V114 pneumococcal vaccine has acceptable safety profile for infants

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VAXNEUVANCE (V114), the 15-valent pneumococcal conjugate

vaccine (PCV) containing the 13 serotypes in Prevnar 13 (PCV13) plus serotypes 22F and 33F, is well-tolerated and safe for infants, according to a study published online June 13 in *Pediatrics*.

Natalie Banniettis, M.D., from Merck & Company in Rahway, New Jersey, and colleagues examined the safety and tolerability of V114 in a phase 3 study involving 2,409 infants who were randomly assigned to receive V114 or PCV13 at ages 2, 4, 6, and 12 months.

The researchers found that recipients of V114 and PCV13 generally had comparable proportions with injection-site, systemic, vaccine-related, and serious adverse events (AEs). The most frequently reported AEs were solicited; in both groups, irritability and somnolence were the most frequent AEs.

The incidence of some AEs was higher in the V114 group, but the differences between groups were small. Most AEs were of mild-to-moderate intensity and had a duration of no more than three days. In the V114 group, there were two vaccine-related serious AEs of pyrexia reported; one non-vaccine-related death occurred in each group. None of the participants discontinued the study vaccine due to AEs.

"Data from this trial suggest V114 has an acceptable safety profile and is well-tolerated among healthy infants," the authors write. "Overall, findings support the use of V114 in pediatric vaccination programs."

Several authors disclosed ties to pharmaceutical companies, including Merck, which manufactures VAXNEUVANCE and funded the study.

More information: Natalie Banniettis et al, Safety and Tolerability of V114 Pneumococcal Vaccine in Infants: A Phase 3 Study, *Pediatrics* (2023). DOI: 10.1542/peds.2022-060428