Reviewer’s report

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

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Reviewer: Noni MacDonald

Reviewer’s report:

While some readers might not see this report of a phase 3 trial of DTP HB HiB vaccine as particularly publishable as many reports of HiB combined vaccine have been published over the past few decades. However, this is an important report as introduction of such combined vaccines in middle and low income countries has on several occasions been accompanied by serious concerns about safety. For example in Sri Lanka- concerns were raised about high rates of HHE- further study showed that HHE had occurred before but was unrecognized. Hence this safety and immunogenicity study is not only important for licensing but also important for future the roll out of the combination vaccine.

1. The article could be strengthened by noting the above point in the introduction- otherwise it becomes just another similar study to many reports over the past two decades. This could also be briefly noted in the discussion- specifically how might address potential for increased recognition and reporting of AEFI that may follow introduction- would phase 4 studies help?- Might be done with effectiveness study component in Phase 4

2. Were Brighton definitions used for side effects? If not why not?

3. Was SAE definition the WHO define- if so say so- or define SAE

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

Quality of written English: Acceptable

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

Declaration of competing interests:

No competing interests