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: Sep 10, 2021
To: "Kathleen Lamont" [redacted]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-21-1658

RE: Manuscript Number ONG-21-1658

Risk of stillbirth recurrence in a subsequent pregnancy

Dear Dr. Lamont:

Your manuscript has been reviewed by the Editorial Board and by special expert referees. Although it is judged not acceptable for publication in Obstetrics & Gynecology in its present form, we would be willing to give further consideration to a revised version.

If you wish to consider revising your manuscript, you will first need to study carefully the enclosed reports submitted by the referees and editors. Each point raised requires a response, by either revising your manuscript or making a clear and convincing argument as to why no revision is needed. To facilitate our review, we prefer that the cover letter include the comments made by the reviewers and the editor followed by your response. The revised manuscript should indicate the position of all changes made. We suggest that you use the "track changes" feature in your word processing software to do so (rather than strikethrough or underline formatting).

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

Your paper will be maintained in active status for 21 days from the date of this letter. If we have not heard from you by Oct 01, 2021, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1: Thank you for performing this research and better trying to understand risk factors for subsequent stillbirth in women with a prior stillbirth. I have several concerns with the manuscript:

1. The methods section is challenging to read with the grammar and punctuation. I would recommend revising this section and potentially make smaller sentences to separate ideas, such as when listing how socioeconomic status was determined in different countries.

2. From what information is listed, I assume there was a large amount of data that was imputed since it is stated that without doing this, the study would be underpowered. This by itself lends caution to readers when interpreting the results. Many of the results were statistically significant between the exposed and unexposed group of women. Could these results potentially be due to how the imputation was done or is this truly a difference between the two groups of women? I would have liked additional information on this as well as elaborating further on it in the discussion section of the paper since I think it is a major weakness of the study.

Reviewer #2:

Overall Comments: The authors describe outcomes from a large retrospective cohort study addressing subsequent risk of stillbirth in a woman after experiencing a stillbirth in a first pregnancy. They determined that after a first pregnancy stillbirth, these women are at higher risk of stillbirth in any subsequent pregnancy controlling for potentially confounding variables. This difference in risk increased with each additional pregnancy. Although of low incidence, if there were modifiable risk factors identified, perhaps the risk of primary and subsequent stillbirths could be mitigated. Overall the paper is well written, would prefer the Tables in the back of the paper. This reviewer's review of the literature and reading of the systematic review noted in the citations (Lamont et al, 2015) notes a smaller cohort for the current paper, however, it differs in being able to comment on prospective risk of future pregnancy outcomes at the time of the first stillbirth.

Specific Comments:

Title: Might consider adding, Prospective risk of stillbirth recurrence

Precis: ok

Abstract: Good synthesis of the study

Introduction: Provides rationale for this study; hypothesis driven

Methods: Well written

Results: Please provide the proportion of stillbirths by country, both from the individual country all total pregnancy perspective and as a proportion of total stillbirths from all countries. Some of the between group statistical differences in pregnancy and maternal characteristics; many are probably not clinically significantly. Would also note that the increased risk of subsequent stillbirths in Finland and Malta (lines 396-7) is modest [maybe these last comments should be addressed in the Discussion]. Was wondering if stillbirth with first pregnancy is also associated with other morbidities such as pre-term labor, small for gestational age, etc for subsequent live-birth babies?

Discussion: Results discussed well in the context of the current literature. The placental insufficiency/dysfunction aspect is novel and hopefully can lead to studies in this regard.

Reviewer #3: This is an original study using national databases to assess the risk of recurrent stillbirth in Scotland, Finland, and Malta. The authors note an approximate double risk of stillbirth in subsequent pregnancies in women with prior stillbirth. Although similar studies have been performed, the authors use novel approaches to note risk differences increase with increasing numbers of pregnancies. The topic is of interest and clinical relevance to readers of the journal. The analysis is carefully done, and the paper is well-written. Questions and suggestions for enhancing this manuscript include:

1. It would be of great interest to stratify the analysis by cause of death for the stillbirths. Recurrence risk likely varies considerably based on cause of death. Although formal classification is not possible with such large datasets, cause of death is often included in administrative databases.

2. Short of evaluating causes of death, it would help to perform some stratified analyses with readily available data. For example, cases with known fetal anomalies of genetic abnormalities could be excluded. It is also of useful to stratify on gestational age of stillbirth. Recurrence risk may vary based on gestational age of the loss. Similarly, assessment of recurrence risk for unexplained stillbirth is of great interest.

3. Some data regarding absolute risks for stillbirth would improve the paper and facilitate counseling.

4. It is unclear how fetal growth restriction was defined. This may be over-estimated in these databases since there is often a lag between death and recognition of the stillbirth / delivery. This should be noted.

5. Some data regarding variation in stillbirth ratios in the countries studied during the relatively long study epoch is of interest.

6. Several confounders of interest such as cesarean delivery and interpregnancy interval are not assessed.

7. It also would be of interest to provide data regarding race / ethnicity if available - especially in Scotland. One U.S. study noted major variance in recurrence of stillbirth by race / ethnicity.

8. Gestational diabetes is also of interest.

9. It is unclear why variables were all chosen a priori for the regression model, without consideration of some that may have differed in univariate analysis. Some may be on the causal pathway but others may not.

10. It is worth noting the stillbirth rates / ratios i these countries in the paper. They are assuredly less than many countries and accordingly these data are most relevant for high resource countries with low SB rates.

STATISTICAL EDITOR COMMENTS:

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

Insert comments

Abstract, Table 1: It is clinically important to give equal emphasis to the rates of subsequent successful live births. That is, although the rates of repeat stillbirth were relatively higher among women with a prior stillbirth, the proportion with live birth in that cohort was > 97%.

Table 2: The missing data for smoking status was 44% for Stillbirth and 33% for live birth cohorts. This is both a significant proportion and a selective difference for the two cohorts. Conceding that smoking has been identified as a risk factor for stillbirth, the inclusion of smoking status in this analysis may be both biased and imprecise. The imputation may be faulty, due to the large proportion of missing data. What proportion of individual data had no missing values for all characteristics? Also, the proportion with anemia or PROM were a function of the length of gestation and surely not a factor associated with less probability of stillbirth.

Fig 1: Should include CIs for the K-M curves and include in figure or text a summary of the stats comparison.

Fig 2: Although there is a step-wise increase in the difference in proportions with increasing number of pregnancies, the number among the stillbirth cohort was smaller and became smaller still with each subsequent pregnancy. Need to include CIs to show the increasing variability with each subsequent birth among the stillbirth cohort.

Table 3, lines 84-88: Since the criteria for stillbirth vs GA varied by country, the comparisons by country are not interpretable, unless data can be provided that used the same definition for stillbirth.

EDITOR COMMENTS:

1. Thank you for submitting your work to Obstetrics and Gynecology. If you choose to submit a revision, please make sure that you comply with word count limitations. Also reduce the length of the results section by avoiding repeating data in the text that is in a table or figure- simply refer to that table or figure.

2. When you submit your revised manuscript, please make the following edits to ensure your submission contains the required information that was previously omitted for the initial double-blind peer review:
* Include your title page information in the main manuscript file. The title page should appear as the first page of the document. Add any previously omitted Acknowledgements (ie, meeting presentations, preprint DOIs, assistance from non-byline authors).
* Funding information (ie, grant numbers or industry support statements) should be disclosed on the title page and in the body text. For industry-sponsored studies, the Role of the Funding Source section should be included in the body text of the manuscript.
* Include clinical trial registration numbers, PROSPERO registration numbers, or URLs at the end of the abstract (if applicable).
* Name the IRB or Ethics Committee institution in the Methods section (if applicable).
* Add any information about the specific location of the study (ie, city, state, or country), if necessary for context.

3. Obstetrics & Gynecology uses an "electronic Copyright Transfer Agreement" (eCTA), which must be completed by all authors. Please add your authors to the submission's record in Editorial Manager. You are the only author currently listed in the metadata.

Each co-author will receive an email with the subject, "Please verify your authorship for a submission to Obstetrics & Gynecology." Please check with your coauthors to confirm that they received and completed this form, and that the disclosures listed in their eCTA are included on the manuscript's title page.

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

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

6. Please submit a completed STROBE checklist.

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

Alliance. Obstetrics & Gynecology has adopted the use of the reVITALize definitions. Please access the obstetric data definitions at https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-obstetrics-data-definitions and the gynecology data definitions at https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-gynecology-data-definitions. If use of the reVITALize definitions is problematic, please discuss this in your point-by-point response to this letter.

8. 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 5,500 words. Stated word limits include the title page, précis, abstract, text, tables, boxes, and figure legends, but exclude references.

9. 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).
* If your manuscript was uploaded to a preprint server prior to submitting your manuscript to Obstetrics & Gynecology, add the following statement to your title page: "Before submission to Obstetrics & Gynecology, this article was posted to a preprint server at: [URL]."

10. 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.

11. 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.

12. 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.

13. 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%").

14. 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.

15. 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 references you are citing are still current and available. Check the Clinical Guidance page at https://www.acog.org/clinical (click on "Clinical Guidance" at the top). If the reference is still available on the site and isn't

listed as "Withdrawn," it's still a current document.

If the reference you are citing has been updated and 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.

16. Figures 1-2: Please upload as figure files in Editorial Manager and move legends to the end of the manuscript.

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If you choose open access, you will receive an Open Access Publication Charge letter from the Journal's Publisher, Wolters Kluwer, and instructions on how to submit any open access charges. The email will be from publicationservices@copyright.com with the subject line, "Please Submit Your Open Access Article Publication Charge(s)." Please complete payment of the Open Access charges within 48 hours of receipt.

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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 as a Microsoft Word document. 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 21 days from the date of this letter. If we have not heard from you by Oct 01, 2021, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

Torri Metz, MD, MS
Associate Editor for OB

2020 IMPACT FACTOR: 7.661
2020 IMPACT FACTOR RANKING: 3rd out of 83 ob/gyn journals

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The Green Journal

REVIEWER COMMENTS:

We thank the reviewers for their comments.

Reviewer #1: Thank you for performing this research and better trying to understand risk factors for subsequent stillbirth in women with a prior stillbirth. I have several concerns with the manuscript:

1. The methods section is challenging to read with the grammar and punctuation. I would recommend revising this section and potentially make smaller sentences to separate ideas, such as when listing how socioeconomic status was determined in different countries.]
Amended as suggested

2. From what information is listed, I assume there was a large amount of data that was imputed since it is stated that without doing this, the study would be underpowered. This by itself lends caution to readers when interpreting the results. Many of the results were statistically significant between the exposed and unexposed group of women. Could these results potentially be due to how the imputation was done or is this truly a difference between the two groups of women? I would have liked additional information on this as well as elaborating further on it in the discussion section of the paper since I think it is a major weakness of the study.
There was a large amount of data missing for two covariates – smoking and BMI and small amounts for marital status, deprivation category and gestational age at birth. As the data were not missing completely at random we also conducted a complete case analysis to test the robustness of the results from the imputed analysis. The results were broadly similar and are presented in Appendix 2. We have now added this information to methods and results.

Reviewer #2:

Overall Comments: The authors describe outcomes from a large retrospective cohort study addressing subsequent risk of stillbirth in a woman after experiencing a stillbirth in a first pregnancy. They determined that after a first pregnancy stillbirth, these women are at higher risk of stillbirth in any subsequent pregnancy controlling for potentially confounding variables. This difference in risk increased with each additional pregnancy. Although of low incidence, if there were modifiable risk factors identified, perhaps the risk of primary and subsequent stillbirths could be mitigated. Overall the paper is well written, would prefer the Tables in the back of the paper. This reviewer's review of the literature and reading of the systematic review noted in the citations (Lamont et al, 2015) notes a smaller cohort for the current paper, however, it differs in being able to comment on prospective risk of future pregnancy outcomes at the time of the first stillbirth.

Specific Comments:

Title: Might consider adding, Prospective risk of stillbirth recurrence

Thank you for this suggestion, we have now added this to the title

Precis: ok

Abstract: Good synthesis of the study

Introduction: Provides rationale for this study; hypothesis driven

Methods: Well written

Results: Please provide the proportion of stillbirths by country, both from the individual country all total pregnancy perspective and as a proportion of total stillbirths from all countries. Some of the between group statistical differences in pregnancy and maternal characteristics; many are probably not clinically significantly. Would also note that the increased risk of subsequent stillbirths in Finland and Malta (lines 396-7) is modest [maybe these last comments should be addressed in the Discussion]. Was wondering if stillbirth with first pregnancy is also associated with other morbidities such as pre-term labor, small for gestational age, etc for subsequent live-birth babies?

Proportions have been added as suggested.

Discussion: Results discussed well in the context of the current literature. The placental insufficiency/dysfunction aspect is novel and hopefully can lead to studies in this regard.

Reviewer #3: This is an original study using national databases to assess the risk of recurrent stillbirth in Scotland, Finland, and Malta. The authors note an approximate double risk of stillbirth in subsequent pregnancies in women with prior stillbirth. Although similar studies have been performed, the authors use novel approaches to note risk differences increase with increasing numbers of pregnancies. The topic is of interest and clinical relevance to readers of the journal. The analysis is carefully done, and the paper is well-written. Questions and suggestions for enhancing this manuscript include:

1. It would be of great interest to stratify the analysis by cause of death for the stillbirths. Recurrence risk likely varies considerably based on cause of death. Although formal classification is not possible with such large datasets, cause of death is often included in administrative databases. We agree this would indeed be helpful. Unfortunately, cause of death data was in a separate file and it was not possible to link to the bigger dataset due to confidentiality issues. We could present a separate analysis in relation to cause of death, but feel that this would divert the focus of the current analysis.

2. Short of evaluating causes of death, it would help to perform some stratified analyses with readily available data. For example, cases with known fetal anomalies of genetic abnormalities could be excluded. It is also of useful to stratify on gestational age of stillbirth. Recurrence risk may vary based on gestational age of the loss. Similarly, assessment of recurrence risk for unexplained stillbirth is of great interest.

We also agree that stratification on gestational age would have been of interest. However, stratification would reduce the numbers in individual groups giving rise to confidentiality issues. We have adjusted for gestational age at delivery which should take account of this variable. With regard to cause of death data as explained in response to the previous point, this was only available as a separate non-linkable file so stratified analysis was not feasible.

3. Some data regarding absolute risks for stillbirth would improve the paper and facilitate counseling.

As suggested we have now added this information and highlighted this in Table 1.

4. It is unclear how fetal growth restriction was defined. This may be over-estimated in these databases since there is often a lag between death and recognition of the stillbirth / delivery. This should be noted.

Amended as suggested

5. Some data regarding variation in stillbirth ratios in the countries studied during the relatively long study epoch is of interest.

We did include year of delivery as a covariate in the model which should account for any changes in diagnosis or management.

6. Several confounders of interest such as cesarean delivery and interpregnancy interval are not assessed.

We had included caesarean section in mode of delivery in univariate analysis (Table 2). As several subsequent pregnancies were recorded, interpregnancy interval as such would be impossible to calculate. The time to event analysis gives an indication of this where women who had an initial stillbirth had a subsequent stillbirth sooner than those who had an initial livebirth.

7. It also would be of interest to provide data regarding race / ethnicity if available - especially in Scotland. One U.S. study noted major variance in recurrence of stillbirth by race / ethnicity.

We agree that it would have been good to include ethnicity in the Cox model, however, Finland did not record information on ethnicity therefore this variable was not included in the dataset.

Scotland did provide information on ethnicity but it was very poorly collected (86% was recorded as unknown and that was at the second pregnancy). Information on ethnicity at the first pregnancy would have been collected earlier, therefore it is likely that a higher proportion of information would have been unknown. Collection of ethnicity in the Maltese dataset was complete but the Maltese dataset was very small.

8. Gestational diabetes is also of interest. Gestational diabetes was included in univariate analysis (Table 2)

9. It is unclear why variables were all chosen a priori for the regression model, without consideration of some that may have differed in univariate analysis. Some may be on the causal pathway but others may not.
The variables were chosen *a priori* based on clinical knowledge and directed acyclic graphs.

10. It is worth noting the stillbirth rates / ratios i these countries in the paper. They are assuredly less than many countries and accordingly these data are most relevant for high resource countries with low SB rates.
Many thanks for this suggestion. This has now been added to the discussion section.

STATISTICAL EDITOR COMMENTS:

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

Insert comments

Abstract, Table 1: It is clinically important to give equal emphasis to the rates of subsequent successful live births. That is, although the rates of repeat stillbirth were relatively higher among women with a prior stillbirth, the proportion with live birth in that cohort was > 97%.

Thank you for pointing this out. We have added this information.

Table 2: The missing data for smoking status was 44% for Stillbirth and 33% for live birth cohorts. This is both a significant proportion and a selective difference for the two cohorts. Conceding that smoking has been identified as a risk factor for stillbirth, the inclusion of smoking status in this analysis may be both biased and imprecise. The imputation may be faulty, due to the large proportion of missing data. What proportion of individual data had no missing values for all characteristics?

As noted above we also conducted a complete case analysis to address these concerns and the findings were very similar (Appendix 2).

Also, the proportion with anemia or PROM were a function of the length of gestation and surely not a factor associated with less probability of stillbirth.

We are not clear why anaemia should be a function of the length of gestation as most cases are diagnosed early in the first or second antenatal visit. Anaemia and PROM were not included in the multivariate analysis.

Fig 1: Should include CIs for the K-M curves and include in figure or text a summary of the stats comparison.

Unfortunately, the permissions to access the raw data, which are archived in a data Safe Haven, have now expired and therefore we are unable to conduct any additional analysis to calculate CIs within the time frame stipulated. It may be noted that we have presented p-values for Cox regression and therefore didn't think it was necessary to add the p-value for the unadjusted log rank test, especially as we have presented an adjusted p-value for stillbirth in Table 2.

Fig 2: Although there is a step-wise increase in the difference in proportions with increasing number of pregnancies, the number among the stillbirth cohort was smaller and became smaller still with each subsequent pregnancy. Need to include CIs to show the increasing variability with each subsequent birth among the stillbirth cohort.

We agree that this is an excellent suggestion. Unfortunately, as explained above this is not feasible as we can no longer access the data. This graph was intended mainly for descriptive purposes and we have added the numbers of risk to indicate that the right-hand side of the graph is based on relatively small numbers at risk. We have added a sentence in the discussion highlighting this.

Table 3, lines 84-88: Since the criteria for stillbirth vs GA varied by country, the comparisons by country are not interpretable, unless data can be provided that used the same definition for stillbirth. The definition of stillbirth in Finland and Malta is from 22 or more completed weeks gestation, in Scotland it is from 24 or more completed weeks gestation, therefore, in the 22-28 week category Scotland only had stillbirths from 24 weeks. It is ideal to standardise the definition and while we did try it meant that we lost a considerable amount of stillbirths. For this reason we included all stillbirths as we were not seeking a comparison by country.

EDITOR COMMENTS:

1. Thank you for submitting your work to Obstetrics and Gynecology. If you choose to submit a revision, please make sure that you comply with word count limitations. Also reduce the length of the results section by avoiding repeating data in the text that is in a table or figure- simply refer to that table or figure.
The revised version adheres to the word limits.
2. When you submit your revised manuscript, please make the following edits to ensure your submission contains the required information that was previously omitted for the initial double-blind peer review:

* Include your title page information in the main manuscript file. The title page should appear as the first page of the document. Add any previously omitted Acknowledgements (ie, meeting presentations, preprint DOIs, assistance from non-byline authors).
* Funding information (ie, grant numbers or industry support statements) should be disclosed on the title page and in the body text. For industry-sponsored studies, the Role of the Funding Source section should be included in the body text of the manuscript.
* Include clinical trial registration numbers, PROSPERO registration numbers, or URLs at the end of the abstract (if applicable).
* Name the IRB or Ethics Committee institution in the Methods section (if applicable).
* Add any information about the specific location of the study (ie, city, state, or country), if necessary for context.

These have all been done.

3. Obstetrics & Gynecology uses an "electronic Copyright Transfer Agreement" (eCTA), which must be completed by all authors. Please add your authors to the submission's record in Editorial Manager. You are the only author currently listed in the metadata.

Each co-author will receive an email with the subject, "Please verify your authorship for a submission to Obstetrics & Gynecology." Please check with your coauthors to confirm that they received and completed this form, and that the disclosures listed in their eCTA are included on the manuscript's title page.

Co-authors have now been added.

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

The websites detailing the process of collection and validation of the country-level databases have been referenced in the methods section.

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

This has now been done.

6. Please submit a completed STROBE checklist.

This has now been added.

7. Standard obstetric and gynecology data definitions have been developed through the reVITALize initiative, which was convened by the American College of Obstetricians and Gynecologists and the members of the Women's Health Registry Alliance. Obstetrics & Gynecology has adopted the use of the reVITALize definitions. Please access the obstetric data definitions at https://eur03.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.acog.org%

2Fpractice-management%2Fhealth-it-and-clinical-informatics%2Frevitalize-obstetrics-data-definitions&data=04%7C01%7Ckathleen.lamont1%40abdn.ac.uk%7C902465a1a36d46f724ac08d974652700%7C8c2b19ad5f9c49d490773ec3cfc52b3f%7C0%7C0%7C637668801112048723%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C1000&sdata=ZsuwH9GYItZxtJ4U5aWj9y9yXnyH54cSr3ruNaWJjxw%3D&reserved=0 and the gynecology data definitions at https://eur03.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.acog.org%2Fpractice-management%2Fhealth-it-and-clinical-informatics%2Frevitalize-gynecology-data-definitions&data=04%7C01%7Ckathleen.lamont1%40abdn.ac.uk%7C902465a1a36d46f724ac08d974652700%7C8c2b19ad5f9c49d490773ec3cfc52b3f%7C0%7C0%7C637668801112048723%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C1000&sdata=9qmgAQcBAgFPzkaSY%2B0j%2BckVyf58%2F8jxM4njp87cZzc%3D&reserved=0. If use of the reVITALize definitions is problematic, please discuss this in your point-by-point response to this letter.

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