

How to Field Patient Questions About Gardasil and Zostavax

BY BETSY BATES
Los Angeles Bureau

MONTEREY, CALIF. — Although most physicians are familiar with the basic facts concerning the newly introduced Gardasil and Zostavax vaccines, questions still surround their use.

Zostavax, a 14-fold concentrated version of Varivax, the varicella zoster vaccine to prevent chicken pox in children, was approved by the Food and Drug Administration in May 2006 for adults aged 60 years and older. A month later, approval was issued for Gardasil in girls and young women aged 9-26 years to prevent cervical cancer, precancerous genital lesions, and genital warts caused by HPV types 6, 11, 16, and 18.

Dr. Stephen K. Tyring, professor of dermatology at the University of Texas Health Sciences Center in Houston, discussed commonly asked patient questions about the vaccines at the annual meeting of the California Society of Dermatology and Dermatologic Surgery.

Gardasil

► **"I'm 30, and I'm in the dating scene. Should I get the Gardasil vaccine even though it's only approved for ages 9-26?"** The vaccine was studied in younger women, but there's no reason that older women who are sexually active shouldn't receive the vaccine, Dr. Tyring said. Yet most insurers probably will not cover the cost of the vaccine in those outside of the FDA-specified age groups.

► **"Shouldn't we be vaccinating boys and young men, too?"** Men obviously play a role in the spread of oncogenic papilloma viruses, but women suffered more anogenital malignancies in countries where the vaccine was studied, so they were included in the trials, he said. Ongoing studies will establish "the safety if not the efficacy" of the vaccine in males.

► **"Why isn't Gardasil being used to treat cervical cancer?"** The few published studies of Gardasil's efficacy in treating cervical cancer have had unimpressive results, so its role remains preventive.

► **"How long will the viral protection last?"** "We don't know," Dr. Tyring said. The duration of

protection was at least 5 years in trial participants. "We hope it's a lifetime."

► **"I've already had genital warts. What would be the point of my getting the vaccine now?"** If a physician can show that a patient has been exposed only to HPV types 6 and 11, she could still receive protection against HPV types 16 and 18, which cause cervical cancer. The American Cancer Society predicts more than 11,000 women will be diagnosed with cervical cancer in the United States this year, and nearly 3,700 will die of the disease.

Zostavax

► **"I've heard the Zostavax vaccine isn't very effective. Why should I get it?"** In a pivotal trial, the Zostavax vaccine prevented herpes zoster in 51% of adults aged 60 and older, an impressive result considering it was being used to do something quite extraordinary: prevent reemergence of a virus that had been lying dormant in the dorsal root ganglia for decades, Dr. Tyring said. Among those who did get shingles after receiving the vaccine, the rate of postherpetic neuralgia was reduced by two-thirds.

► **"I'm 55, but I've seen what shingles was like in my dad, and I don't want to get it. Should I get the vaccine?"** Dr. Tyring and associates have given the vaccine to people in their 50s and found that their immunogenicity is superior to that of older adults. Pending trials may lead to approval in younger adults, but until that time, there may be no reimbursement for what appears to be a safe and effective vaccine.

► **"I have had shingles, and I never want to go through it again. Will the disease prevent recurrence?"** Even without the vaccine, an immunocompetent person has only a 5% chance of getting shingles a second time.

► **"I don't think I even had chicken pox as a child, so would the vaccine be unnecessary?"** Fully 99% of people over age 60 are seropositive, whether or not they recall having scratchy bumps, and can be presumed to be at risk for shingles, he said.

Dr. Tyring receives research support and has served on the speaker's bureau and as a consultant to Merck, maker of both vaccines. ■

Rocky Mountain Spotted Fever Cases on the Rise

BY DOUG BRUNK
San Diego Bureau

SAN DIEGO — Cases of Rocky Mountain spotted fever increased nearly threefold between 2001 and 2005, John Openshaw reported at the annual meeting of the Infectious Diseases Society of America.

The rising number of suburban homes that encroach on rural

ettisial zoonoses branch of the Centers for Disease Control and Prevention, said in a statement.

Researchers analyzed data from the National Electronic Telecommunications System for Surveillance and found that during 2001-2005, there were 6,598 cases of Rocky Mountain spotted fever reported in 45 states, said Mr. Openshaw, a medical student at the University of Pennsylvania, Philadelphia, who worked on the study during a CDC Applied Epidemiology Fellowship in 2006. The disease resulted in death in 22 people (0.3%).

The number of cases in the United States increased from 695 cases in 2001 to 1,936

cases in 2005. The incidence was higher in suburban areas than rural ones, and the largest increase was in the southern Atlantic states.

Despite the increase in cases, the rates of hospitalization fell from 29% in 2001 to 18% in 2005, while the rates of complications from the disease fell from 8% to 4%. Immunocompromised patients were most likely to be hospitalized with the disease (41%), followed by adults over the age of 70 (40%) and children under the age of 5 (35%).

The disease was reported in every state except Alaska, California, Hawaii, Maine, and Washington. "Physicians should be aware of the increase in Rocky Mountain spotted fever," he said. ■



'Physicians should be aware of the increase in Rocky Mountain spotted fever.'

MR. OPENSHAW

al areas is one possible reason for the spike in reported cases. "Increased physician awareness and increased surveillance efforts are [also] involved," Mr. Openshaw said during a press briefing. "The true explanation is likely a combination of many factors."

Rocky Mountain spotted fever is caused by the *Rickettsia rickettsii* bacteria, which are typically spread through tick bites. Early signs include acute onset of fever and other flulike symptoms followed by rash.

"The biggest problem is that people don't often remember being bitten by a tick, and by the time the classic rash appears, the disease has already progressed significantly, and it may be too late," Dr. David Swerdlow, previous team leader for the rick-

Adjunctive Gabapentin May Help in Postherpetic Neuralgia

BY JOHN R. BELL
Associate Editor

NEW YORK — The combination of gabapentin with an antiviral and analgesics was more effective than were those drugs without gabapentin for reducing pain in patients with herpes zoster, suggesting that it may prevent postherpetic neuralgia in these patients, said Dr. Stephen Tyring, who presented as-yet-unpublished findings at the American Academy of Dermatology's Academy 2007 meeting.

Dr. Tyring, professor of dermatology, microbiology/molecular genetics, and internal medicine at the University of Texas, Houston, and colleagues enrolled 934 patients with herpes zoster whose pain measured at least a 4 on the Likert Pain Scale.

A control group of 800 patients received valacyclovir for 7 days along with various standard analgesics. An additional 134 patients also received gabapentin in the following regimen: 300 mg nightly for 1

week, followed by 300 mg three times daily for another week, then 600 mg t.i.d. for the following week, followed by yet another higher dosage until the patient complained of side effects (dizziness, drowsiness), at which point the dose was reduced to the highest tolerated dose and maintained until the end of the first month of treatment.

If, at that point, a patient's Likert score had dropped to below 4, the gabapentin was gradually discontinued over 3-4 days and the patient followed for 6 months. If the pain score was 4 or higher at the end of the fourth week, the patient received the highest tolerated dose of gabapentin for another 4 weeks and was then tapered off the drug.

Of those who received gabapentin in ad-

dition to valacyclovir and analgesics, only 12 patients (9%) had any pain at 6 months. In marked contrast, 33% of the 800 shingles patients who received valacyclovir and analgesics without gabapentin still had pain after 6 months. These results suggest

that gabapentin may induce a neuroimmunomodulation of neuralgia, Dr. Tyring said.

The study was supported by GlaxoSmithKline, which provided the valacyclovir used.

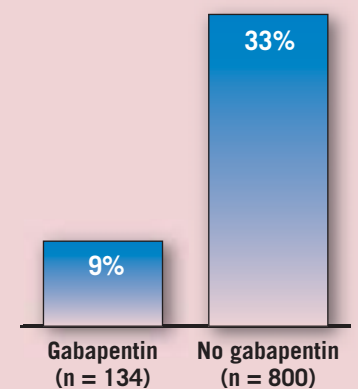
Patients with a pain score of less than 4 were excluded "because the most effective predictor of postherpetic neuralgia, in addition to age, is degree of pain. So if the pain score has not even hit a 4 by the time they present to us with their vesicles, it will probably do no harm, but there's probably no benefit in



'The most effective predictor of postherpetic neuralgia, in addition to age, is degree of pain.'

DR. TYRING

Shingles Patients With Pain At 6 Months



Note: All patients received valacyclovir and analgesics.
Source: Dr. Tyring

giving the gabapentin or the pregabalin," he said, noting that gabapentin is more economical than pregabalin (Lyrica). ■