

# Gardasil, Zostavax Shots: Questions and Answers

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MONTEREY, CALIF. — Although most physicians are familiar with the basic facts concerning the newly introduced Gardasil and Zostavax vaccines, patients still have many questions about 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 Administra-

tion in May 2006 for adults aged 60 years and older.

A month later, Gardasil was approved for 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 provided some answers that patients often ask 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 in the world in terms of safety and efficacy” that older women who are sexually active shouldn’t receive the vaccine, said Dr. Tyring, professor of dermatology at the University of Texas Health Sciences Center in Houston. However, most insurance

companies probably will not cover the cost of the vaccine in children or young women outside of the FDA-specified age groups.

► “What about vaccinating boys and young men?”

Men obviously play an important role in the cycle of spread of oncogenic papilloma viruses, but women suffered more anogenital malignancies in the countries where the vaccine was studied, so they were included in the trials, he said. Ongoing studies will establish “at least the safety if not the efficacy” of the vaccine in males.

► “Why isn’t Gardasil being used to treat cervical cancer?”

Studies assessing its efficacy in treating cervical cancer have had unimpressive results; therefore its role remains preventive.

► “How long will the viral protection last?”

“We don’t know,” said Dr. Tyring. Protection lasted at least 5 years in trial participants. “We hope it’s a lifetime.”

► “I’ve had genital warts. What would be the point of my getting the vaccine now?”

If a patient’s gynecologist has demonstrated a patient has been exposed only to HPV types 6 and 11, studies have proven she could still receive protection against HPV types 16 and 18, which cause cervical cancer.

## 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, a fairly 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, said Dr. Tyring. And even 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. Trials will soon be underway that 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’ve had shingles and never want 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. Although there is likely no harm in giving the vaccine to someone who has had the disease, it would cost about \$250 (again, unlikely to be reimbursed) to reduce the risk from 5% to 4%. The vaccine is contraindicated in immunocompromised patients, since it is a live attenuated vaccine.

► “I don’t think I had chicken pox as a child. Would the vaccine be unnecessary?”

Of people over age 60, nearly 99% are seropositive, whether or not they’ve had chicken pox. Everyone over 60 can be presumed to be at risk for shingles and could benefit from the vaccine, said Dr. Tyring, who is a consultant for and receives funding from Merck, maker of both vaccines, and has served on its speaker’s bureau. ■

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