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.*

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: Jun 12, 2020
To: "Jessica M Page" [redacted]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-20-1375

RE: Manuscript Number ONG-20-1375

Characteristics of stillbirths associated with diabetes in a diverse United States cohort

Dear Dr. Page:

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).

Due to the COVID-19 pandemic, your paper will be maintained in active status for 30 days from the date of this letter. If we have not heard from you by Jul 12, 2020, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1:

The authors report on potential causes of fetal death from a cohort of women who had singleton stillbirths, and compared findings between those who had diabetes and those who did not.

Line 108: The authors mention placental vascular pathology as a potential cause of stillbirths. On lines 142-3 they mention that the SCRN protocol (from which their data were derived) included a placental pathology examination and a postmortem examination. Do the authors have any data on placental appearance, weight, or microscopy that they can add? Can they list the anomalies found? Can they compare all of the above within their groups (diabetic and non-diabetes related stillbirths)?

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Lines 164-165: This study is a comparison of independent variables potentially related to stillbirth in women with and without diabetes, all of whom had a fetal demise. It would be of great value to know how women in each of these groups compared in the prevalence of these variables with contemporaneous controls who did not have stillbirths and both did and did not have diabetes (e.g. from among the 1871 livebirths). Do the authors have data at their disposal to make these comparisons?

Lines 164-170: To better understand the data in Tables 1-3, could the authors present a brief discussion of how weighting was performed?

Lines 201-5: It would be useful to know the prevalence of each of these complications among the patients in each group. Would the authors prepare another table presenting these data?

Line 254: It would seem more accurate to state that most stillbirths in women with GDM were "associated with" or "ascribed to" causes other than diabetes or medical complications.

Table 3: It would be of interest to add a row documenting the number (%) of women and neonates in each group who had none of the listed probable and possible causes of death.

Reviewer #2:

"A secondary analysis of stillbirths enrolled in a prospective, multisite, geographically, racially and ethnically diverse Stillbirth Collaborative Research Network (SCRN), case-control study in the U.S. Objective was to characterize stillbirths associated with pre gestational diabetes (PGDM) and gestational diabetes (GDM) from the SCRN and compare to stillbirths without diabetes

Results-
Table 2: could you comment on Intra partum stillbirths in the women with diabetes? This needs an explanation

Lines 190-196 in Results describes the gestational age as later with >30% happening after 37 weeks for PGDM and >50% stillbirth after 37 weeks for GDM. Table 2 does not show this. It does show a later gestational age than non diabetics but does not support that 30% cited in the narrative portion. Would there be another way to show gestational age iExample use epochs. 24-28, 28-32,32-37, >37

Table 3 When comparing medical conditions with PGDM and GDM; c hypertension and HDP are included in the narrative (lines 201-205)and are then separated out in their individual rows-) Did you do this because the numbers worked? Please define in Methods or explain in Results when you are discussing Table 3. The other medical conditions were not separated out? Is this because numbers were to low?

line 162: It would be nice for the reader if you extrapolated "An algorithm for estimating gestational age at the time of fetal death incorporating both clinical and postmortem examination data was utilized." most will not have read the original article and one could easily say that dating, was foot length

An excellent job delineating strengths and limitations

Reviewer #3:

I appreciate the opportunity to review the article, "Characteristics of stillbirths associated with diabetes in a diverse United States cohort" by Page et al. In this manuscript, the authors perform a secondary analysis of a prospective, multisite, case-control study examining stillbirths, with the purpose of characterizing stillbirths in pregnancies complicated by pregestational and gestational diabetes compared to pregnancies without diabetes.

1. The manuscript is well-written and addresses a knowledge gap in the obstetric literature. The findings are particularly interesting with regards to determining optimal timing of delivery in pregnancies with diabetes.

2. Lines 128-129: Understanding that a full description of the evaluations performed in the SCRN study can be found elsewhere, it would be useful for ease of reading in this manuscript to specify what was needed for "complete information regarding diabetes status", since this was part of the inclusion criteria.

3. As the authors state, a key difference between the diabetes and no-diabetes groups is BMI. Since the risk for stillbirth is known to increase with increasing BMI in a continuous fashion, can the authors control for BMI in their analyses?

4. The data presented in Figure 2 regarding timing of stillbirth between groups is striking. I would also be interested to know the proportions of probable cause of death within the groups in each epoch (i.e. what was the most common probable cause of death in the 37+ week demises vs the earlier demises, and did causes of death differ among the groups?). Did the authors look at causes of death in this way?

STATISTICAL EDITOR COMMENTS:

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

Table 1: Among diabetics and the subsets of diabetes, the sample sizes are each < 100, so the n(%) format should round

the %s to nearest integer %, not cite to 0.1% precision. Need units for age, BMI. Need to specify in Methods the threshold for inference testing and hence, whether p = .05 is significant.

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CONSULTANT EDITOR

After careful discussion of this manuscript at the editorial conference call, we would like to ask you and your co-authors if this could be considered for a Research Letter? The length would need to be reduced to 600 words with Figures or Tables limited to two, total (perhaps Table 2 and Figure 3). However, you may provide some additional supplemental digital content if you wish.

The guidelines for Research Letters are as follows:

"The Research Letter is a concise, focused report of original research (including pre-clinical research, sub-analyses or updates of previously published research, small studies, or pilot studies). Length should not exceed 600 words (approximately 2 1/2 manuscript pages). Figures or tables are limited to two, total.

Research Letters should be organized using the following headings: Introduction, Methods, Results and Discussion. An abstract should not be included.

Submitted Research Letters undergo the same external peer review as other article types, and the policies outlined in the journal's Instructions for Authors likewise apply."

Results
Minor point – The manuscript describes "pre-gestational" diabetes mellitus but the tables have "preexisting diabetes." These should be consistent.

Table 2 – What proportion of women with gestational diabetes were on pharmacologic interventions?

Line 184 (and Table 2) – Women with diabetes were more likely to have "Preeclampsia/Gestational Hypertensive" disorder than those without diabetes. Why in Table 3 were there no differences between groups with "hypertensive disorders"? This information seems to contradict each other. Please clarify.

Lines 187 to 189 – While this statement is true, Table 2 seems to suggest this statistical difference in LGA was driven by preexisting diabetes and not gestational diabetes. Please clarify.

Table 3 – For a given group, if the classification of gestational diabetes or pre-gestational diabetes were excluded from the maternal medical complications would there still be differences when compared to non-diabetic women?

Discussion
Lines 256 to 267 – Women with diabetes were more likely to be 35 years of age or older. Should this be mentioned as a risk for stillbirth as well?

Lines 281 to 282 – This conclusion may need to be refined based on my comments above (lines 184 to 189).

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. 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.

3. 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.

4. Because of space limitations, it is important that your revised manuscript adhere to the following length restrictions by manuscript type: Research Letter (600 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.

5. 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).

6. 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.

7. 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.

8. ACOG is moving toward discontinuing the use of "provider." Please replace "provider" throughout your paper with either a specific term that defines the group to which are referring (for example, "physicians," "nurses," etc.), or use "health care professional" if a specific term is not applicable.

9. In your submission, 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%").

10. 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.

11. Each supplemental file in your manuscript should be named an "Appendix," numbered, and ordered in the way they are first cited in the text. Do not order and number supplemental tables, figures, and text separately. References cited in appendixes should be added to a separate References list in the appendixes file.

12. 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.

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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.

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 30 days from the date of this letter. If we have not heard from you by Jul 12, 2020, we will assume you wish to withdraw the manuscript from further consideration..

Sincerely,

Mark A. Turrentine, MD
Consultant Editor

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

_____

[redacted]

Dear Dr. Chescheir,

Thank you for allowing us to submit our revised manuscript and reviewer responses for the manuscript, “Characteristics of Stillbirths Associated with Diabetes in a Diverse United States Cohort”. We have addressed each of the reviewers and editors’ comments below. The Instructions for Authors document has been reviewed and we believe our manuscript is in compliance.

This work has not been submitted to other journals previously. The lead author, Jessica Page, 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 have been explained. The authors report no conflicts of interest. This work was presented in poster format at the 2018 SMFM 37th Annual Conference in Dallas, TX. This study was approved by the University of Utah IRB committee.

Thank you for considering this manuscript and please let us know if we can make additional changes.

Sincerely,

Jessica Page, MD
University of Utah
Department of Obstetrics and Gynecology

RE: Manuscript Number ONG-20-1375

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We agree that a description of associated placental lesions is of interest. However, given the large amount of data (over 50 histologic variables in each case and control) we collected, it is beyond the scope of this paper to include. We are analyzing these data for a stand-alone paper on diabetes, placental histology and stillbirth.

Lines 134-139: Granting the difficulty of discerning whether glucose intolerance antedated pregnancy or not, as well as the multiplicity of definitions of gestational

diabetes (GDM), clues regarding severity and whether or not glucose intolerance antedated pregnancy may be obtained from the knowledge of whether GDM was first diagnosed in first trimester and whether the fasting GTT results equaled or exceeded 126 mg/dl. Can the authors access and present those data?
We agree that data regarding the timing of diagnosis of GDM and severity of disease would add to our analysis. Unfortunately, detailed data on GTT results were collected for a minority of patients in the SCRN parent study which was a cross-sectional study at the time of delivery. Thus, we were unable to analyze the data proposed by the reviewer. This was acknowledged as a limitation of the study.

Lines 319-320: We did not have data regarding the quality of glycemic control and glucose tolerance test data was available for only a small subset of patients, precluding meaningful analyses.

Lines 148-150: The authors state that standard testing included genetics, fetal-maternal testing, antibody testing, testing for infectious disease, APLS, and toxicology and serology testing. Can they give results of these tests in some detail?
These data have been presented previously in a series of prior papers which are referenced below in the current paper. While we agree that the results are of interest, we believe that presentation of these results is outside the focus of the current manuscript and would also entail redundancy with prior papers.

1. Stillbirth Collaborative Research Network Writing group. Causes of death among stillbirths. JAMA 2011;306:2459-68.
2. Silver RM, Parker CB, Reddy UM, Goldenberg R, Coustan D, Dudley DJ, et al. Antiphospholipid antibodies in stillbirth. Obstet Gynecol 2013;122:641-57.
3. Reddy UM, Page GP, Saade GR, Silver RM, Thorsten VR, Parker CB, Pinar H, Willinger M, Stoll BJ, Heim-Hall J, Varner MW, Goldenberg RL, Bukowski R, Wapner RJ, Drews-Botsch CD, O'Brien BM, Dudley DJ, Levy B; NICHD Stillbirth Collaborative Research Network. Karyotype versus microarray testing for genetic abnormalities after stillbirth. N Engl J Med 2012 Dec 6;367(23):2185-93.
4. Varner MW, Silver RM, Hogue CJ, Willinger M, Parker CB, Thorsten VR, Goldenberg RL, Saade GR, Dudley DJ, Coustan DR, Stoll B, Bukowski R, Koch MA, Conway D, Pinar H, Reddy UM; Eunice Kennedy Shriver National Institute of Child Health and Human Development Stillbirth Collaborative Research Network. Association Between Stillbirth and Illicit Drug Use and Smoking During Pregnancy. Obstet Gynecol. 2014 Jan;123(1):113-25.
5. Page JM, Bardsley T, Thorsten V, Allshouse AA, Varner MW, Debbink MP, Dudley DJ, Saade GR, Goldenberg RL, Stoll B, Hogue CJ, Bukowski R, Conway D, Reddy UM, Silver RM. Stillbirth Associated With Infection in a Diverse U.S. Cohort. Obstet Gynecol. 2019 Dec;134(6):1187-1196.

Lines 164-165: This study is a comparison of independent variables potentially related to stillbirth in women with and without diabetes, all of whom had a fetal demise. It would be of great value to know how women in each of these groups compared in the

prevalence of these variables with contemporaneous controls who did not have stillbirths and both did and did not have diabetes (e.g. from among the 1871 livebirths). Do the authors have data at their disposal to make these comparisons?
We added this analysis as suggested and we agree that it enhances the paper. The text, tables and figures have been modified to reflect this change.
Lines 171-172: A supplemental analysis was performed comparing characteristics of stillbirths to live births according to diabetes status.
Lines 192-195: Women with stillbirth and PGDM were more likely to be non-Hispanic Black compared to women with live births. Women with GDM and stillbirth were more likely to have higher BMI compared women with live births and GDM. (Appendix 1)

Lines 164-170: To better understand the data in Tables 1-3, could the authors present a brief discussion of how weighting was performed?
An additional description of data weights has been added as requested.
Lines 175-177: The analytic weights accounted for sampling design and participation rate among study groups with oversampling of preterm and non-Hispanic Black live births.

Lines 201-5: It would be useful to know the prevalence of each of these complications among the patients in each group. Would the authors prepare another table presenting these data?
We agree that better characterization of the maternal medical conditions is desirable. We prepared a table showing the maternal medical conditions for each group in supplemental table 2 and edited the text appropriately.
Lines 236-249: All PGDM and GDM stillbirth cases with a maternal medical condition listed as a cause of death, had either PGDM or GDM as the probable or possible cause of death. An analysis of additional medical conditions was performed. The only clinically significant comorbidity was one case of antiphospholipid syndrome in a PGDM patient. (Appendix 2)

Line 254: It would seem more accurate to state that most stillbirths in women with GDM were "associated with" or "ascribed to" causes other than diabetes or medical complications.
We agree that this is a better way to present this point in the discussion and the text has been edited accordingly.
Line 301-302: Most stillbirths in women with GDM were ascribed to causes other than diabetes or medical complications.

Table 3: It would be of interest to add a row documenting the number (%) of women and neonates in each group who had none of the listed probable and possible causes of death.
We agree that adding this information is important to our analysis and table 3 has been updated as suggested.

Reviewer #2:

"A secondary analysis of stillbirths enrolled in a prospective, multisite, geographically, racially and ethnically diverse Stillbirth Collaborative Research Network (SCRN), case-control study in the U.S. Objective was to characterize stillbirths associated with pre gestational diabetes (PGDM) and gestational diabetes (GDM) from the SCRN and compare to stillbirths without diabetes

Results-
Table 2: could you comment on Intra partum stillbirths in the women with diabetes? This needs an explanation
We added an explanation pertaining to the reduced number of intrapartum stillbirths in the diabetic stillbirth population as compared to the non-diabetic stillbirth population as described below.
Line 203-209: Fewer intrapartum stillbirths were observed in the combined PGDM and GDM group as compared to stillbirths without diabetes (5.5% versus 18.5%; p=0.049). This is likely due to the higher proportion of intrapartum stillbirths at previable gestational ages in the setting of preterm labor disorders. Many women may not have been screened for GDM at this point in pregnancy and thus diminished the number of intrapartum stillbirths in the diabetes group.

Lines 190-196 in Results describes the gestational age as later with >30% happening after 37 weeks for PGDM and >50% stillbirth after 37 weeks for GDM. Table 2 does not show this. It does show a later gestational age than non diabetics but does not support that 30% cited in the narrative portion. Would there be another way to show gestational age iExample use epochs. 24-28, 28-32,32-37, >37
Thank you for pointing this out. The mean GA shown in table 2 as a continuous measure differs from the categorical analysis shown in figure 2 due to the use of analytic weights. We hope that this clarification will help, and we ask to include both measures if the editors agree.

Table 3 When comparing medical conditions with PGDM and GDM; c hypertension and HDP are included in the narrative (lines 201-205)and are then separated out in their individual rows-) Did you do this because the numbers worked? Please define in Methods or explain in Results when you are discussing Table 3. The other medical conditions were not separated out? Is this because numbers were to low?
We thank the reviewer for this clarification. We updated the text to correspond correctly with the INCODE cause of death classification system and Table 3. The reviewer is correct. The medical conditions in the category of maternal medical conditions were not analyzed separately due to low numbers.
Line 225-231: Maternal medical conditions included GDM, PGDM, systemic lupus erythematosus, intrahepatic cholestasis of pregnancy, thyroid disorders, renal diseases, asthma, seizure disorders, substance use, shock due to conditions

other than infection, antiphospholipid antibody syndrome, thrombophilias and others suspected to be related to the fetal death. Maternal hypertensive disorders including chronic hypertension and hypertensive disorders of pregnancy were analyzed as a separate cause of death category.

line 162: It would be nice for the reader if you extrapolated "An algorithm for estimating gestational age at the time of fetal death incorporating both clinical and postmortem examination data was utilized." most will not have read the original article and one could easily say that dating, was foot length
We updated the text with more specific information as requested by the reviewer and appreciate this point of clarification.
Line 162-164: An algorithm for estimating gestational age at the time of fetal death incorporating the reliability of the estimated due date, ultrasound data, fetal maceration and foot length was utilized.

An excellent job delineating strengths and limitations

Reviewer #3:

I appreciate the opportunity to review the article, "Characteristics of stillbirths associated with diabetes in a diverse United States cohort" by Page et al. In this manuscript, the authors perform a secondary analysis of a prospective, multisite, case-control study examining stillbirths, with the purpose of characterizing stillbirths in pregnancies complicated by pregestational and gestational diabetes compared to pregnancies without diabetes.

1. The manuscript is well-written and addresses a knowledge gap in the obstetric literature. The findings are particularly interesting with regards to determining optimal timing of delivery in pregnancies with diabetes.

2. Lines 128-129: Understanding that a full description of the evaluations performed in the SCRN study can be found elsewhere, it would be useful for ease of reading in this manuscript to specify what was needed for "complete information regarding diabetes status", since this was part of the inclusion criteria.
Thank you for pointing this out, we updated the text as described below to better describe this aspect of the study.
Line 129-131: Information regarding diabetes status was considered complete if the patient had been classified as either GDM, PGDM or no diabetes.

3. As the authors state, a key difference between the diabetes and no-diabetes groups is BMI. Since the risk for stillbirth is known to increase with increasing BMI in a continuous fashion, can the authors control for BMI in their analyses?
We agree that the women with diabetes also had a higher prevalence of

established risk factors for stillbirth including advanced maternal age and higher BMI. Given that the scope of this paper is a characterization of diabetes stillbirths we did not perform statistical modeling. Unfortunately, the small number of women in each category prevents us from performing further stratified analyses by BMI or other strata and as such we were unable to include this in the paper.

4. The data presented in Figure 2 regarding timing of stillbirth between groups is striking. I would also be interested to know the proportions of probable cause of death within the groups in each epoch (i.e. what was the most common probable cause of death in the 37+ week demises vs the earlier demises, and did causes of death differ among the groups?). Did the authors look at causes of death in this way?
We agree that further characterization of the term stillbirths is of clinical interest. We stratified cause of death by preterm and term deliveries as suggested and included the results in the text as shown below.
Lines 251-257: Given the high proportion of stillbirths at term in the diabetes population an additional analysis was performed to assess differences in cause of death in preterm versus term stillbirths according to diabetes status. Causes of death were similar among these groups with a higher number of deaths due to maternal medical complications in term and preterm stillbirths (preterm 48% versus 5%; p<0.001, term 35% versus 2%; p=0.013).

STATISTICAL EDITOR COMMENTS:

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

Table 1: Among diabetics and the subsets of diabetes, the sample sizes are each < 100, so the n(%) format should round the %s to nearest integer %, not cite to 0.1% precision. Need units for age, BMI. Need to specify in Methods the threshold for inference testing and hence, whether p = .05 is significant.
Thank you for these clarifications. We updated table 1 as suggested and methods text as below.
Line 169-171: P-values from a weighted Wald chi-square are reported for comparisons of categorical measures. P-values less than 0.05 are referred to as statistically significant.

Tables 2, 3, lines 164-166: Some of the counts are low, thus requiring Fisher's test rather than chi-square. Since many of the counts among diabetics and their subsets are few, there is little stats power to discern differences. Therefore, one cannot generalize the NS findings. For example, note the statistical difference in all DM vs no diabetes in timing of stillbirth (ante vs intra partum), while no statistical difference for subsets, despite nominal differences in rates for all, pre-existing and gestational in Table 2. IN Table 3, again there is low stats power and the NS findings cannot be generalized based on these modest counts.

Thank you for raising these points. Due to the need for weighted methods with the SCRN data, Fisher's Exact Test could not be used. We report p-values from a Wald chi-square (vs the default Rao Scott chi square in SAS survey methodology frequency procedures). We updated the methods section as described above. We additionally agree that we have low power given the small n in our diabetes groups and updated the limitations section to reflect this.
Line 325-327: Despite the SCRN being one of the largest and best characterized stillbirth cohorts there were small numbers of patients in the PGDM and GDM groups limiting the generalizability of our findings.

CONSULTANT EDITOR

After careful discussion of this manuscript at the editorial conference call, we would like to ask you and your co-authors if this could be considered for a Research Letter? The length would need to be reduced to 600 words with Figures or Tables limited to two, total (perhaps Table 2 and Figure 3). However, you may provide some additional supplemental digital content if you wish.

The guidelines for Research Letters are as follows:

"The Research Letter is a concise, focused report of original research (including pre-clinical research, sub-analyses or updates of previously published research, small studies, or pilot studies). Length should not exceed 600 words (approximately 2 1/2 manuscript pages). Figures or tables are limited to two, total.

Research Letters should be organized using the following headings: Introduction, Methods, Results and Discussion. An abstract should not be included.

Submitted Research Letters undergo the same external peer review as other article types, and the policies outlined in the journal's Instructions for Authors likewise apply."

We appreciate the editor's consideration of our manuscript. Given the amount of information presented, and additional data requested by the reviewers, we strongly prefer to keep the paper as a traditional manuscript if possible. We worry that reducing the length to 600 words would compromise our ability to clearly communicate our results to the reader. It also would limit our ability to communicate the nuances of our findings which we hope are clinically relevant. Of course, we are willing to consider using the research letter format if the editors feel strongly.

Results
Minor point – The manuscript describes "pre-gestational" diabetes mellitus but the tables have "preexisting diabetes." These should be consistent.

Thank you for pointing this out. The tables have been updated accordingly.

Table 2 – What proportion of women with gestational diabetes were on pharmacologic interventions?
Unfortunately, we do not have data regarding pharmacologic treatment among patients in each diabetes category. We agree that it would add to our analysis. This is noted in the limitations.

Line 184 (and Table 2) – Women with diabetes were more likely to have "Preeclampsia/Gestational Hypertensive" disorder than those without diabetes. Why in Table 3 were there no differences between groups with "hypertensive disorders"? This information seems to contradict each other. Please clarify.
Thank you for this clarification. Table 3 shows the probable/possible causes of death for each group while the text and table 2 show the overall prevalence of various clinical characteristics. While hypertensive disorders of pregnancy were more prevalent in patients with PGDM and GDM, hypertensive disorders as a cause of death were not more likely in these groups. We clarified this in the text as described below.
Line 249-251: Despite a higher prevalence of hypertensive disorders of pregnancy, hypertensive disorders were not more common as a cause of death in stillbirths with diabetes. (Table 3)

Lines 187 to 189 – While this statement is true, Table 2 seems to suggest this statistical difference in LGA was driven by preexisting diabetes and not gestational diabetes. Please clarify.
Thank you for pointing this out. We updated the text to reflect this point as shown below.
Line 201-203: In contrast, more women with PGDM and stillbirth had large for gestational age infants (25.8% versus 3.4%; $p < 0.001$) while women with GDM did not (5.8% versus 3.4%; $p=0.594$).

Table 3 – For a given group, if the classification of gestational diabetes or pre-gestational diabetes were excluded from the maternal medical complications would there still be differences when compared to non-diabetic women?
Thank you for raising this issue. We performed an additional analysis of our data and found that all PGDM and GDM stillbirths with a cause of death categorized as maternal medical condition had PGDM or GDM as the underlying cause. We updated the text as below.
Line 236-238: All PGDM and GDM stillbirth cases with a maternal medical condition listed as a cause of death, had either PGDM or GDM as the probable or possible cause of death.

Discussion
Lines 256 to 267 – Women with diabetes were more likely to be 35 years of age or older. Should this be mentioned as a risk for stillbirth as well?

Thank you for pointing this out. We added this information to the discussion section as recommended.
Line 314-316: Our data also showed a higher number of women age 35 years and greater in the diabetic groups, which is also a recognized risk factor for stillbirth.

Lines 281 to 282 – This conclusion may need to be refined based on my comments above (lines 184 to 189).
Thank you for this clarification. We edited the text to state that stillbirths in pregnancies complicated by diabetes are associated with hypertensive disorders although the hypertensive disorders are not causative in our dataset.
Line 334-338: In summary, most stillbirths in women with diabetes occurred late in gestation and were associated with large for gestational age infants when compared to stillbirths in women without diabetes. They were additionally associated with hypertensive disorders, although hypertensive disorders were not more common as a potential cause of fetal death.

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.
We are happy to opt-in to this process.

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.
All coauthors have confirmed that their disclosures are correct.

3. 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.
We have reviewed the reVITALize definitions and believe our manuscript is in compliance.

4. Because of space limitations, it is important that your revised manuscript adhere to the following length restrictions by manuscript type: Research Letter (600 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.
Our current manuscript is formatted as original research given our request above. The abstract is 298 words and the main text is 2413 words, in compliance with this publication type. We hope that this is acceptable to the editors and are happy to discuss the matter further if desired.

5. 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).
These elements have been addressed in our final manuscript.

6. 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.
We have reviewed our work to ensure compliance with this guideline.

7. 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.
We have ensured that this symbol is not used in our manuscript.

8. ACOG is moving toward discontinuing the use of "provider." Please replace "provider" throughout your paper with either a specific term that defines the group to which are referring (for example, "physicians," "nurses," etc.), or use "health care professional" if a specific term is not applicable.
We have removed the term “provider” from our manuscript.

9. In your submission, 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%").
The appearance of p-values has been standardized in our text.

10. 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.
We have reviewed the table checklist and believe our tables are in compliance.

11. Each supplemental file in your manuscript should be named an "Appendix," numbered, and ordered in the way they are first cited in the text. Do not order and number supplemental tables, figures, and text separately. References cited in appendixes should be added to a separate References list in the appendixes file.
The supplemental tables have been labeled as appendices and are provided in a separate file.

12. 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.

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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.

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 30 days from the date of this letter. If we have not heard from you by Jul 12, 2020, we will assume you wish to withdraw the manuscript from further consideration..

Sincerely,

Mark A. Turrentine, MD
Consultant Editor

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