

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Multilevel determinants of racial/ethnic disparities in severe maternal morbidity and mortality in the context of the COVID-19 pandemic in the United States: protocol for a concurrent triangulation, mixed methods study
AUTHORS	Liu, Jihong; Hung, Peiyin; Liang, Chen; Zhang, Jiajia; Qiao, Shan; Campbell, Berry; Olatosi, Bankole; Torres, Myriam; Hikmet, Neset; Li, Xiaoming

VERSION 1 – REVIEW

REVIEWER	Pickett, Kate University of York, Health Sciences
REVIEW RETURNED	11-Apr-2022

GENERAL COMMENTS	This is a complex study of racial/ethnic disparities in maternal health, where the complexity, admirably, arises from the application of a full socio-ecological framework. This does, however, make the protocol lengthy and dense, and the study design could probably be usefully represented by a figure. The current Figure 1 is simplistic and says nothing more than that the issue is being considered- within a multilevel context and Table 1 simply lists data sources in relation to study objectives. A more thorough diagrammatic representation of the study design would be a lot more helpful for the reader and could replace both Figure 1 and Table 1. This would also help to show how the qualitative work is integrated with the quantitative work within the design.
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REVIEWER	Bailey, Helen Curtin University, Curtin Medical School
REVIEW RETURNED	13-Apr-2022

GENERAL COMMENTS	Thank you for the opportunity to review this protocol which deals with an important topic – racial/ethnic disparities in health-related outcomes, using a mixed methods approach. For this study, the outcomes of interest will be severe maternal morbidity and mortality (SMMM) (with and without concurrent COVID). The investigators plan to use two sources 1) existing South Carolina birth cohort (all births 2018-21) (S3C) which links a wide range of administrative data) and 2) electronic health records of pregnant women in the National Cohort Collaborative (N3C). as well as the quantitative analyses, there will also be qualitative part of the study (interviews of mothers and care providers). The protocol is well-written and clear so I only have a few suggestions. 1) It would be useful to put the numbers from the Power and Sample Size calculations into a flow diagram (expected numbers
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	<p>from each of the data sources- subdivided by race and COVID period status and with and without SMMM).</p> <p>2) Since the investigators are basing SMMM on the validated CDC algorithm (Ref 37), have they considered using an obstetric comorbidity algorithm¹ which is also based on ICD-CM diagnosis codes to more systematically identify maternal pre-existing and pregnancy complications?</p> <p>1. Leonard SA, Kennedy CJ, Carmichael SL, Lyell DJ, Main EK. An Expanded Obstetric Comorbidity Scoring System for Predicting Severe Maternal Morbidity. <i>Obstet Gynecol.</i> 2020; 136:440-449.</p>
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VERSION 1 – AUTHOR RESPONSE

Reviewer: 1

Dr. Kate Pickett, University of York

Comments to the Author:

This is a complex study of racial/ethnic disparities in maternal health, where the complexity, admirably, arises from the application of a full socio-ecological framework. This does, however, make the protocol lengthy and dense, and the study design could probably be usefully represented by a figure. The current Figure 1 is simplistic and says nothing more than that the issue is being considered- within a multilevel context and Table 1 simply lists data sources in relation to study objectives. A more thorough diagrammatic representation of the study design would be a lot more helpful for the reader and could replace both Figure 1 and Table 1. This would also help to show how the qualitative work is integrated with the quantitative work within the design.

Response: Thank you for the positive comments. We really liked the idea of using a figure to present our study design (See new Figure 2). We also revised our conceptual framework to reflect the complexity of a full socio-ecological framework used in this study (see new Figure 1). The elements in original Table 1 were merged into new Figures 1 and 2. We found it more informative and clear to illustrate conceptual framework and study design in separate figures rather than in one figure as suggested. Due to these changes, our texts were updated accordingly. Changes were made on Page 6 and old Table 1 on Page 13 was deleted.

Reviewer: 2

Dr. Helen Bailey, Universite Paris Descartes, Telethon Kids Institute

Comments to the Author:

Thank you for the opportunity to review this protocol which deals with an important topic – racial/ethnic disparities in health-related outcomes, using a mixed methods approach. For this study, the outcomes of interest will be severe maternal morbidity and mortality (SMMM) (with and without concurrent COVID). The investigators plan to use two sources 1) existing South Carolina birth cohort (all births 2018-21) (S3C) which links a wide range of administrative data) and 2) electronic health records of pregnant women in the National Cohort Collaborative (N3C) as well as the quantitative analyses, there will also be qualitative part of the study (interviews of mothers and care providers).

Response: Thank you for the positive comments about the importance of this study.

The protocol is well-written and clear so I only have a few suggestions.

1) It would be useful to put the numbers from the Power and Sample Size calculations into a flow diagram (expected numbers from each of the data sources- subdivided by race and COVID period status and with and without SMMM).

Response: Thank you for the thoughtful comments. Because the power and sample size calculations section is a required component by the journal, we still keep this section. Figure 2 illustrates the study

design as suggested by reviewer 1. Currently, we are still in the process of obtaining linked databases for the year 2021 and coding variables (e.g., SMMM). With the integration of multiple databases, it is not feasible to provide the expected sample sizes by race, COVID periods, and SMMM. The expected total sample sizes for S3C, N3C, SC PRAMS etc. are provided. (See Pages 8, 9, 17).

2) Since the investigators are basing SMMM on the validated CDC algorithm (Ref 37), have they considered using an obstetric comorbidity algorithm¹ which is also based on ICD-CM diagnosis codes to more systematically identify maternal pre-existing and pregnancy complications?

1. Leonard SA, Kennedy CJ, Carmichael SL, Lyell DJ, Main EK. An Expanded Obstetric Comorbidity Scoring System for Predicting Severe Maternal Morbidity. *Obstet Gynecol.* 2020; 136:440-449 [PubMed](#) .

Response: Thank you so much for this insightful comment. For our S3C database, which has ICD-CM diagnosis codes, we will use the newly developed obstetric comorbidity scores (Leonard S et al. 2020) to better understand our study populations. We have included this as one maternal-level clinical indicator in our multilevel conceptual framework (Page 6).

VERSION 2 – REVIEW

REVIEWER	Pickett, Kate University of York, Health Sciences
REVIEW RETURNED	12-May-2022

GENERAL COMMENTS	The revisions to the paper, in particular the addition of Figure 2, have greatly enhanced the clarity of the protocol.
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REVIEWER	Bailey, Helen Curtin University, Curtin Medical School
REVIEW RETURNED	09-May-2022

GENERAL COMMENTS	Thank you for the opportunity to re-review this protocol. The new Figure 2 is useful, but would be improved with the addition of the estimated size from each cohort. This would save the reader searching through the dense text to find them. I think that the author misinterpreted my comments re the Power and Sample Size calculations. I did not mean to delete this section, but rather to complement it with a figure summarising the assumptions about sample size, racial mix, COVID and SMMM (much easier for the reader).
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VERSION 2 – AUTHOR RESPONSE

Reviewer: 2

Dr. Helen Bailey, Curtin University, Telethon Kids Institute Comments to the Author:

Thank you for the opportunity to re-review this protocol.

The new Figure 2 is useful, but would be improved with the addition of the estimated size from each cohort. This would save the reader searching through the dense text to find them.

Response: Thank you for the great comment. The estimated or planned sample sizes for each study population was added to Figure 2.

I think that the author misinterpreted my comments re the Power and Sample Size calculations. I did not mean to delete this section, but rather to complement it with a figure summarising the assumptions about sample size, racial mix, COVID and SMMM (much easier for the reader).

Response: Sorry for the misunderstanding. The power and sample size calculations are kept in the paper. The estimated sample sizes were added to Figure 2. At this stage, we can't provide the sample sizes by race, COVID and SMMM status etc.

Reviewer: 1

Dr. Kate Pickett, University of York

Comments to the Author:

The revisions to the paper, in particular the addition of Figure 2, have greatly enhanced the clarity of the protocol.

Response: Thank you so much for the insightful comments.

COI statements:

Reviewer: 2

Competing interests of Reviewer: Nil

Reviewer: 1

Competing interests of Reviewer: NA