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: Lucy Smith

Reviewer’s report:

This is a very well written paper, exploring an extremely important area, namely the impact of variation in the classification of births as live or fetal deaths. This has major implications in terms of comparing mortality rates at regional and international levels.

Major revisions

However there are limitations to the analyses performed. The methods are clearly defined and easy to read but would considerably benefit from the use of multilevel models to analyse the data. Ordinary (single level) logistic regression is usually inappropriate for births-within-hospital outcomes because this assumes all births are independent. However births within a given hospital tend to be more similar than births from different hospitals, both in terms of those characteristics that predict outcome, some of which can be measured e.g. gestation and some that can’t be measured. Furthermore, at the hospital-level, the implementation of specific protocols such as treatment protocols for <24 week gestation births are likely to result in less heterogeneity in the care following delivery at a particular hospital. If the clustering present in multilevel data is ignored, as happens when performing ordinary logistic regression, this will result in an over inflated number of independent observations at the hospital level of the hierarchy, and consequently this is likely to underestimate the magnitude of the standard error for the effect of hospital-level characteristics. If multilevel statistical techniques are used which have been developed to deal with data arranged in a natural hierarchy, this will provide more reliable estimates of the standard errors.

Birth weight was used in preference over gestation in the analyses as there was a small amount of missing gestational age data. However it is much more likely that decisions are made based on gestational age rather than birth weight at delivery as live birth and stillbirth registrations are generally defined based on gestational age (Joseph et al BMJ. 2012; 344: e746). It is extremely likely that the variation will depend on the proportion of extremely preterm births in each hospital (Smith et al Arch Dis Child Fetal Neonatal Ed. 2013 Mar;98(2):F103-7). By performing the analyses on gestational age bands and assess whether between hospital variation was similar for all gestational ages or this could be further explored or in a multilevel model gestation could be included as a hospital level factor to allow for differences in gestational age structure between hospitals.

If these issues were addressed this would be an extremely important paper.
Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: Yes, and I have assessed the statistics in my report.

Declaration of competing interests:

'I declare that I have no competing interests’