Reviewer’s report

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

Version: 6 Date: 4 September 2014

Reviewer: Stephanie Dr Dellicour

Reviewer’s report:

I thank Mosha and colleagues for the reply to my comments. I have a few minor comments:

Minor Essential Revisions

i. In the abstract and introduction please revise the sentence “The aim of the present study was to demonstrate feasibility of using Health and Demographic Surveillance System (HDSS) as a platform to monitor drug safety in pregnancy and its relation to pregnancy outcome.” The last part of this sentence needs to be reformulated as it isn’t clear (“its relation to pregnancy outcome”)

ii. The method section on Study design and population would benefit from subheadings (for example: enrollment; follow up and pregnancy outcome ascertainment; drug exposure and illness ascertainment; gestational age assessment).

iii. Some of the previous comments have not be addressed adequately as detailed below:

2.4.1 Provide information on how you chose the covariates for the adjusted models (i.e. which other covariates did you assess for potential confounding?)-the revised text does not provide details on the covariate selection procedures for the final model.

2.4.2 Did you consider potential confounding by indication? The author did not address the question of confounding by indication (where the disease for which the drug of interest was taken can cause the adverse effect itself).

4 In the result section (including the result section in the abstract): there is a need to be cautious with the interpretation of the analysis looking at antimalarial and antibiotic exposures in pregnancy. The effect estimates (i.e. odds ratio) the study was powered to detect or exclude is not provided- this would need to be specific by trimester of pregnancy since different adverse effect are expected for exposures in 1st versus 2nd /3rd trimesters.

5.1 Information on drug exposure: mean gestational age at enrollment was 14 weeks and information on drug used prior to enrollment was self-reported by the participants. Although the authors included some text regarding limitation than didn't include information on the reliability of self-reported information for the
early weeks of pregnancy before enrollment in the study. This is important to include as exposures in the 1st trimester is of most concerns due to organogenesis and potential for exposure misclassification needs to be addressed.

7 Under “Study design and population” P.4, please spell out the FDA drug categories as not all readers will be familiar with this. Although a sentence has been added in the method section this doesn't describe the actual FDA categories- I would suggest to include a table describing each category.

**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 declare that I have no competing interests