INTRODUCTION

Nepal introduced PCV10 in 2015 using a unique 3-dose schedule (4-week interval between 2-priming doses; 6 weeks/10 weeks/9 months). A previous Nepal study demonstrated better and longer-lasting immunity after the third dose of a 2p+1 schedule (8-week interval between priming doses; 6/14w/9m) than after the 3p+0 schedule (6w/10w/14w) used in most GAVI countries; both schedules are now WHO-recommended. However, as injectable polio was also being added to Nepal’s EPI schedule at 14 weeks, it was felt that going for a 6w/10w+9m schedule would be programmatically difficult for both parents and vaccinators, so a 6w/10w+9m schedule was chosen.

A single centre open-label, parallel-group, randomised, controlled trial was undertaken to determine whether the 6w/10w schedule is non-inferior to the 6w/14w vaccine schedule, each followed by a booster dose at 9 months of age (9m).

METHODS

- From August 2015 to April 2016, 304 healthy Nepali children were randomised to 2 groups of 152 participants each.
- Blood was collected one month after the PCV10 second priming dose, and pre-post boost at 9 and 10 months of age.
- Serotype-specific antibody concentrations were determined by ELISA using 22F adsorption at a WHO pneumococcal serology reference laboratory.

RESULTS

IgG Antibody Titres ≥ 0.35μg/mL:

- At 9m, the 6w/10w schedule was non-inferior to the 6w/14w schedule for serotypes 5, 9V, 14, and 19F, but not for serotypes 1, 4, 6B, 7F, 18C, and 23F.
- One month after the second dose, the proportion of children above the protective threshold for the 6w/10w schedule was significantly different to the 6w/14w schedule, for serotypes 1, 6B, 18C and 23F.
- One month after the booster dose at 9 months, there was no difference between the two groups for any of the serotypes.

CONCLUSION

- One month after the second dose and at 9 months, the 6w/14w schedule is more immunogenic for some serotypes.
- After the 9 month booster, at 10 months the 6w/10w/9m and 6w/14w/9m schedules are comparably immunogenic.
- The 6w/14w/9m schedule is preferred where delivery logistics allow.

REFERENCE


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