Herpes Zoster Vaccine Safety Sustained at 1 Year

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ATLANTA — The safety profile for Zostavax, the herpes zoster vaccine manufactured by Merck & Co., was reinforced during its first year of widespread use, based on adverse event reports collected from clinicians, patients, and others.

"Zostavax seems to have a very good safety profile, which was expected based on data from prelicensure trials," said Dr. Sandra Chaves of the Centers for Disease Control and Prevention's Division of Viral and Rickettsial Disease.

A total of 590 reports related to Zostavax (including 44 classified as serious) had been submitted as of June 1 to the Vaccine Adverse Event Reporting System (VAERS), a vaccine safety surveillance system operated by the CDC and the Food and Drug Administration. The overall reporting rate was 73.3/100,000 doses distributed, and the serious event reporting rate was 5.5/100,000 doses distributed. Two of the 44 serious events reported were deaths.

Most (90%) of the reports referred to the Zostavax vaccine administered alone, and 82 reports involved possible off-label use or medical error.

Serious events were defined as instances of hospitalization, death, life-threatening conditions, disabling illness, or other medically important conditions, said Dr. Chaves, who presented the VAERS postlicensure safety data at the late June meeting of the CDC's Advisory Committee on Immunization Practices (ACIP). The herpes zoster vaccine was first licensed in May 2006 and recommended by ACIP for prevention of herpes zoster in adults aged 60 years and older in October 2006.

An injection site reaction—the most commonly reported adverse event—was reported in 307 cases. The next most frequent events were a rash (177 cases) and herpes zoster (145 cases). Some reports included more than one event.

The rate of serious adverse events was higher among vaccine recipients, compared with those who received a placebo, in an adverse event monitoring substudy of approximately 6,000 patients, but no specific pattern was observed, Dr. Chaves said.

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More than half (59%) of the 44 serious events occurred in women, and most (43%) occurred in patients aged 70-79 years.

Examples of nonfatal events included three cases of anaphylaxis in patients aged 71, 76, and 79 years, all of whom recovered fully, and one case of a woman who requested vaccination and discovered 10 days later that she was pregnant. No pregnancy outcome data are available; the woman was being followed by the Pregnancy Registry for Varicella Zoster Virus–Containing Vaccines, sponsored by Merck.

The two deaths that occurred within 6 months of vaccination occurred in female patients aged 80 and 83 years, who died from a heart attack and pneumonia with sepsis, respectively.

In addition, administration errors were reported in both adults and children, including 34 reports of Zostavax being given to children instead of Varivax, Merck's childhood varicella vaccine. The adverse event reports suggest that the errors were simply human error and not caused by confusing medication labels, Dr. Chaves said.

One of the committee members expressed concern about the outcomes in children who received Zostavax instead of Varivax, inasmuch as each dose of Zostavax contains 14 times the amount of varicella zoster virus as Varivax.

A Merck spokesperson at the meeting said that the company had studied titers as high as 50,000 plaque-forming units in healthy children and found a plateau of response, so an accidental dose of Zostavax should not be dangerous in most cases and should not prevent a second dose of varicella vaccine in children who received Zostavax accidentally as the first dose.

Safety surveillance for the zoster vaccine is challenging because of the many comorbid conditions in the 60-years-and-older population, Dr. Chaves noted.

Merck has agreed to conduct postlicensure studies to further assess the rates of serious adverse events. ■