Reviewer’s report

Title: The Immunogenicity, Safety, and Consistency of an Indonesia Combined DTP-HB-Hib Vaccine in Expanded Program on Immunization Schedule

Version: 6 Date: 18 August 2015

Reviewer: Marina Ulanova

Reviewer's report:

The manuscript presents data of a prospective, randomized, double blind, multicenter phase III clinical trial of 3 batches of a combined DTP-HB-Hib vaccine to be implemented for routine pediatric immunization in Indonesia. The study is relevant for informing immunization providers in this country and appropriately conducted.

- Minor Essential Revisions

The authors should use some terminology more accurately. For example, they use titers and GMT to describe all the findings, both titers (antibody against pertussis) and concentrations (antibody against diphtheria toxoid, tetanus toxoid, HBsAg and PRP). As titer and concentration are not equivalent the authors should change their denominations throughout the manuscript and use GMC rather than GMT while describing the antibody to diphtheria toxoid, tetanus toxoid, HBsAg and PRP.

Line 133: It is unclear what “Phipps ELISA” means and the authors should provide an appropriate reference.

Line 292: It is unclear what “p=0.000” means.

Line 309: the authors state that “high maternal antibody titers...were present in all subjects...” but they have not directly studied maternal antibody levels. If they mean transplacentally acquired antibody they should indicate this.

Line 342: they indicate that data for the tested vaccines “were pooled for comparison against the control vaccine”, but no corresponding data are presented and it is unclear what the control vaccine is.

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

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

Statistical review: Yes, but I do not feel adequately qualified to assess the statistics.
Declaration of competing interests:

I have no competing interests in relation to this paper.