Herpes Zoster Vaccine Safe in 50- to 59-Year-Olds

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BALTIMORE — The herpes zoster vaccine is as immunogenic in adults aged 50-59 as it is in those aged 60 and older, Santosh C. Sutradhar, Ph.D., reported at a conference on vaccine research sponsored by the National Foundation for Infectious Diseases.

Zostavax, manufactured by Merck & Co., was licensed by the U.S. Food and Drug Administration in May 2006 for the prevention of herpes zoster in adults aged 60 and older only. Merck had sought an indication for those aged 50-59 years, but an earlier FDA advisory panel had recommended against it because data on safety and efficacy in that age group were lacking, as were overall data on duration of immunity for the vaccine (INTERNAL MEDICINE NEWS, Jan. 15, 2006, p. 1).

In October 2006, the Advisory Committee on Immunization Practices recommended universal use of Zostavax among adults aged 60 and older (INTERNAL MEDICINE NEWS, Nov. 15, 2006, p. 1).

Nonetheless, epidemiologic data suggest that the annual risk of developing herpes zoster actually begins to increase markedly around age 50 years and rises sharply afterward. Thus, "it is important to assess the immunogenicity and safety of Zostavax in this age group," said Dr. Sutradhar, senior biometrician at Merck.

In combined data from two protocols that had been presented separately to the FDA, the vaccine was administered to 389 subjects aged 50-59 and to 733 aged 60 and older. Of those, 377 and 731, respectively, completed the 28-day follow-up. Antibody response, assessed by geometric mean fold rise of varicella zoster virus antibody from prevaccination to 4 weeks post vaccination, was increased substantially in both groups: by 2.6 in the younger group and 2.3 in the older subjects.

Both of those levels exceeded the predefined threshold for "acceptable" antibody response, and the response for the younger group met the "noninferiority" criteria, compared with that of the older group, he said.

Adverse events within 28 days following vaccination were more common in the 50- to 59-year-olds, with 60.3% reporting one or more, compared with 44.2% of the 60-plus group. Vaccine-related adverse events were reported by 51.9% and 35.1%, respectively. Injection-site reactions were the most common, reported by 50.4% of the younger subjects and 34.1% of the older ones. Systemic vaccine-related adverse events were far less common, reported by 5.7% and 2.9%, respectively, and no subject in either age group reported any serious vaccine-related adverse events.

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In response to a question from the audience as to the reason that local reactions are more common in 50- to 59-year-olds than in older adults, Dr. Jeffrey L. Silber, Merck's senior director of Vaccine/Infectious Disease Clinical Research, responded that the same phenomenon has been observed in the company's studies of other vaccines, even among placebo recipients. The data show that "people aged 50-59 simply complain more," he said. "They also tend to have more headaches, perhaps because they're working and have more teenagers at home."

Merck is working with the FDA to develop a protocol that will provide vaccine efficacy data as well as additional safety data specifically for the 50- to 59-year-old age group, as had been done previously with those aged 60 and older in the Shingles Prevention Study (SPS). Those findings, from more than 38,000 adults older than 60, showed that the vaccine reduced the burden of illness related to herpes zoster pain, the incidence of postherpetic neuralgia, and the incidence of herpes zoster (N. Engl. J. Med. 2005;352:2271-84).

The SPS also showed that the vaccine was generally well tolerated and that varicella zoster virus antibody response measured at 6 weeks post vaccination correlated with protection against herpes zoster, Dr. Sutradhar noted.

Merck hopes to launch the new protocol sometime this year, according to a company spokeswoman. ■

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