Reviewer's report

Title: Laboratory Testing and Diagnostic Coding for Cytomegalovirus among Privately Insured Infants in the United States: a Retrospective Study using Administrative Claims Data

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Reviewer: Sheetal Manicklal

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The study by Leung et al. attempts to address an important gap in our knowledge of the disease burden from symptomatic congenital CMV infection in the U.S. To this end, the use of a medical claims database is an interesting approach, and provides insight into whether CPT codes could reflect the true disease burden. This is clearly of interest to public health officials as well as clinicians as there is no routinely collected field data to monitor the detection of congenital CMV in the U.S. However, there are major limitations and weaknesses to the study and the authors' interpretation of the findings. These include:

1. The sensitivity of this approach of analyzing a claims database is not known and cannot be ascertained from the design of this study.
2. Most of the clinical findings are non-specific and in the absence of laboratory confirmatory data (gold standard for diagnosis) linked to the codes, it is not known whether infants may have been misclassified or have had other conditions/diseases with similar clinical findings.
3. The fact that there was a tenfold difference between the observed rate of symptomatic infection using claims data and the expected rate is unlikely to be explained mainly on the basis of the characteristics of the population or low awareness among clinicians, and suggests the claims data is highly insensitive for ascertaining actual prevalence and disease burden. This is further supported by the fact that the claims data shows more than 100,000 infants had symptoms suggestive of congenital CMV but a lab test was only associated with around 200 of them.
4. Although one can conclude based on the findings that the rates of CMV-specific testing in infants is very low, it is impossible to determine the causes for this.
5. The conclusion that low rates of CMV testing suggests gaps in knowledge and/or awareness is purely speculative. Given the limitations of the study and perhaps the low sensitivity of this approach, it is equally possible that the findings indicate flaws in the study design and that the objectives of the study are not achievable by the analysis of such databases rather than gaps in knowledge/awareness. Therefore, the authors should revise the conclusion section of the abstract and the discussion.
6. The authors suggest validation of the claims data but the findings of this study
suggest that it is unlikely that claims data could be shown to be valid for clinical activities. Therefore, this approach would have to be coupled with ongoing prospective monitoring of the quality of data.

7. As the authors have pointed out, the increased practice of bundling of services may have led to incomplete coding. Therefore, not all laboratory tests may have been coded separately for billing.

The authors have pointed out the need for further research but they have not proposed how to address this issue. Only prospective studies will provide data on the true disease burden. The apparent problems with using claims data as a surveillance method serves to strengthen the case for routine national virologic screening of newborns, and this should be highlighted.

**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Acceptable

**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