Reviewer's report

**Title:** Primary and booster vaccination in Latin American children with a DTPw-HBV/Hib combination: a randomized controlled trial

**Version:** 3  **Date:** 16 April 2010

**Reviewer:** Giovanni Gabutti

**Reviewer's report:**

The paper is interesting and sufficiently original. English is appropriate. The question posed by authors is well defined. The authors should declare when the study has been performed.

Concerning methods, even if these are appropriate and well described, a comment on samples seronegative for anti-diphtheria antibodies by ELISA should be included at least in the Discussion section. Were these samples retested with an in vitro neutralization assay on Vero cells? If not, how should be considered samples ELISA negative?

Concerning Statistical analysis, the last paragraph in page 8 and the last but one in page10 should be included in the discussion section.

Concerning Results section, in page 11 line 10 it seems that GMCs for anti-tetanus antibodies should be included. As a general comment on the results section, it should be clearly stated if any difference in GMCs is statistically significant.

In page 11 line 18 it is written that 32.7% and 36.4% of subjects remained seropositive for anti-BTP antibodies but these data are not included in table 1.

In table 2 data for rectal temperature post primary dose regarding any temperature and >38°C are the same; does it mean that all rectal temperatures were >38°C or is it a mistake?

Considering that one of the co-primary objectives of the study was to demonstrate lot-to-lot consistency a more detailed explanation of results and a comment in the Discussion section should be included.

Limitations of the study should be clearly stated in the Discussion session.

In the Abstract, page 2 line 16, 97.7% should be corrected in 97.3%

These major compulsory revisions should be addressed.

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

**Quality of written English:** Acceptable

**Statistical review:** Yes, and I have assessed the statistics in my report.
Declaration of competing interests:

I declare that I have no competing interest