# Comparison of antibody levels for four different immunization schedules for PCVs

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The use of 4 different 13-valent pneumococcal conjugate vaccine immunization schedules in healthy term infants resulted in no statistically significant differences in antibody levels between the infants after the booster dose at 12 months of age for almost all serotypes, according to a study in the September 4 issue of *JAMA*.

"The World Health Organization (WHO) estimated that more than 800,000 children younger than 5 years died from pneumococcal disease in 2000, making it the leading vaccine-preventable cause of death. Since the licensure in 2000 of the first 7-valent pneumococcal polysaccharide conjugate vaccine (PCV) for infants, many countries have added PCV to their existing national immunization programs. As a result, PCV immunization schedules differ between countries with respect to number of doses, age at vaccinations, and intervals between doses," according to background information in the article. "The optimal vaccine schedule for infants should provide maximal, sustained direct and indirect protection against invasive pneumococcal disease while using a minimal number of doses. The latter is particularly relevant in the context of overcrowded national immunization programs, public resistance to vaccines, and cost-effectiveness estimates."

Judith Spijkerman, M.D., of the University Medical Centre, Utrecht, the Netherlands, and colleagues compared immunogenicity of 4 different schedules using the 13-valent PCV (PCV13) to assess the optimal primary regimen with respect to antibody induction. The randomized clinical trial of healthy term infants in a general community in the

Netherlands was conducted between June 2010 and January 2011, with 99 percent follow-up until age 12 months. Infants (n = 400) were randomly assigned (1:1:1:1) to receive PCV13 either at ages 2,4, and 6 months (2-4-6); at ages 3 and 5 months (3-5); at ages 2,3, and 4 months (2-3-4); or at ages 2 and 4 months (2-4), with a booster dose at age 11.5 months.

The researchers found that one month after the booster dose, there were no differences in IgG (Immunoglobulin G) geometric mean concentrations (GMCs) between the schedules for 70 of 78 comparisons. "The 2-4-6 schedule was superior to the 2-3-4 schedule for serotypes 18C and 23F and superior to the 2-4 schedule for serotypes 6B, 18C, and 23F. For serotype 1, the 3-5 schedule was superior to the 2-4-6, 2-3-4, and 2-4 schedules."

Secondary outcomes (GMCs measured 1 month after the primary series, at 8 months of age, and before the booster) demonstrated differences 1 month after the primary series. "The 2-4-6 schedule was superior compared with the 3-5, 2-3-4, and 2-4 schedules for 3,9, and 11 serotypes, respectively. Differences between schedules persisted until the booster dose," the authors write.

"To our knowledge, this is the first randomized controlled trial investigating immunogenicity of PCV13 in 4 different primary immunization schedules currently used in most high income countries. The primary outcome of this study, GMCs l month after the booster dose, showed that there were no statistically significant differences between the 4 schedules in IgG levels for most serotypes. However, differences between schedules were noted in secondary analyses. … Our findings demonstrate that optimal timing of the primary series, i.e., older age at vaccinations combined with longer intervals between vaccinations, is important to maintain optimal antibody levels during the period between the primary series and the booster dose."

"The choice of PCV schedule will require a balance between the need for early protection and maintaining protection between the primary series and the booster, in particular before herd effects offer clinical protection against vaccine serotype disease to as yet unvaccinated or incompletely vaccinated infants. When herd immunity is established, clinical relevance of the observed differences in immune responses may become of minor importance," the researchers conclude.

"A good deal remains to be learned about how best to use PCVs to protect the most vulnerable and the greatest number of community members," writes Katherine L. O'Brien, M.D., M.P.H., of the Johns Hopkins Bloomberg School of Public Health, Baltimore, in an accompanying editorial.

"Immunogenicity is just one aspect of biological effect, perhaps more important for some serotypes than others. Focus should remain squarely on ensuring that every child is immunized with at least 3 doses of PCV, beginning early in life and administered in a timely fashion. The study by Spijkerman and colleagues reassures that PCV products now in use provide a robust immune response across a range of dosing schedules and focuses attention on specific serotypes of concern. It is good news that PCVs are adaptable to various dosing schedules and therefore to demands of vaccine programs across countries. Emphasis on immunogenicity differences should not be separated from the larger context of protection at the individual level, pneumococcal disease epidemiology, vaccine program performance, and ultimately clear measures of disease outcome."

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