Author’s response to reviews

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

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Our manuscript on pregnancy pharmacovigilance (PV) system in resource-limited countries is of a great public health importance. Safety of some of therapies is unknown during pregnancy for the reason that pregnant women are not involved in clinical trials related to drug development process and hence, most pharmaceutical products come to market with little human data available regarding safety in pregnancy.

Active (PV) system, an important mechanism to monitor safety of drugs which are already in the market does not exist in almost all developing countries. It is of more concern for medicines against tropical diseases which are highly used in developing countries as opposed to developed countries where effective PV system in pregnancy is in place.

There are many complexities which may be responsible for difficulties in establishing effective and reliable PV system in developing countries. However, there are a lot of contraindicated drugs in pregnancy which are still used by pregnant women. It is therefore important to take advantage of these inadvertent exposures to study medicines safety among pregnant women in relation to pregnancy outcome.

Little has been documented to address the solution to this problem. To our knowledge there is no convincing published documentation to date that demonstrates a feasible, reliable and manageable solution to this problem in developing countries. Our manuscript justifies the feasible of having active PV system which may be easily manageable and produce reliable safety data pool in pregnancy. The study findings from this pilot PV system show the magnitude of different medicine exposure among pregnant women in the country as may apply to other sub-Saharan African counties. The results have also been presented
according to their pregnancy drug risk categories in relation to pregnancy and birth outcomes.