IMMUNOGENICITY AND SAFETY OF FULLY LIQUID HEXAVALENT VACCINE GIVEN TO VIETNAMESE INFANTS PREVIOUSLY VACCINATED AT BIRTH WITH HEPATITIS B VACCINE

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Abstract. This open-label, single center, bridging study in Vietnam evaluated immunogenicity and safety of a 3-dose infant primary series and toddler booster vaccination with a fully liquid, hexavalent diphtheria (D), tetanus (T), acellular pertussis (aP), inactivated poliovirus (IPV types 1, 2, and 3), hepatitis B (HB), and *Haemophilus influenzae* type b polysaccharide conjugate (Hib [PRP~T]) vaccine (DTaP-IPV-HB-PRP~T). Participants had previously received a dose of stand-alone HB vaccine at birth per local regulations. After enrollment, participants received a DTaP-IPV-HB-PRP~T infant vaccination series at 2, 3 and 4 months of age (n =354) and a DTaP-IPV-HB-PRP~T booster at 16-17 months of age (n = 349). Immunogenicity was assessed at one month post-infant series, pre-booster and post-booster vaccinations using validated assays and a bridging (non-inferiority) analysis was performed to compare infant series immunogenicity data to historical immunogenicity data following administration at 6, 10 and 14 weeks of age in South Africa. Safety was assessed from parents' reports. Primary series and booster immune responses were high (>94% and >96%, respectively) for all antigens in terms of seroprotection and vaccine response rates, and antibody persistence prior to booster vaccination was also good for all antigens. Comparison to historical data showed non-inferiority of the responses for each antigen. The vaccine was well tolerated with no safety concerns. These data support, following HB vaccination at birth, use of the fully liquid hexavalent DTaP-IPV-HB-PRP~T vaccine in a 2-, 3- and 4-month primary series followed by a booster in the second year of life in Vietnamese infants.

Keywords: booster vaccination, hexavalent vaccine, infant, primary vaccination, Vietnam

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