Reviewer's report

Title: Potential Impact of Variation in Classification of Live Birth with Early Neonatal Death versus Fetal Death on Reported Infant Mortality Rate

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Reviewer: Michael Kramer

Reviewer's report:

This manuscript reports the study of hospital-level variation in the ratio of fetal deaths (stillbirths) to first-day neonatal deaths in North Carolina from 1995 to 2000. The study makes a useful contribution to the existing literature of registration and classification of births near the borderline of viability. Comparisons have previously been made among countries and, within the United States, among states. This study focuses on variations among hospitals within a single state, and the authors observe substantial differences in different groups of hospitals. These results suggest the influence of a local “culture” as to which births are registered and how those births are classified (stillbirths vs live births).

Major compulsory revisions

In my view, the major weakness of this study is the fact that it is based on data from 1995 to 2000. These data are thus older than the two references cited in the last paragraph of the Introduction. The authors’ only justification for using such old data is their claim (last sentence of the same paragraph) that “Prenatal and delivery room care of fetuses and newborns at the border of viability has been largely unchanged since the years in which the study data were collected, and no change has been made in definitions for fetal and infant death.” But registration and classification of these infants may well have changed over time, and therefore it is unclear whether the large variations reported among hospitals are still present in North Carolina. Moreover, increasing trends of prenatal diagnosis and early termination of fetuses with congenital anomalies may well have impacted more recent data. Finally, the authors do not state whether birth weight and/or gestational age guidelines for registration of stillbirths and/or live births have changed since year 2000, nor even whether the numbers and rates of stillbirths and live births registered have changed since then.

In the second paragraph of the Methods (the lack of page numbers in this manuscript is extremely reviewer-unfriendly!), the authors mention four groups of hospitals for purposes of comparisons within the study. In the legend to Table 2, the authors provide very complicated reasons for their grouping, but some of these reasons suggest that the grouping was determined post hoc, i.e., after data analysis. If so, that would seriously bias the selection of the groups in a way that would heighten the observed contrasts. Moreover, it is not clear whether the comparisons made are as useful as they could be. The authors should justify the grouping they have chosen and explain why the differences in registration and/or
classification of stillbirths and live births were expected to differ among the four
chosen groups.

In the copy of the article that I received, Table 1 was included as an “additional
file.” It is unclear if this was an administrative error or if there is some reason for
not including Table 1 in the main paper. In any case, the most important data
reported are near the end of Table 1: the geographic variation among birth
hospitals. These data are too detailed to be digestible, and I strongly advise the
authors to present these data in graphic format instead of a table.

Minor essential revisions

1. Please add page numbers.

2. In the second paragraph of the Discussion, the wording of the second
sentence is strange and confusing: “Preterm birth and related diagnoses are
significant causes of infant death, associated with low birth weight and gestation
age….”. It seems rather silly to say that preterm birth is related to low birth weight
and gestational age. Please revise the wording here.

3. At the end of the same paragraph as for #2, a reference is needed to support
the claim made in the last sentence.

4. In the last sentence of the next-to-last paragraph of the Discussion, the
wording is confusing and should be clarified.

5. In the next-to-last sentence of the manuscript, the sentence is confusing. I
assume that fetal and neonatal deaths are already reported based on birth
weight and gestational age. Please clarify.

6. In the last sentence of the manuscript, it is not clear which “new outcome
measures” the authors would like to see that combine fetal death and neonatal
death beyond 20 weeks. This is the conventional definition of perinatal mortality.
What else are the authors calling for here?

Level of interest: An article of importance in its field

Quality of written English: Needs some language corrections before being
published

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

I declare that I have no competing interests.