorrhage (peripartum hemorrhage or placental abruption with a coagulation defect, and transfusion for intrapartum hemorrhage, postpartum hemorrhage, placenta previa, or complications of curettage), cardiac complications (cardiomyopathy, cardiac arrest and resuscitation, myocardial infarction, pulmonary edema and heart failure, complications of anesthesia), cerebrovascular accidents, acute renal failure or dialysis, embolism, shock, disseminated intravascular coagulation, sepsis, uterine rupture, hysterectomy, surgical complications (Appendix 1), assisted ventilation, intensive care unit admission, and other serious disorders (acute fatty liver, hepatic failure, cerebral edema or coma, and similar conditions)*" (page 6, lines 23-24; page 7, lines 1-7). In the Abstract, we clarified that "*Severe maternal morbidity included conditions such as cerebrovascular accidents, acute renal failure, severe preeclampsia, and other life-threatening complications*" (page 4, lines 6-8).

Methods:

R2.3a. -Overall: It would be helpful if the authors could include a line or two about the health care structure in Canada (specifically Quebec) and how well documented health care information is tracked. For readers who are mostly not familiar with the Canadian system, it would help put things in context since the registry was limited to those who had health insurance. Additionally, it would be helpful to add a line about whether in-hospital deaths are common or whether more people in Quebec are likely to die at home. This would provide context for the readers since this registry was limited to in-hospital deaths only.

Response: We added that "*Quebec provides universal health coverage for the population, except for temporary visitors, tourists, and undocumented residents*" (page 6, lines 8-9) and that "*The majority of deaths are recorded in hospital data, although deaths due to intentional or unintentional injuries, including homicides and accidents, may be missed*" (page 7, lines 17-19).

R2.3b. -Lines 91-99: It may be helpful to list the ICD-10 codes for the morbidity exposure variables in Table S1, like the authors did for the cause of death ICD-10 codes. It would give more transparency as to how the exposure variables were grouped together and how diagnoses were defined.

Response: We added the codes to Appendix 1.

R2.3c. -Lines 121-122: The authors chose obesity, type 1 or 2 diabetes, alcohol, tobacco or substance use as preexisting comorbidity covariates. However, I would be very interested to see other important preexisting comorbidities such as chronic

hypertension, cardiac disease, hematologic conditions such as sickle cell disease, and neurologic conditions that could increase risk for future mortality. If these other conditions are available in the registry, I would encourage looking at these other conditions. If these are not available in the registry, it should be acknowledged in the manuscript and explain why they weren't considered.

Response: We updated the comorbidity variable to include hypertension and all disorders in the Charlson comorbidity index (Charlson 1987; Quan 2005). The Charlson comorbidity index is a validated predictor of mortality in adults. Sickle cell disease is not included in the Charlson index, thus we opted to retain sickle cell crisis in the definition of severe maternal morbidity as recommended by the Canadian Perinatal Surveillance System. Please refer to R1.7 for more detail on the Charlson comorbidity index.

R2.4. Discussion:
-If other preexisting comorbidities such as hypertension and cardiac disease can't be added as covariates, I would definitely list that as a limitation.

Response: We added these preexisting comorbidities and reran all analyses. Please refer to R1.7 and R2.3c for changes in the manuscript.

Tables:
R2.5a. -Table 1: While it is understandable that p-values were not provided given the very large sample size, I still think it would be interesting to list the p-values for Table 1 baseline data.

Response: We added p-values to Table 1. The Reviewer is correct that p-values were low because of the large sample size.

R2.5b. -Table S1: as above in Methods section

Response: We added codes for severe maternal morbidity in Appendix 1.

R2.5c. -In the Methods, it may be helpful to describe what the definition of "obstetric" cause of death was with the ICD-10 code? Was this a general category for any death that occurred <42 days from delivery or are there specific causes of death that would meet the definition? The HR was 249 (but was this because these were deaths directly related to severe maternal morbidity?) -May be helpful to add a figure flowsheet of numbers of patients being excluded based on criteria.

Response: We clarified that "*Obstetric deaths were deaths within 42 days of delivery with obstetric causes in the ICD*" (page 8, lines 1-2). As the only exclusion criterion was a missing health insurance number, we did not feel that adding a figure flowsheet would be very informative. In the Methods, we added that "*We excluded 22,573 (1.8%) deliveries with missing health insurance numbers*" (page 6, lines 9-10).

Reviewer #3:

R3.1. What is the process for reporting deaths in Quebec? Must all deaths be pronounced in a hospital or can they be pronounced out of hospital as well? This study was limited to in-hospital deaths so there is likely underreporting of deaths if out of hospital are not included.

Response: In the Methods, we added that "*The majority of deaths are recorded in hospital data, although deaths due to intentional or unintentional injuries, including homicides and accidents, may be missed*" (page 7, lines 17-19). In the limitations, we added that "*We were limited to in-hospital mortality which may exclude some deaths due to suicide, homicide, or accidents*" (page 15, lines 22-23).

R3.2. The study included only patients with valid health insurance numbers. Can the authors estimate the percentage of patients excluded for no insurance?

Response: We added in the Methods that "*We excluded 22,573 (1.8%) deliveries with missing health insurance numbers*" (page 6, lines 9-10).

R3.3. Can the authors also estimate the movement of their patient population out of Quebec during the study period? Most likely this was the same for women with and without severe morbidity but is there any data to give the reader an idea of this potential impact?

Response: Most Quebecers are French and do not migrate due to discomfort with English (this is a cultural phenomenon due to the historical context of Quebec). Out-of-province migration is not frequent. We wrote in the limitations that "*The results do not generalize to patients who died out of hospital or migrated out of the province. However, out-of-province migration is not common in Quebec.*[34]" (page 16, lines 5-7).

R3.4. What was the definition of a surgical complication?

Response: We added that surgical complications included "*Cardiac arrest, cardiac failure, cerebral anoxia, renal failure or residual ovary syndrome following obstetric surgery or procedures, evacuation of incisional hematoma with red cell transfusion, repair of small or large intestine, and postpartum surgical repair of obstetric laceration of bladder and urethra, laceration of corpus uteri, or wound dehiscence following cesarean section or hysterectomy*" (page 2, lines 31-35) in the footnote of Appendix 1.

R3.5. The authors state that some causes of death were not coded until 2006 but suicide was included from the start. In table 4, the second most common cause of death in the no morbidity group was suicide but there very few in the severe morbidity group. This seems odd. It is possible that limiting deaths to in-hospital missed many deaths by suicide, but more information on this seems needed.

Response: The Reviewer is correct that some suicide deaths may be missed, as indicated in the Discussion: "*not all suicide deaths may be counted in hospital statistics*" (page 14, lines 19-20). In the Limitations, we added that "*We were limited to in-hospital mortality which may exclude some deaths due to suicide, homicide, or accidents*" (page 15, lines 22-23).

R3.6. Also, homicide and accidents are very common causes of death but not mentioned in the outcomes. Can the authors address this?

Response: Homicide and accidents were included in the category of injuries. In the Methods, we clarified that injuries included "*homicides and accidents*" (page 7, line 19). Homicide is extremely rare in Quebec (https://www150.statcan.gc.ca/t1/tbl1/en/tv.action?pid=3510007101). Nonetheless, in the Limitations, we added that "*We were limited to in-hospital mortality which may exclude some deaths due to suicide, homicide, or accidents*" (page 15, lines 22-23).

R3.7. How was socioeconomic status determined?

Response: We clarified that "*Socioeconomic status was measured using a composite score from a principal component analysis of Census data on mean neighbourhood income, education level, and employment in Quebec*" (page 8, lines 15-17)

R3.8. The text states there were differences in the populations of women with and without morbidity for age, parity, socioeconomic issues and preexisting comorbidity (line 153 and table 1.) There were no statistics addressing these differences and multiple gestations also seemed dramatically different. Please address.

Response: We added p-values in Table 1 and clarified the text as follows: "*Compared with no morbidity, women with severe maternal morbidity were more likely to be ≥35 years (23.5% vs 20.0%), primiparous (54.9% vs 43.4%), socioeconomically deprived (22.5% vs 18.8%), and have multiple births (5.4% vs 1.8%) or preexisting comorbidity (17.0% vs 9.7%)*" (page 10, lines 1-3).

R3.9. For line 161, "after adjusting for confounders," are these the same as noted above in Question 8?

Response: We confirm that we adjusted for the confounders in R3.8. In the Methods, we wrote that "*We adjusted models for age, parity, multiple birth, preexisting comorbidity, socioeconomic deprivation, and time period*" (page 8, lines 22-23). We also provide the list of confounders in the footnotes of the tables.

R3.10. How were the data interpreted for women that had multiple severe morbidities? How do the numbers reflect, say a woman that had a severe postpartum hemorrhage from a ruptured uterus that ended up intubated in the ICU? Multiple morbidities all in one woman. How was this addressed in tables 2 and 3?

Response: We clarified that morbidities were "*not mutually exclusive*" (page 7, line 9). Women with more than one morbidity were included in each exposure category. In this study, we focused on any severe maternal morbidity and the timing/cause of mortality.

R3.11. It is very hard to address the nature of the deaths in this study and draw conclusions about causality. Clearly the authors identified associations, but it may be that women at risk for death in the years after a pregnancy would also be at increased risk for death, had they not been pregnant, and the pregnancy was complicated due some unknown underlying predisposition to illness. This is only briefly addressed in the discussion.

Response: We agree with the Reviewer and clarified that "*The methods in our study were not causative analyses. We cannot confirm that severe maternal morbidity was the cause of mortality. Women with pregnancy complications may already be predisposed to chronic conditions that are either revealed during pregnancy or manifest at a later date. Further, a failure to completely recover after severe maternal morbidity may later lead to chronic disorders. Nonetheless, the findings suggest that severe maternal morbidity may help identify women at risk of premature mortality*" (page 15, line 24; page 16, lines 1-5).

STATISTICAL EDITOR COMMENTS:

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

E1.1. Table 1: Need to statistically compare the two cohorts. Many of the baseline characteristics are statistically different.

Response: We added p-values to Table 1, and wrote in the results that "*Compared with no morbidity, women with severe maternal morbidity were more likely to be ≥35 years (23.5% vs 20.0%), primiparous (54.9% vs 43.4%), socioeconomically deprived (22.5% vs 18.8%), and have multiple births (5.4% vs 1.8%) or preexisting comorbidity (17.0% vs 9.7%)*" (page 10, lines 1-3).

E1.2. Table 2: For some of these subsets, the number of person years is < 100,000. Therefore estimates of mortality rates per 100,000 person years must be rounded to more practical numbers. For example, one cannot estimate mortality rate as 1008.0 when there were only ~ 10,00 person years in the denominator. Further, for some of the subsets with few deaths, ie, < 60, one cannot adjusted for 6 variables in the aHR models. Likely those aHRs are over fitted.

Response: We now provide mortality rates per 1,000 person-years. To address overfitting, we reran the Cox regression adjusting "*only for age and preexisting comorbidity*" (page 8, line 24), and added the results to Table 2. The partially adjusted models yielded similar findings.

E1.3. Table 3: Should provide (as on line material, the numerators and denominators for each of the time periods and subsets of morbidity. The issues of potential over fitting are amplified by counts that were too small for many of the subsets.

Response: We added numerators and denominators for the population at risk in Appendix 2, and cited Appendix 2 in the footnote of Table 3. We estimated HRs adjusted for age and preexisting comorbidities only, and placed the results in Appendix 3 with a footnote in Table 3.

E1.4. Table 4: The issue of over fitting the aHR model applies to each of these estimates, particularly since the deaths are allocated among the various follow-up times.

Response: We estimated HRs adjusted for age and preexisting comorbidities only, and placed the results in Appendix 4 with a footnote in Table 4.

E1.5. Table 5: Need to include the median follow-up times for each of these row entries. Again, for the entry with n = 26 deaths, adjustment for 5 variables likely results in an over fitted model.

Response: We added the median follow-up times for each row in Table 5. We estimated HRs adjusted for age and preexisting comorbidities only, and placed the results in Appendix 5 with a footnote in Table 5.

E1.6. General: More of the women with SMM had preexisting comorbidities (table 1, 8.7 vs 4.9%). If those women were omitted from both the SMM and no SMM groups, were the subsequent mortality rates still different? In other words, to what extent could the increased mortality be associated with preexisting comorbidities, rather than the SMM event itself? Similarly, if analysis removed those with socioeconomic deprivation, what were the respective mortality risks of SMM vs no SMM?

Response: We performed additional sensitivity analyses by excluding women with preexisting comorbidities and socioeconomic deprivation (Appendix 6). We added in the Results that "*Excluding women with preexisting comorbidities or socioeconomic deprivation, and women who had their first delivery after 2010, did not substantially affect the results*" (page 12, lines 2-4).

EDITOR COMMENTS:

E2.1. 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.

Response: OPT-IN

E2.2. Obstetrics & Gynecology uses an "electronic Copyright Transfer Agreement" (eCTA). 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.

Response: We verified that the coauthors provided correct disclosures on the title page.

E2.3. Please submit a completed STROBE checklist.

Response: We uploaded a STROBE checklist.

E2.4. Standard obstetric and gynecology data definitions have been developed through the reVITALize initiative, which was convened by the American College of Obstetricians and Gynecologists and the members of the Women's Health Registry Alliance. Obstetrics & Gynecology has adopted the use of the reVITALize definitions. Please access the obstetric data definitions at HYPERLINK. If use of the reVITALize definitions is problematic, please discuss this in your point-by-point response to this letter.

Response: We confirm that the definitions in our manuscript match with the Obstetric Data definitions.

E2.5. Because of space limitations, it is important that your revised manuscript adhere to the following length restrictions by manuscript type: Original Research reports should not exceed 22 typed, double-spaced pages (5,500 words). Stated page limits include all numbered pages in a manuscript (i.e., title page, précis, abstract, text, references, tables, boxes, figure legends, and print appendixes) but exclude references.

Response: We confirm that we followed manuscript guidelines.

E2.6. Specific rules govern the use of acknowledgments in the journal. Please note the following guidelines:

*** All financial support of the study must be acknowledged.**
*** 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).**

Response: We confirm that we followed manuscript guidelines.

E2.7. The most common deficiency in revised manuscripts involves the abstract. Be sure there are no inconsistencies between the Abstract and the manuscript, and that the Abstract has a clear conclusion statement based on the results found in the paper. Make sure that the abstract does not contain information that does not appear in the body text. If you submit a revision, please check the abstract carefully.

In addition, the abstract length should follow journal guidelines. The word limit for Original Research articles is 300 words. Please provide a word count.

Response: We confirm that the abstract matches the main text.

E2.8. Only standard abbreviations and acronyms are allowed. A selected list is available online at HYPERLINK. 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.

Response: We confirm that we followed manuscript guidelines.

E2.9. The journal does not use the virgule symbol (/) in sentences with words. Please rephrase your text to avoid using "and/or," or similar constructions throughout the text. You may retain this symbol if you are using it to express data or a measurement.

Response: We confirm that we followed manuscript guidelines.

E2.10. 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%").

Response: We confirm that we followed manuscript guidelines.

E2.11. Please review the journal's Table Checklist to make sure that your tables conform to journal style. The Table Checklist is available online here: HYPERLINK.

Response: We confirm that we followed manuscript guidelines.

E2.12. Please review examples of our current reference style at HYPERLINK (click on the Home button in the Menu bar and then "Reference Formatting Instructions" document under "Files and Resources). Include the digital object identifier (DOI) with any journal article references and an accessed date with website references. Unpublished data, in-press items, personal communications, letters to the editor, theses, package inserts, submissions, meeting presentations, and abstracts may be included in the text but not in the reference list.

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Opinions and Practice Bulletins) may be found at the Clinical Guidance page at HYPERLINK (click on "Clinical Guidance" at the top).

Response: We confirm that we followed manuscript guidelines.

E2.13. 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 HYPERLINK.

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.

Response: Thank you.