

Study finds new pneumococcal vaccine appears to be as safe as previously used vaccine

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The new 13-valent pneumococcal conjugate vaccine (PCV13) appears to be as safe as the previous version used prior to 2010, the 7-valent pneumococcal conjugate vaccine (PCV7), according to a Kaiser Permanente study published today in *Vaccine*.

The U.S. [Food and Drug Administration](#) approved PCV13 for use beginning in 2010 after a series of trials. These trials found that PCV13, which protects against a broader range of pneumococcal types than the previously used PCV7, did not increase the risk for any [serious adverse events](#) related to the vaccine.

In a study funded by the [Centers for Disease Control and Prevention](#), Kaiser Permanente researchers evaluated the [electronic medical records](#) of nearly 600,000 children, ages 1 month to 2 years, who received PCV13 over a two-year period. Comparing the number of rare adverse events associated with the PCV13 vaccine to the number of events associated with the previously used PCV7 vaccine, the study authors found there were no increased risks for any of the following pre-specified conditions: [febrile seizures](#), encephalopathy (a type of brain disorder), hives/angioedema, asthma, low platelet counts or systemic allergic reactions.

"It is important that children receive the pneumococcal conjugate vaccine as it provides protection against very serious and potentially [fatal infections](#), including meningitis and bloodstream infections. The new vaccine protects against an additional six types of [pneumococcal bacteria](#)," said study lead author Hung Fu Tseng, PhD, MPH, a research scientist at the Kaiser Permanente Southern California Department of Research & Evaluation.

Early in the study, there was a statistically significant but very small increase in the risk of Kawasaki's disease, a rare condition in children that causes inflammation of the blood vessels, associated with PCV13 (7 diagnoses per 52,000 doses, compared to 4.24 expected). At the end of the study, when the diagnoses were confirmed by medical-record review, the risk of Kawasaki disease in the 28 days following PCV7 was 1 per 100,000 doses and 2 per 100,000 doses of PCV13. Although this difference was not statistically significant, the researchers note it warrants further studies. Researchers also emphasized that this is a statistical association and therefore may not represent a cause-and-effect relationship.

The CDC recommends all children ages 5 years and younger receive PCV13. The vaccine protects against pneumococcal disease, an infection caused by *Streptococcus pneumoniae*. The most common types of pneumococcal infections include middle-ear infections, sinus infections, lung infections, bloodstream infections and meningitis. According to the CDC, each year in the U.S. pneumococcal bacteria cause about 4,000 cases of [bloodstream infections](#) (bacteremia), [meningitis](#), or other invasive disease in children younger than 5 years of age.

Researchers used medical records from the Vaccine Safety Datalink, a collaborative effort between the CDC and integrated care organizations, including Kaiser Permanente, to conduct the study. The Vaccine Safety Datalink project monitors immunization safety and addresses the gaps in scientific knowledge about any rare and serious events that occur following immunization.

This study is part of Kaiser Permanente's ongoing efforts to study the safety and effectiveness of

vaccines. Last year, a Kaiser Permanente study conducted through the Vaccine Safety Datalink found the herpes zoster vaccine, also known as the shingles vaccine, is generally safe and well tolerated. Additionally late last year, Kaiser Permanente researchers found immunizing older adults with the tetanus-diphtheria-acellular-pertussis vaccine (Tdap) to prevent whooping cough was found to be as safe as immunizing them with the tetanus and diphtheria (Td) vaccine.

Provided by Kaiser Permanente

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