Reviewer’s report

Title: Medication exposure during pregnancy: a pilot pharmacovigilance system using health demographic surveillance platform

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Reviewer: Ushma Mehta

Reviewer’s report:

Mosha and colleagues have submitted a convincing manuscript that shown the value of HDSS sites as settings for pregnancy pharmacovigilance systems in resource limited countries. However, the impressive follow-up rates and systematic prospective collection of validated drug information suggest that it may not be entirely representative of non-HDSS African settings where home-based deliveries account for more than 40% of all deliveries and where access to quality maternal and newborn care and treatments are not reliable. Regardless, the authors are congratulated for this impressive achievement.

- Minor Essential Revisions

To my understanding the previous reviewers are not asking for a famously invalid “post hoc power calculation using their actual data” but is simply asking for a conventional power calculation using effect sizes and precision. The wording of the objective does not seem amenable to a power calculation. Moreover, it seems to me that the main objective of this study is to pilot a pharmacovigilance system for pregnant women in an African setting – I would therefore suggest that the authors delete the last 3 sentences in the “sample size” section from “To comply with....” As it is irrelevant both to the initial reviewer’s request as well as to the manuscript.

The discussion should more explicitly state some of the limitations and challenges of the study such as – whether the HDSS cohort is representative of the national population, the possibility of recall bias for drug exposures given that two-thirds of the sample was only recruited in the second trimester and the challenge of achieving a sample size that would be adequate for detecting even a 10-fold increase in risk of a particular congenital anomaly in HDSS settings.

The authors raise the issue of cost of different approaches in their discussion but do not address this issue in terms of their own approach..

The methods should mention how newborns were examined and assessed, particularly for congenital anomalies and how exposures reported by women were verified at the facility level. Was any training done or dedicated staff employed at the health facilities to improve recording of medication use and to standardize maternal and neonatal assessment and clinical record-keeping of these assessments?
Level of interest: An article of importance in its field

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

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

Declaration of competing interests:

I have no conflicting interests to declare.