WASHINGTON — Children who received a combined pertussis, diphtheria, tetanus, polio, and Haemophilus influenzae type b vaccine experienced fever and injection site reactions at rates similar to, or less than, those seen in children who received the component vaccines, Arnd Herz, M.D., said in a poster presented at the annual meeting of the Pediatric Academic Societies.

Dr. Herz of the Kaiser Permanente Vaccine Study Center, Oakland, Calif., presented the combined results of three U.S. studies and one Canadian study at the meeting sponsored by the American Pediatric Society, the Society for Pediatric Research, Ambulatory Pediatric Association, and the American Academy of Pediatrics. These studies examined safety of the combined pertussis, diphtheria, tetanus, polio, and Haemophilus influenzae (Hib) type b vaccine (Pentacel) in both the infant series and fourth dose of the toddler series, sponsored by Sanofi Pasteur Inc.

In the infant series, 4,198 infants received the combination vaccine, and 2,486 received control vaccines given separately. In the fourth dose studies, 5,031 children received the combination vaccine, and 1,157 received the control vaccines given separately.

All combination and control vaccines were given along with other recommended childhood vaccines. The rate of fever was similar between groups in both series. In the infant series, fever occurred in 28% of the combination group and 31% of the control group. In the fourth dose studies, fever occurred in 11% of both groups.

Injection site reactions were similar among groups in both studies. In the infant series, 10% of the combination group experienced mild redness, 5% experienced swelling, and 60% experienced tenderness. Among the control group, 20% experienced redness, 10% experienced swelling, and 78% experienced tenderness.

One infant in the combination group had an immediate reaction of urticaria. In the fourth dose studies, redness occurred in 20% of both groups. Swelling occurred in 10% of both groups, and tenderness occurred in 90% of the combination group and 60% of the control group.

Crying and fussiness in the 3 days after vaccination were similar in all groups. In the infant series, fussiness occurred in 80% of both groups and crying in 78% of both groups. In the fourth dose studies, crying occurred in 60% of both groups and fussiness in 40% of both groups.

The number of adverse events within 60 days of vaccination was similar between both groups in the infant series: 7.2% of combination group and 9.3% of the control group.

For the fourth dose studies, the rate was 2.4% in both groups. The most common adverse events in the infant series were injection site bruising, pain, and erythema; fever; somnolence; irritability; nonspecific pain; dermatitis; nasal congestion; decreased activity; and cough.

The most common adverse events in the fourth dose studies were nasopharyngitis, injection site bruising and erythema, rhinorrhea, dermatitis, fever, cough, and insomnia.

There were no serious vaccine-related adverse events in any of the studies.