Immunogenicity of pneumococcal conjugate vaccine formulations containing pneumococcal proteins, and immunogenicity and reactogenicity of co-administered routine vaccines – a phase II, randomised, observer-blind study in Gambian infants

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Objective

Two conserved pneumococcal proteins, pneumolysin toxoid (dPly) and pneumococcal histidine triad protein D (PhtD), combined with 10 polysaccharide conjugates from pneumococcal non-typeable Haemophilus influenzae protein D-conjugate vaccine (PHiD-CV) in two investigational pneumococcal vaccine (PHiD-CV/dPly/PhtD) formulations were immunogenic and well-tolerated when administered to Gambian children. Here, we report immunogenicity of polysaccharide conjugates, and immunogenicity and reactogenicity of co-administered routine vaccines.

Methods

In this phase II, controlled, observer-blind, single-centre study, healthy infants aged 8–10 weeks were randomised (1:1:1:1:1:1) to six groups. Four groups received 3+0 schedule (2-3-4 months [M]) of PHiD-CV/dPly/PhtD (10 or 30 µg of each protein), PHiD-CV, or 13-valent PCV; and two groups received 2+1 schedule (2-4-9M) of PHiD-CV/dPly/PhtD (30 µg of each protein) or PHiD-CV. All infants received DTPw-HBV/Hib and OPV at 2-3-4M, and measles, yellow fever, and OPV vaccines at 9M. We evaluated immune responses at 2.5-9-12M; and reactogenicity 0–3 days post-vaccination.

Results

1152 out of 1200 infants enrolled completed the study. 1M post-primary vaccination, for each PHiD-CV serotype except 6B and 23F, ≥97.4% (3+0 schedule) and ≥96.4% (2+1 schedule) of infants had antibody concentrations ≥0.2 µg/mL. Observed antibody GMCs increased by 1M post-primary vaccination compared to pre-vaccination. Subsequently, GMCs and opsonophagocytic activity titres waned, with an increased post-booster for the 2+1 schedule. Immune responses to protein D and, DTPw-HBV/Hib, OPV, measles, and yellow fever vaccines were not altered by co-administration with pneumococcal proteins.

Conclusion

Immune responses to the 10 PHiD-CV polysaccharide conjugates and co-administered vaccines were not altered by addition of dPly and PhtD.