Answers for Patients' Questions on New Vaccines

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 across the age range of 9 to 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 in the world in terms of safety and efficacy" that older women who are sexually active shouldn't receive the vaccine, said Dr. Tyring. 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.

► "Shouldn't we be vaccinating boys and young men too?"

Men obviously play an important role in the cycle of spread of oncogenic papilloma viruses, but women suffered more anogenital malignancies in the countries in which the vaccine was studied, so they were included in the trials, he explained. 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?"

The few published studies assessing Gardasil's 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. 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 patient's gynecologist has demonstrated that a patient has been exposed only to HPV types 6 and 11, studies have proved 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, 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. Fortunately, trials will be underway very soon 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.

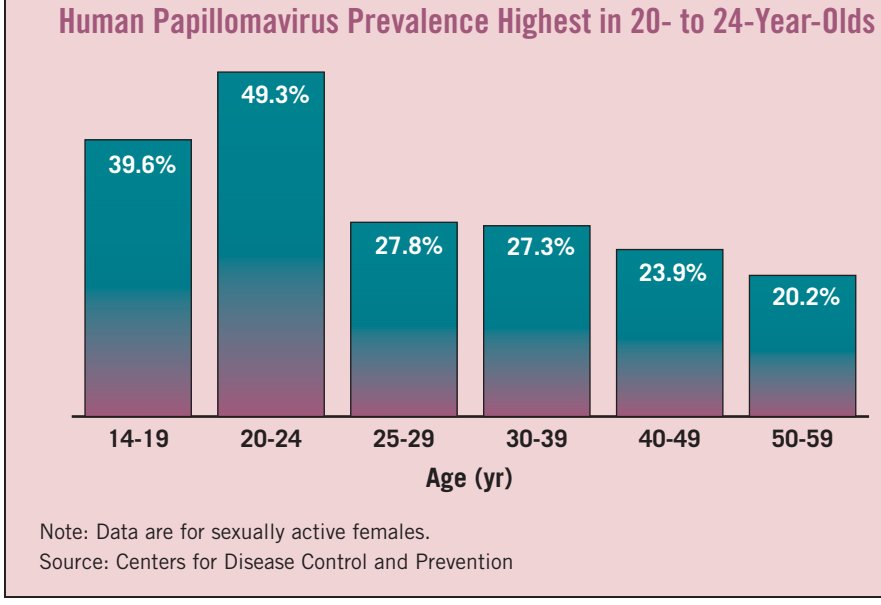
► "I have had shingles, and I never want to go through it again. Will the disease prevent recurrence?"

Even without the vaccine, an immunocompetent person has only a 5% chance of getting shingles a second time. So while there is likely no harm in giving the vaccine to someone who has had the disease, it would cost approximately $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 even had chickenpox as a child, so would the vaccine be unnecessary?"

Fully 99% of people over age 60 are seropositive, whether or not they recall staying home from school with scratchy bumps. Dr. Tyring said all people over 60 can be presumed to be at risk for shingles and therefore could potentially benefit from the vaccine. Dr. Tyring receives research support and has served on the speaker's bureau and as a consultant to Merck, maker of both vaccines. ■

DATA WATCH



Note: Data are for sexually active females.
Source: Centers for Disease Control and Prevention

Elsevier Global Medical News

DNA Test Found More Effective Than Pap for Detecting CIN

BY MARY ANN MOON
Contributing Writer

Testing for human papillomavirus DNA, either alone or in addition to routine Pap screening, improves the detection of cervical intraepithelial neoplasia, two research groups reported in separate studies.

One of the groups of investigators also found that adding human papillomavirus (HPV) DNA testing to Pap testing also decreased the incidence of high-grade lesions and cancers found on subsequent screens over the next few years.

"This result indicates that the improved sensitivity of HPV testing is not merely due to overdiagnosis but is attributable, at least in part, to earlier diagnosis of lesions that do not regress," they said.

In an editorial comment accompanying the two reports, Dr. Carolyn D. Runowicz of the University of Connecticut Health Center, Farmington, said that if additional studies confirm these findings, HPV DNA testing may eventually replace cytologic testing.

However, "we are not there yet," she cautioned.

In the first study, Dr. Marie-Hélène Mayrand and her associates in the Canadian Cervical Cancer Screening Trial (CCCaST) directly compared HPV and Pap testing as stand-alone screens for cervical cancers and their high-grade precursors in more than 10,000 women aged 30-69 years who presented to 30 Canadian clinics for routine screening in 2002-2005. A total of 5,059 women were randomly assigned to undergo Pap testing followed by HPV testing, and the remaining 5,095 to undergo HPV testing followed by Pap testing.

Both tests were found to have negative predictive values higher than 99%.

However, HPV testing proved to be 39% more sensitive than Pap testing. This improved sensitivity was not achieved at the expense of drastically reduced specificity, as HPV testing was only 2.7% less specific than Pap testing, said Dr. Mayrand of McGill University, Montreal, and her associates.

Moreover, combining the results of both tests improved sensitivity only "marginally" over that achieved with HPV testing alone, "while doubling the number of tests and increasing referrals" for colposcopy.

"It is difficult to predict whether a change from Pap testing to HPV testing will further reduce the rates of death from cervical cancer." However, "we believe that a shift from cellular to viral tests, coupled with education and vaccination, will contribute to a more efficient control of cervical cancer," the investigators said (N. Engl. J. Med. 2007;357:1579-88).

The second study was a population-based trial in which more than 12,000 women in their mid-30s in five Swedish cities were randomly assigned to undergo Pap testing plus HPV DNA testing or Pap testing alone between 1997 and 2000. With the addition of HPV testing, 51% more cases of grade 2 or 3 cervical intraepithelial neoplasia (CIN) or cancer were detected, said Dr. Pontus Naucler of Lund (Sweden) University and associates.

The incidence of such lesions detected on subsequent screens during 4 years of follow-up decreased by a statistically significant 47%. This "represents a gain in lead time"—earlier diagnosis of high-grade lesions rather than overdiagnosis of lesions that otherwise would have regressed spontaneously, they noted (N. Engl. J. Med. 2007;357:1589-97).

This also means that HPV testing may reduce mortality from cervical cancer in women who undergo screening less often than is recommended, Dr. Naucler and associates added.

Dr. Runowicz said that if further studies confirm these findings, "there will be a need to develop a rapid, simple, accurate, and affordable HPV DNA test." New algorithms for screening also will need to be developed.

The optimal screening approach—based on cytology, virology, or both—"will depend on the prevalence of disease, access to screening, and available resources" in any given region, Dr. Runowicz noted (N. Engl. J. Med. 2007;357:1650-3).

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