Author's response to reviews

Title: The Study of Women, Infant Feeding and Type 2 Diabetes after GDM Pregnancy and Growth of Their Offspring (SWIFT Offspring Study): Prospective Design, Methodology and Baseline Characteristics

Authors:

Erica P Gunderson (erica.gunderson@kp.org)
Shanta R Hurston (shanta.r.hurston@kp.org)
Kathryn G Dewey (kgdewey@ucdavis.edu)
Myles S Faith (mfaith@email.unc.edu)
Nancy Charvat-Aguilar (Nancy.Charvat-Aguilar@kp.org)
Vicky C Khoury (vickykhoury@gmail.com)
Van T Nguyen (Van.T.Nguyen@kp.org)
Charles P Quesenberry Jr (cpq@dor.kaiser.org)

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Editorial Board
BMC Public Health Journal

Subject: Submission of an original manuscript – Study Protocol

Dear BMC Public Health Editors,

Please find enclosed the manuscript entitled “The Study of Women, Infant Feeding and Type 2 Diabetes after GDM Pregnancy and Growth of Their Offspring (SWIFT Offspring Study): Prospective Design, Methodology and Baseline Characteristics” for your consideration for publication in the BMC Public Health Journal. All co-authors have revised and agree with the contents of the manuscript and there is no financial interest to report. We certify that the submission is original work and is not under review at any other publication.

This manuscript submitted details the study protocol for the prospective cohort study funded by the American Diabetes Association. The study tests the hypothesis that intensive breastfeeding as compared to intensive formula feeding slows infant growth during the first year of life among offspring born to women with recent gestational diabetes mellitus (GDM). The study is unique in being the first, prospective study to enroll mother-infant pairs with recent GDM and measure their growth from birth to one year of age with the goal of evaluating the independent relationship of infant feeding methods to overall growth and adiposity of GDM offspring. The SWIFT offspring cohort is comprised of health plan members who were diagnosed with GDM via standardized criteria, had singleton, term births, and agreed to three in-person study exams. The cohort comprises the most diverse multi-racial and ethnic sample to date, and utilized quantitative methods to assess infant feeding and other behaviors.

In this manuscript we describe the study design and methodologies implemented for this study to prospectively gather data on anthropometry, breastfeeding, socio-demographics and behaviors among GDM offspring and the parents. The specific study instruments developed for the offspring cohort are described, including the quality control and data collection procedures. We also provide data on the baseline characteristics for the 462 mother-infant GDM pairs enrolled in the study from 2009-2011 and followed through 2013.

We believe that the description of our study protocol and the cohort characteristics will be of intense interest to BMC Public Health Journal readers because this manuscript includes an updated and comprehensive literature review, detailed assessments of methods for the main exposure (infant feeding), perinatal attributes, and numerous potential confounders that have not been assessed in previous studies of breastfeeding and future health of GDM offspring. This study is likely to have important public health implications about the role of breastfeeding in diabetes and obesity prevention in high-risk infants who were
exposed to maternal diabetes in utero. The study findings are likely to have important policy implications for optimal health and diabetes prevention in the offspring of mothers with diabetes.

All authors have fully participated in the conception and design, or analysis and interpretation of data, drafting the article or revising it critically for important intellectual content, and final approval of the version to be published. Dr. Quesenberry discloses a conflict of interest as he has received research funding, also unrelated to the current study, from pharmaceutical companies (Takeda, Merck & Company, Inc., Sanofi-Aventis, Lilly, Genentech, Valeant and Pfizer). There are no conflicts of interest to disclose for any other authors for this manuscript.

The SWIFT Offspring Study received approval from the Kaiser Permanente Northern California Institutional Review Board, and participants provided written informed consent for all study procedures.

Please contact Dr. Erica Gunderson, corresponding author, at Erica.Gunderson@kp.org or 510-891-5917 with any questions regarding this submission. Thank you again for your consideration of our manuscript for publication.

Yours sincerely,

Dr. Erica P. Gunderson, PhD, MS, MPH
Senior Research Scientist,
SWIFT and SWIFT Offspring Studies, Principal Investigator
Cardiovascular and Metabolic Conditions Section

Kaiser Permanente Northern California
Division of Research
2000 Broadway
Oakland, California 94612