Reviewer's report

Title: The impact of HBV or HCV infection in a cohort of HIV-infected pregnant women receiving a nevirapine-based antiretroviral regimen in Malawi

Version: 1 Date: 28 September 2013

Reviewer: Claudia A. Hawkins

Reviewer's report:

Strengths: well written paper, provides data on HBeAg/Ab and HBV DNA which is seldom performed in these settings, also provides somewhat encouraging data supporting the use of NVP in pregnancy at all CD4 levels in places where alternative PI based regimens are not readily available. Even though an association was found between CD4>250 and grade >=2 hepatotoxic events, the number of events were v. small.

Major comments:
1. The numbers of patients with viral co-infection very small making results difficult to interpret and draw conclusions from. The effect of viral co-infection on any ALT outcome only marginally significant and most other results are ‘over-interpreted’. For instance there was no significant different in virologic outcomes (p=0.1) between co-infected and mono-infected patients and I would disagree with the statement of a ‘trend towards lower…’ in the text of the results.  
2. No molecular methods used to determine whether HCV infections were active or past. A previous study of Malawian HCV ab+ pregnant patients found no detectable HCV RNA in any of the patients [1]. Unless the authors have HCV RNA results on these HCV ab+ patients, I would consider excluding.
3. Adherence to therapy is not addressed- did the significant association between co-infection on hepatotoxicity at 6 months correlate with any interruptions to therapy (ie. hepatitis flares). On that same note, it is not clear which patients or how many stopped therapy after 6 months post partum. Can the authors comment on whether there are any guidelines that recommend ART continuation HIV/HBV co-infected patients post-partum (given the risk for hepatitis flare and death with discontinuation)
4. In the results it would be interesting to show how liver enzyme elevations correlated with HBV DNA – if longitudinal measurements of the latter are available.

Minor comments:
1. Abstract: background is not clear on whether studying effects of viral coinfection or hepatotoxic drugs and what the outcome being studied is. The more interesting findings (effect of HBV DNA) are not presented in the results. The conclusions mention an protective effect of nevirapine on outcome (liver toxicity) yet this are not in the results (of the abstract or the main text).
2. second sentence of background needs editing….’…..,being HCV’ doesn’t make sense.
3. was AST also run –in the methods the authors mention ‘liver enzymes’ were tested
4. the second paragraph under ‘viroimmunologic response’ and second sentence of first paragraph seem to be referring to the same population, but findings are different-clarification needed
5. in discussion – unfrequent should be infrequent
6. ? significance of third paragraph of discussion (seems to contraindicate the second paragraph above)- suggest removing
7. not sure how the second paragraph of conclusion relates to the study- this study did not focus on specific HBV regimens or the effect of them on HIV or HBV outcomes.
8. the discussion is missing a limitation section.

References

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.