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: 21 April 2010

Reviewer: Helen Marshall

Reviewer's report:

This is a well written paper of significant importance in providing data on use of a combination whole cell pertussis vaccine, with particular importance for use in developing countries. I have outlined several comments to authors that will require minor amendments to the manuscript.

Major Compulsory Revisions
1. Abstract should clearly outline the aim/objective of the study
2. Method section, use of the term "single" rather than "partially" blind multicenter study
3. Method section: study design and subjects should describe sample size determination
4. Low number of participants returning for booster vaccination should be explained in the results or discussion section - important to understand whether this was low return number or due to only a few select countries being involved in the booster phase. Inherent biases should be outlined in the discussion section.

Minor Essential Revisions

Discretionary Revisions:
1. Abstract: methods section use term "single" rather than "partially" blind multicenter study
2. Why was the study not double blind? I would expect labelling of the vaccines could have resulted in a double blind study that would be the optimal study design to investigate the safety component of this study.
3. Statistical analysis - first paragraph should be included in background/aims section rather than in statistical analysis section
4. Results section - Immunogenicity, need to indicate in the text where there is a statistically significant difference in GMCs or proportion showing seroprotection between the 2 groups for all results provided
5. Is there any further information about the child who developed an abscess post vaccination - this is very unusual
6. Table 1 and 2 - results that are statistically significant should be highlighted with an asterix in the table for easier review by readers with a note explaining
significance of asterix

**Level of interest:** An article of importance in its field

**Quality of written English:** Acceptable

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

Dr Helen Marshall has received travel grants from GSK and other companies to attend scientific meetings to present independent scientific data. She has been an investigator on vaccine studies and been a member of vaccine advisory boards for GSK and other companies. She has no shares, paid employment or consultancies with GSK or any other pharmaceutical companies.