Pentacel Vaccine as Safe as Component Vaccines

The investigation compared the combined results of three U.S. studies and one Canadian study.

BY MICHELE G. SULLIVAN
Mid-Atlantic Bureau

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, 5,033 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 50% 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

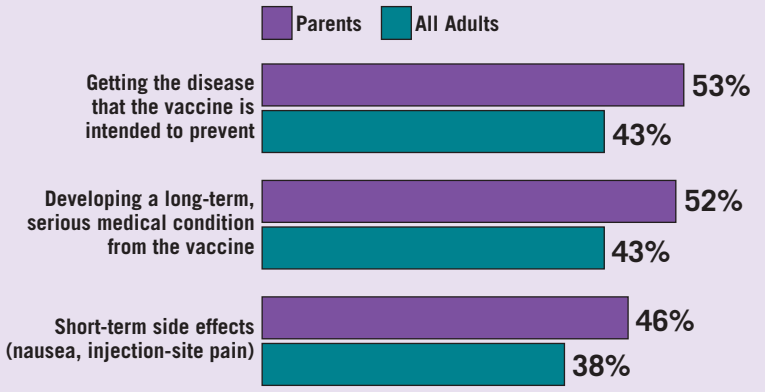
The most common adverse events in the infant series were injection site bruising, pain, and erythema; fever; somnolence; irritability; nonspecific pain; dermatitis; nasal congestion; decreased activity; and cough.

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. ■

DATA WATCH

Half of Parents Have Concerns About Childhood Vaccinations



Note: Based on a nationwide survey of 2,093 adults, 461 of whom are parents of preschool- or school-aged children, conducted Aug. 18-20, 2004.

Source: Harris Interactive

KEVIN FOLEY, RESEARCH/ELIZABETH B. LOBDELL, DESIGN

Protocol That Saved Rabies Patient Needs Study

BY SHARON WORCESTER
Tallahassee Bureau

The doctors who treated the first known patient to survive rabies without prior vaccination have published their aggressive and previously untested treatment protocol, but they caution that it requires further study.

"Clearly, our experience with this patient requires replication in other patients and proof-of-concept experiments in animal models," said Rodney E. Willoughby Jr., M.D., of the Medical College of Wisconsin, Milwaukee, and his colleagues.

The 15-year-old patient developed confirmed clinical rabies 1 month after being bitten on the left index finger by a bat. She was treated with a strategy that involved induction of therapeutic coma, and antiexcitatory and antiviral drug therapy under supportive intensive care. The concept was to protect the brain from injury while allowing the launch of a natural immune response against the virus (N. Engl. J. Med. 2005;352:2508-14).

The patient was treated with ketamine, midazolam, ribavirin, and amantadine. Doses were adjusted as needed due to responses and probable drug-related toxicities, which included hemolysis, pancreatitis, acidosis, and hepatotoxicity. She did not receive rabies vaccine or rabies immunoglobulin because she demonstrated immune response and because of concern regarding harm from a potentiated immune response, the investigators noted.

On the eighth day of hospitalization, a lumbar puncture indicated an increased level of rabies antibody, and sedation was tapered. On hospital day 31, the patient was determined to be cleared of transmissible rabies, and was removed from isolation.

She was discharged to home on hospital day 76. At a follow-up visit 131 days after her initial hospitalization, the patient was progressing, and had returned to school part time. She continues to experience dysarthrotic speech, buccolingual choreoathetosis with generalized choreoathetosis, and intermittent dystonia and ballismus, which affect her gait and fine-motor skills, Dr. Willoughby and his associates said.

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Fifteen-year-old Jeanna Giese, the first known person in the world to survive the disease without receiving the rabies vaccine, is pushed in a wheelchair by her father, John Giese.

Prior to this case, five cases of survival following rabies had been well documented, but all received occupationally related preexposure rabies vaccination or postexposure prophylaxis; this is the first known patient to survive with only naturally acquired immunity. It should be noted that the patient was young and athletic, and may have received a limited quantity of inoculum, the investigators stressed, adding that since the bat was not recovered, it is unclear if the patient's survival was due to an "unusual, more temperate or attenuated variant of the virus, or a rare host polymorphism."

"Therapy may have been more effective than in past cases because of the inferred limited exposure to rabies virus, early recognition of the disease, and aggressive management," the investigators said, noting that the survival of this patient doesn't change the fact that rabies has the highest case fatality ratio of any infectious disease. ■

Soft White Cheese Poses Risk To Newborns

Soft white cheeses made with raw milk present a health risk, the U.S. Food and Drug Administration has warned.

Such cheeses can cause listeriosis, brucellosis, salmonellosis, and tuberculosis.

They pose a particular risk to pregnant women, newborns, older adults, and those with weakened immune systems.

Consumption of *queso fresco*–style cheeses that were imported from or eaten in Mexico were linked with recent cases of tuberculosis in New York City and found to be contaminated with *Mycobacterium bovis*, according to the FDA.

The cheeses of greatest concern are those originating in Mexico and Central American countries and include *queso panela*, *asadero*, *blanco*, and *ranchero*.

The FDA has warned against consumption of any unripened raw-milk soft cheeses, including those obtained at flea markets or from door-to-door sellers or vendors selling out of their trucks, cheeses that are made at home by individuals, and those shipped or carried in luggage from the areas of concern.

—Sharon Worcester