UCSF experts are cautious about vaccine for cervical cancer

Karen Smith-McCune, MD

May 22, 2007

Unknowns about the effectiveness and safety of the new human papillomavirus (HPV) vaccine demand thoughtful deliberation by clinicians on its role in cervical cancer prevention, according to two UCSF women's health specialists.

The lack of long-term follow-up to assess vaccine efficacy and safety, as well as the lack of testing in the age group targeted for the vaccine (11 to 12 year-old girls), are among the main reasons for such caution, they say.

Their analysis is reported in the May 10, 2007 issue of the *New England Journal of Medicine*, which focuses on the new vaccine. The editorial and other NEJM articles are available online at **http://content.nejm.org**.

The vaccine, which has received international attention since its approval by the Food and Drug Administration last June, targets four HPV types, two of which can cause cervical cancer, according to George F. Sawaya, MD, and Karen Smith-McCune, MD, who are co-authors of the editorial and are associate professors in the UCSF Department of Obstetrics, Gynecology and Reproductive Services.

Previously published data about the vaccine have indicated 100 percent effectiveness against the pre-cancerous cervical lesions that are associated with the HPV types targeted by the vaccine.

That data applied to women who had not previously been exposed to those viral types. New studies reported in this issue of the NEJM confirm these positive findings, but also provide information about the impact of vaccination in a larger, more representative population of all trial participants, the UCSF co-authors say. The new data cover all participants regardless of prior HPV exposure and all pre-cancerous lesions, regardless of HPV type.

"These new studies provide a preliminary glimpse of what we might expect from vaccinating women up to age 26 who have already been sexually active, as is recommended by the Centers for Disease Control and Prevention," Sawaya says.

The overall efficacy of the vaccine for reducing pre-cancerous cervical lesions from any HPV type was modest: over 3 years, 3.6 percent of vaccinated women received this diagnosis compared to 4.4 percent of unvaccinated women. Rates of the most severe lesions were not significantly reduced by vaccination, the co-authors say.

"There has been an understandably positive response to the promise of this vaccine, but we have to balance that promise with what is actually known," says Smith-McCune, who has chosen not to vaccinate her own teenage daughters against HPV at this time.

An estimated 9,700 American women were diagnosed with cervical cancer in 2006, according to the American Cancer Society. The vast majority of those cancers can be avoided with regular cervical cancer screening with the Pap test, the authors say.

"The Pap test is a proven and effective way to reduce cervical cancer risk, whereas we are just beginning to find out about the overall effectiveness and safety of the vaccine," Smith-McCune says.

"So far, the HPV vaccine looks promising," says Sawaya. "The diagnosis of a rare cancer usually related to HPV in one woman who received the vaccine, however, gives us pause and argues for a cautious approach until the current studies are completed and final outcomes reported."

Both stressed that since screening is widely available, cervical cancer is not a public health emergency in this country.

"The rush toward mandatory vaccination is puzzling, but it is important to realize that the major studies are on-going," Sawaya says. "As with any preventive measure, we need to be quite certain that the benefits of vaccination outweigh the harms before we embark on widespread vaccination programs."

Both doctors urged women to continue to receive regular cervical cancer screening, regardless of whether they have received the vaccine.

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