Author’s response to reviews

Title: The Association between Gestational Weight Gain Z-Score and Stillbirth: A Case-Control Study

Authors:
Cassandra Gibbs Pickens (cassandra.pickens@gmail.com)
Carol Hogue (chogue@emory.edu)
Penelope Howards (phoward@emory.edu)
Michael Kramer (mkram02@emory.edu)
Martina Badell (mbadell@emory.edu)
Donald Dudley (DD7SS@hscmail.mcc.virginia.edu)
Robert Silver (bsilver@hsc.utah.edu)
Robert Goldenberg (Rlg88@columbia.edu)
M. Halit Pinar (hpinar@brown.edu)
George R Saade (gsaade@utmb.edu)
Michael W Varner (michael.varner@hsc.utah.edu)
Barbara Stoll (Dean.Stoll@uth.tmc.edu)

Version: 1 Date: 10 Jul 2018

Author’s response to reviews:

Thank you for the opportunity to revise my manuscript. My replies to each inquiry are below. In addition, I tracked changes in the manuscript text.

Question 1: Please confirm whether the consent was written or verbal in the Ethics Approval and Consent to participate section.
Response 1: Consent was written. I added the following sentence to the 'Ethics Approval and Consent to Participate' section, as well as the methods section (please see tracked changes): "Written informed consent was obtained from participants or from their legal guardians (if participants were minors)."

Question 2: Please also clarify whether any of the participants involved in your study were under the age of 16. If so, please clarify whether written or verbal consent was obtained from a parent or legal guardian on behalf of the participants under the age of 16. If the need for parental consent was waived by an IRB or national guidelines indicated that it is not needed in the case of adolescent mothers, please clearly state this in this section.

Response 2: There were some participants <16 years in this study, and legal guardians provided written informed consent on behalf of minors. (Note that the definition of 'minor' may vary by state.) I added the following sentence to the end of the methods section and to the 'Ethics Approval and Consent to Participate' section (please see tracked changes): "Written informed consent was obtained from participants or from their legal guardians (if participants were minors)." I also added the following information to the methods section: "Women had to be ≥13 years of age to participate."

Question 3: Please include an ethics and consent statement in the methods section of your manuscript.

Response 3: I added an ethics and consent statement to the end of the methods section (please see tracked changes). It reads: "This study was reviewed and approved by the Institutional Review Boards of each of the participating sites (Brown University, Emory University, University of Texas Health Science Center at San Antonio, University of Texas Medical Branch at Galveston, University of Utah) and by the data coordinating center (RTI International). Written informed consent was obtained from participants or from their legal guardians (if participants were minors)."

Thank you for your patience and consideration,

Cassandra Pickens