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Safety and reactogenicity of the 10-valent pneumococcal non-typeable *Haemophilus influenzae* protein D conjugate vaccine (PHiD-CV) co-administered with DTPa-HBV-IPV/Hib in Vietnamese infants

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Background: Pneumococcal infections are a major cause of infant mortality/morbidity in developing countries. This study assessed the safety and reactogenicity of PHiD-CV (*Synflorix*™; GlaxoSmithKline Biologicals) co-administered with DTPa-HBV-IPV/Hib (*Infanrix hexa*™; GlaxoSmithKline Biologicals) to infants in Vietnam, a developing country setting.

Methods: In this phase III, single centre, open-label study (NCT01153841), infants were randomised (2:1) to receive 3-dose primary vaccination at 2, 3 and 4 months of age with either PHiD-CV co-administered with DTPa-HBV-IPV/Hib (PHiD-CV/Hx group), or DTPa-HBV-IPV/Hib alone (Control group). Solicited and unsolicited adverse events (AEs) (any and grade 3) were recorded within 4 days and 31 days post-vaccination, respectively. Serious AEs (SAEs) were recorded throughout the study. Safety analyses were carried out on the total vaccinated cohort.

Results: Between February and July 2011, 300 infants were enrolled; 298 received between one and three vaccine doses (PHiD-CV/Hx group: n = 199; Control group: n = 99). Within 31 days post-vaccination, 8.2% and 3.0% of overall doses in the PHiD-CV/Hx and Control groups, respectively, were followed by ≥1 grade 3 AE (solicited and/or unsolicited, local and/or general). Within 4 days post-vaccination, the most frequent solicited local symptom was pain (PHiD-CV/Hx group: 48.9% of doses; Control group: 31.0% of doses) and the most frequent solicited general symptom was irritability (PHiD-CV/Hx group: 58.0% of doses; Control group: 40.4% of doses). The most frequent grade 3 local symptom was pain; following 6.5% and 1.0% of doses in the PHiD-CV/Hx and Control groups, respectively. Grade 3 solicited general symptoms were uncommon in both groups (PHiD-CV/Hx group: ≤1.9% of doses; Control group: ≤0.3% of doses). Unsolicited symptoms were reported following 12.3% and 14.8% of doses in the PHiD-CV/Hx and Control groups, respectively. Grade 3 unsolicited symptoms were reported following ≤0.3% of doses; none were considered related to vaccination. Fifteen infants reported ≥1 SAE (PHiD-CV/Hx group: 9/199; Control group: 6/99); none were fatal; none were considered related to vaccination.

Conclusion: A PHiD-CV 3-dose primary vaccination, co-administered with DTPa-HBV-IPV/Hib at 2, 3 and 4 months of age was well tolerated by Vietnamese infants. PHiD-CV reactogenicity was comparable to that observed in other South-East Asian populations.1,2

1Chevallier PIDJ 2009;28:S109-18.
2Kim PIDJ 2011;30:e235-43.

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Assessment of the immunogenicity and safety of Quinvaxem® (DTwP-HepB- Hib) against diphtheria, pertussis, tetanus, hepatitis B and diseases caused by *H. influenzae* among healthy Vietnamese children

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Background: An open, uncontrolled, single center, interventional study, performed between March 2010 and September 2011 in nine villages in Long An province, Vietnam, to assess the immunogenicity and safety of Quinvaxem® (DTwP-HepB-Hib) in 131 healthy children who had not previously received DTP vaccination.

Methods: Subjects received three doses of Quinvaxem® using a 2-3-4 month schedule according to the local EPI. Immunogenicity blood samples were collected at baseline, one month after the third injection and one year after the first injection. Solicited local and systemic adverse events (AEs) and unsolicited AEs were collected by active monitoring up to 30 minutes post-vaccination and at 6, 24 and 48 hours, 3 to 7 days and 28 days.

Results: Seroprotection rates were defined as the percentage of subjects with titers as follows: anti-diphtheria ≥0.1 IU/mL, anti-tetanus ≥0.1 IU/mL, Hib ≥0.15 μg/mL, anti-HBs ≥10mIU/mL, and anti-*B. pertussis* (seroconversion) ≥20 EU/mL or a four-fold increase compared with baseline titers.

One month after the third dose, seroprotection rates for hepatitis B and for diphtheria were both 93.1%, for tetanus 98.5%, for pertussis 99.2% (seroconversion) and for Hib was 100% (≥0.15 μg/mL); 99.2% attained a Hib concentration of ≥1.0 μg/mL. Twelve months after the first vaccination seroprotection rates were lower: hepatitis B 76.7%, diphtheria 88.4%, tetanus 82.2%, Hib 97.7% (≥0.15 μg/mL) and pertussis 49.6% (seroconversion). This decline in immunogenicity is in line with published data and is the reason why some countries opt for a booster dose.

Overall incidence rates of swelling (≥5 mm), redness (≥5 mm), and pain at the injection site were 5.6%, 2.8%, and 4.1%, respectively (for all 392 injections). The incidence rates of systemic AEs were: fever (38–38.9 °C, auxillary) 15.8%, fever (>39 °C) 2.6%, refusal to suckle 2.6%, rash 0.3%, vomiting 1.0%, diarrhea 3.0%, easily irritated 7.9%, persistent crying over 3 hours 0.5%, and drowsiness/sleepiness 0.5%. Eleven serious adverse events were reported, mostly infections of the lower respiratory tract; none were considered related to Quinvaxem®.