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Synergy of Bacterial Flora in the Nasopharynx: Impact on Prevention Strategies

3.002

Antibody Responses Following Administration of 10-Valent Pneumococcal Non-Typeable *Haemophilus influenzas* Protein D-Conjugate Vaccine (PHiD-CV) in Filipino Infants

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Background: This double-blind, controlled study (107007/NCT00344318) evaluated the immune responses of the candidate vaccine, PHiD-CV (GlaxoSmithKline Biologicals), designed to protect infants against pneumococcal and non-typeable *Haemophilus infiuenzae* diseases, following co-administration with DTPw-HBV/Hib + OPV at 6-10-14 weeks of age (EPI schedule) in the Philippines.

Methods: 400 healthy Filipino infants 6 to 12 weeks of age were randomized (3:1) to receive either PHiD-CV or licensed 7vCRM vaccine (*Prevenar*™/*Prevnar*™) co-administered with DTPw-HBV/Hib + OPV. Vaccine immune responses were assessed one month post-dose III (22F-inhibition ELISA, ELISA, micro-neutralization assays).

Results: For each of the pneumococcal serotypes common between both vaccines, observed percentages of infants with antibody concentration $\geq$0.2 μg/mL were within the same range for both groups (PHiD-CV group: $\geq$91.2%; 7vCRM group: $\geq$86.3%). At least 99.6% of PHiD-CV vaccinees had antibody concentrations $\geq$0.2 μg/mL against pneumococcal serotypes 1, 5 and 7F. Anti-pneumococcal geometric mean antibody concentrations were within the same range for both vaccines except for serotypes 18C and 19F for which higher immune responses were observed in the PHiD-CV group. Moreover, immune responses of all co-administered vaccines were in line with previous observations, with the exception of responses against polio virus types 1 and 3 which seemed lower in the 7vCRM group. Based on these immunogenicity results, PHiD-CV could potentially prevent 79% of IPD in Filipino infants compared to 62% for 7vCRM (abstract# 3.003), reflecting the importance of the additional serotypes (especially 1 and 5) for IPD in the Philippines.

Conclusions: PHiD-CV elicited high immune responses for each of the 10 pneumococcal vaccine serotypes in infants vaccinated according to the 6-10-14 week's schedule. No evidence of negative immunological interference beiween PHiD-CV and co-administered vaccines was observed.

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3.003

Impact Estimate of the 10-Valent Pneumococcal Non-Typeable *Haemophilus influenzae* Protein D-Conjugate Vaccine (PHiD-CV) on Invasive Pneumococcal Disease (IPD) in Middle East and Asian Countries

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Background: The candidate PHiD-CV vaccine (GlaxoSmithKline Biologicals), contains 3 additional serotypes (1, 5, 7F) in comparison to the licensed 7vCRM vaccine (*Prevenar*™/*Prevnar*™).

Methods: Public health impact of PHiD-CV was estimated based on serotype-specific vaccine effectiveness (SSVE) val-

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