IMMUNOGENICITY AND SAFETY OF A DTAP-IPV//PRP~T VACCINE (PENTAXIMTM) BOOSTER DURING THE SECOND YEAR OF LIFE IN THAI CHILDREN PRIMED WITH AN ACELLULAR PERTUSSIS COMBINED VACCINE

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Abstract. This study assessed the booster immune response to a pentavalent combination vaccine containing diphtheria, tetanus, acellular pertussis, inactivated poliovirus, and conjugated-Hib polysaccharide antigens, (DTaP-IPV//PRP~T, PentaximTM, an AcXim family vaccine) at 18-24 months of age. Study subjects received a three-dose primary vaccination at 2, 4 and 6 months with a hexavalent vaccine containing the same antigens plus recombinant hepatitis B surface antigen. Antibody concentrations were measured immediately before and one month after vaccination. Reactogenicity and safety were evaluated from parent reports. Before the booster dose, 92.9% of the 156 children included in this study still had anti-PRP antibody titers ≥0.15 μg/ml. Seroprotective concentrations of anti-diphtheria, tetanus and poliovirus antibodies were maintained in 97 to 100% of subjects in the interval between primary and booster vaccination. One month after the booster dose, all subjects had seroprotective anti-PRP (≥1 µg/ml), diphtheria and tetanus (≥0.1 IU/ml) and poliovirus types 1, 2, 3 (≥8 1/dil) antibody levels. At least 92.3% of subjects had 4-fold increases in concentrations of anti-pertussis antigens from pre- to post-booster dose. Geometric mean titers (GMTs) increased from 3.8 to 181.2 EU/ml and from 18.0 to 289.7 EU/ml for anti-PT and anti-FHA, respectively. The anti-PRP GMT increased from 1.6 to 58.0 µg/ml. The pentavalent DTaP-IPV//PRP~T vaccine booster was well tolerated and highly immunogenic, following primary vaccination with a hexavalent vaccine.

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