Response to outcomes from the Centers for Disease Control and Prevention 2018 breastfeeding report card: Public policy implications

To the Editor:

Thank you for publishing content highlighting the importance of evaluating breastfeeding programs and policies. We wish to raise several methodological concerns with the recent analysis[1] of the Center for Disease Control and Prevention's (CDC) breastfeeding report card data[2] and percent Baby Friendly Hospital Initiative (BFHI) births.[3]

Bass et al used the percentage of BFHI births in 2016 to predict 2015 breastfeeding outcomes.[1] We instead used predictor data from 2014 and found that the percentage of BFHI births was significantly and positively associated with all 4 long-term breastfeeding outcomes (LTBFOs).[4]

Delaware and Rhode Island, 2 small states with fewer than 7 birthing hospitals each, drove the lack of association found by Bass et al. We ran a sensitivity analysis excluding these 2 states and found significant positive associations between 2016 percent BFHI births and 2 of the 4 LTBFOs.[3]

Ecological fallacy occurs when individual-level inferences are made based on group-level analyses.[5] Despite the authors' claim, they did not address this issue. The only way to avoid ecological fallacy for inferences on individuals is to conduct an individual-level analysis. An individual analysis of BFHI hospital birth and LTBFOs is possible but must be conducted internally at the CDC because of privacy concerns.

The authors did not use weighting in their regression models. Each state was treated the same despite a wide variation in the number of births; for instance, California (491 748 births in 2015) was treated as equivalent to Wyoming (7765 births in 2015).[6] After repeating their analysis with inverse-variance weighting using 2014 predictor data, we found significant positive associations between the percentage of BFHI births and all LTBFOs.[2,4,7]

We support critical, evidence-based evaluation of policies and programs designed to increase breastfeeding, such as BFHI. However, we suggest that the results of the article by Bass et al contain weaknesses and should not serve as a basis for making broad policy decisions.

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Reply

To the Editor:

We appreciate the opportunity to respond to the thoughtful comments on the methodology that we used in our analysis of breastfeeding outcomes and their relationship to the designation as a Baby Friendly Hospital. The authors state that they performed alternative analyses using the 2014 birth cohort and weighted regression, as well as sensitivity analysis of the 2016 births, and obtained results that differ from ours.

As we explained in our article, the 2018 CDC Breastfeeding Report card is based on the 2015 birth cohort.[1] Because there is no published 2015 report card, we used the 2016 birth cohort because it includes all the 2015 Baby Friendly–designated facilities, as well as those that were in the final stages of designation. Our use of the 2016 birth cohort thus provided a greater opportunity for all facilities participating in Baby Friendly designation to show a positive impact on outcomes. This was an important consideration, given the

implementation during that same time period of 2 major federal initiatives, including the Best Fed Beginnings Program, in which Louisiana (the authors' home state) participated. In 2016, 18.6% of US births occurred in Baby Friendly facilities, including 2 states with >85% Baby Friendly penetrance.[2] In contrast, in 2014, only 7.79 % of births occurred in Baby Friendly facilities, with the highest penetrance of 35.98% in a single state.[3] Therefore, we feel that using of that 2014 birth cohort for this analysis lacks construct validity. Of note, the breastfeeding initiation rates in 2014 and 2016 were quite similar (79.2% and 81.1%, respectively), and the outcomes that the authors noted may simply reflect the positive results of breastfeeding initiation, consistent with our conclusions.

The authors note that we did not use population weighting in our regression analysis but instead treated each state equally. Given the unique and heterogeneous characteristics of the individual states, including their demographics and coexisting programs for support of breastfeeding, weighting by population would erroneously diminish the impact of those important differences. The authors also performed a sensitivity analysis, excluding Delaware and Rhode Island, the 2 states with >85% Baby Friendly penetrance, treating these as outliers. We suggest that this is not appropriate, because these states, which are the least subject to the ecological fallacy and thus have the greatest relevance to the results, should be included for subgroup analysis, as we reported.

The authors also dismiss our use of an ecological design to address the relationships that we examined. We disagree, and note that this method is considered particularly applicable to the evaluation of public health strategies when obtaining individual data may be impractical.[4] There are many historical examples of important and unanticipated results that have come to light from such studies. We agree that the issue of the ecological fallacy is a limitation; however, there are accepted methods to diminish the impact of that limitation,[4] including multiple comparative regression analytics, subgroup analysis of groups with high factor penetrance, and contextual examples of alternate analyses and contemporary approaches, all of which we included to support our findings and confirm that Baby Friendly designation might not be the optimal approach to achieving the US Healthy People 2020 postdischarge breastfeeding objectives.

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Synthetic surfactant CHF5633 vs poractant alfa

To the Editor:

In a recent trial, Ramanathan et al claimed that the efficacy and safety of the new synthetic surfactant (CHF5633) were equivalent to that of poractant alfa.[1] However, closer analysis reveals that for several important clinical outcomes, the 95% CI indicates that there could be a significant benefit but also considerable harm from CHF5633 compared with poractant alfa.[2] For example, compared with poractant, the relative risk of death at 28 days of life with CHF5633 was 65% lower to 509% higher. Using absolute values, the results indicate that CHF5633 may reduce deaths by up to 7 deaths per 100 babies (best-case scenario) or increase deaths by up to 11 deaths per 100 babies (worst-case scenario). These results do not allow us to differentiate between the equivalence of the 2 surfactants or the noninferiority of CHF5633.[2]

The authors claim equivalence when there is a possible type II error. They did not calculate a sample size, stating that this was not required because this was an exploratory trial. If this was truly an exploratory trial, the authors firm conclusion that "CHF5633 is as effective and as safe as poractant alfa" is unjustified. Also, we are not aware of any reason, even in a phase II or exploratory trial,[3] to omit a sample size calculation, and not aim to recruit the optimal number of patients.[4] Without a sample size calculation, how did the authors decide to stop recruitment after enrolling 126 neonates?

We caution readers not to draw any definitive conclusions about the relative efficacy or harm of either surfactant from this trial. We hope that the authors will conduct a larger trial of these 2 surfactants designed to demonstrate superiority, noninferiority, or equivalence to draw some definitive conclusions.

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