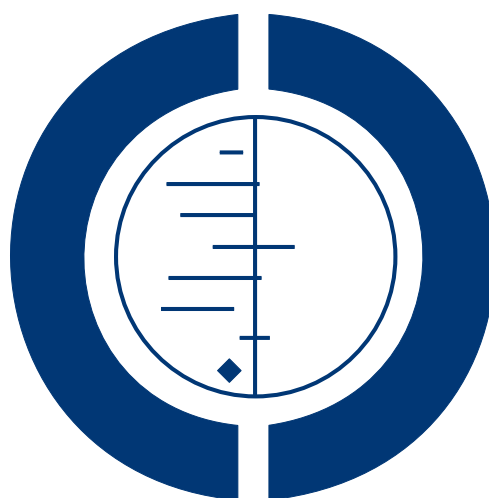


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[Intervention Review]

# Pneumococcal vaccination during pregnancy for preventing infant infection

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## ABSTRACT

### Background

Approximately 450,000 children worldwide die of pneumococcal infections each year. The development of bacterial resistance to antimicrobials adds to the difficulty of treatment of diseases and emphasizes the need for a preventive approach. Newborn vaccination schedules could substantially reduce the impact of pneumococcal disease in immunized children, but do not have an effect on the morbidity and mortality of infants less than three months of age. Pneumococcal vaccination during pregnancy may be a way of preventing pneumococcal disease during the first months of life before the pneumococcal vaccine administered to the infant starts to produce protection.

### Objectives

To assess the effect of pneumococcal vaccination during pregnancy for preventing infant infection.

### Search methods

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register (31 July 2014) and reference lists of retrieved studies.

### Selection criteria

Randomized controlled trials in pregnant women comparing pneumococcal vaccine with placebo or doing nothing, or with another vaccine to prevent infant infections.

### Data collection and analysis

Two review authors independently assessed trials for inclusion and risk of bias, extracted data and checked them for accuracy. We contacted study authors for additional information.

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## Main results

Seven trials were included, but only six trials (919 participants) contributed data. There was no evidence that pneumococcal vaccination during pregnancy reduces the risk of neonatal infection (risk ratio (RR) 0.66; 95% confidence interval (CI) 0.30 to 1.46; two trials, 241 pregnancies, *low quality evidence*). Although the data suggest an effect in reducing pneumococcal colonization in infants by 16 months of age (average RR 0.33; 95% CI 0.11 to 0.98; one trial, 56 pregnancies), there was no evidence of this effect in infants at two to three months of age (average RR 1.13; 95% CI 0.46 to 2.78; two trials, 146 pregnancies, *low quality evidence*) or by six to seven months of age (average RR 0.67, 95% CI 0.22 to 2.08; two trials, 148 pregnancies, *low quality evidence*). None of the trials included in this review reported neonatal death as a result of pneumococcal infection.

Neonatal antibody levels were reported as geometric mean and 95% CI. There were inconsistent results between studies. Two studies showed significantly higher immunoglobulin G (IgG) levels in cord blood in the pneumococcal vaccine group when compared with the control group for all serotypes. In contrast, another trial showed no difference in neonatal antibody levels between the pneumococcal vaccine group and the control group.

Maternal antibody levels were also reported as geometric mean and 95% CI. One study showed significantly higher IgG levels in maternal serum in women immunized with pneumococcal vaccine when compared with control vaccine regardless of any serotypes. Another study showed significantly higher maternal antibody levels only for serotype 14, but no evidence of an effect for other serotypes.

The percentage of women with seroprotection was measured in one trial at delivery and at 12 months post-delivery. At delivery, results favored the intervention group for serotype 6 (RR 1.49, 95% CI 1.31 to 1.69), serotype 14 (RR 1.40, 95% CI 1.25 to 1.56) and serotype 19 (RR 2.29, 95% CI 1.89 to 2.76). There were no group differences seen at 12 months post-delivery for serotypes 6 or 14 (RR 1.06, 95% CI 1.00 to 1.12 and RR 1.06, 95% CI 0.98 to 1.15, respectively), but results favored the intervention group for serotype 19 (RR 1.59, 95% CI 1.37 to 1.85).

No significant difference for tenderness at the injection site between women who received pneumococcal vaccine and those who received control vaccine (average RR 3.20; 95% CI 0.32 to 31.54; two trials, 130 women).

The overall quality of evidence is low for primary outcomes. Most outcomes had wide confidence intervals crossing the line of no effect, and most of the included trials had small numbers of participants and few events which led to downgrading evidence for imprecision of findings.

## Authors' conclusions

There is insufficient evidence to assess whether pneumococcal vaccination during pregnancy could reduce infant infections.

## PLAIN LANGUAGE SUMMARY

### Pneumococcal vaccination during pregnancy for preventing infant infection

There is not enough evidence to assess whether using pneumococcal vaccination during pregnancy can prevent infant infections.

Although the incidence of invasive pneumococcal disease is variable across the world, the rate of serious illness or death is high in children who get this infection. The *Streptococcus pneumoniae* (pneumococcus) organism colonizes the upper respiratory tract and can cause bacteremia, meningitis, pneumonia and other lower respiratory tract, and upper respiratory tract infections, including otitis media and sinusitis. Newborn vaccination schedules of three primary doses with a booster dose could reduce the impact of pneumococcal disease in immunized children, but these vaccinations have no protective effect in infants less than three months of age. Maternal pneumococcal immunization during pregnancy may be a way of preventing pneumococcal disease during the infant's first months of life. We included seven randomized controlled trials. A total of 919 pregnant women participated in the six randomized controlled trials that contributed data to this review. The trials compared 23-valent pneumococcal polysaccharide vaccine with control vaccine. All women received a single injection of pneumococcal or control vaccine (where used). The women's mean gestational age at the time of immunization was between 27 and 38 weeks, where stated. Only two trials with 241 pregnancies reported on neonatal infections. This was not enough information to say whether pneumococcal vaccination during pregnancy led to fewer infant infections. Two trials with 146 pregnancies reported on infant nasal carriage of pneumococci (pneumococcal colonization), which was not enough evidence to show an effect in reducing colonization at two to three months of age or six to seven months of age. The included trials were of reasonable quality. There was no difference between pneumococcal vaccine and control vaccine for tenderness at the injection site. No serious adverse events were reported in the trials.

