Safety Tops Parents' Concerns on HPV Vaccine

BY HEIDI SPLETE
Senior Writer

Safety, not sexuality, was a key factor in the reluctance of mothers to have their teenage daughters vaccinated against human papillomavirus, according to results from a study published in the Journal of Adolescent Health.

The Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices currently recommends a three-dose vaccine against the human papillomavirus (HPV) for all girls aged 11-12 years and young women aged 13-26 years. HPV has been identified as a leading cause of cervical cancer.

Previous studies have shown that parents were in favor of vaccination for adolescents but hesitant to vaccinate younger girls. But data from these studies have shown that in most cases, this resistance was not brought on by concerns that the vaccination might make teenage girls more likely to engage in risky sexual activities.

To examine the factors that influence parents' acceptance of the HPV vaccine, Susan L. Rosenthal, Ph.D., of the University of Texas Medical Branch in Galveston, Tex., and her colleagues interviewed mothers with daughters aged 11-17 years who were visitors to a university-based primary care clinic.

The study included complete results from 153 mothers of various ethnicities (average age 41 years) who completed a questionnaire. The questionnaire included ratings of seven health beliefs including perceptions of HPV disease severity and barriers to vaccination, such as cost.

The questionnaire also addressed aspects of the parent/child relationship, including how closely the girls' activities were monitored by parents and whether the parents had discussed topics such as birth control, dating, and making decisions about sex (J. Adolesc. Health 2008;43:239-45).

It appeared that mothers who had been counseled by a physician had more positive attitudes toward the vaccine and understood the reasons for it better.

Overall, 18% (27) of the mothers had been offered the HPV vaccination for their daughters but had not chosen it, and did not plan to vaccinate their daughters within the next year, while 34% (52) had not been offered the vaccination and did not plan to vaccinate their daughters within the next year. Another 22% (34) had not been offered the vaccine but were aware of it and planned to vaccinate their daughters within the next year, and 26% (40) of the mothers reported that their daughters had started or completed the vaccination series.

None of the mothers whose daughters had been vaccinated said they viewed the vaccine as unsafe, but objections to the vaccine were focused mostly on the lack of safety data because of the newness of the vaccine. Mothers who were offered the vaccine but did not plan to vaccinate their daughters within the year often cited a lack information about the vaccine, and some cited a lack of urgency based on their perceptions of their daughters' likely exposure to HPV.

Significant predictors of HPV vaccination after a multivariate analysis were mothers who had less than a high school education, had a history of sexually transmitted infections, had monitored their daughters' activities with peers, and had thought their daughters would not mind getting the shots.

There was no significant association between HPV vaccine acceptance and the ages and ethnicities of the mothers and daughters, the daughters' dating status, mothers' history of HPV, mother/daughter discussion of sex topics, or the general family environment.

"Although the study was not designed to examine the process of and impact of physician counseling, it appeared that those who had been counseled had more positive attitudes toward the vaccine and understood better the reasons for vaccinating their daughters prior to initiation of sexual activity," the researchers noted.

The study was funded by grants from Merck & Co. and the National Institutes of Health. ■

Simulation Model Results Don't Favor HPV Vaccines for Women Over 21 Years

BY MARY ANN MOON
Contributing Writer

Human papillomavirus vaccination should be targeted at preadolescent girls, with initial "catch-up" programs aimed at women and girls aged younger than 21 years, but should not be directed at older women, according to a results of a mathematical model.

The impact of the HPV vaccination will not be "observable for decades," so decisions regarding vaccine policy must rely on estimates and mathematical simulation models, according to Jane J. Kim, Ph.D., and Dr. Sue J. Goldie of Harvard School of Public Health, Boston. They devised such a model to examine possible outcomes of current HPV vaccination programs.

In creating this simulation model, the investigators took into consideration the cost-effectiveness of vaccinating various age groups as well as "the dynamics of HPV transmission, the duration of vaccine efficacy, the potential benefits of preventing noncervical HPV-related conditions, the anticipated changes in screening practice, and potential disparities in access to care."

If it is assumed that the HPV vaccine confers lifelong immunity, the simulation model showed that routine vaccination of 12-year-old girls had a cost effectiveness ratio of $43,600 per quality-adjusted life year gained. This is well within the commonly cited threshold of good value for resources spent, which is $50,000-$100,000 per quality-adjusted life year gained, the investigators said (N. Engl. J. Med. 2008;359:821-32).

Adding a "catch-up" program to vaccinate girls aged 13-21 years also was found to be reasonably cost effective, especially when the benefits of averting genital warts and of cross-protection against other high-risk types of HPV were added into the model. However, extending such a catch-up program to women older than 21 was not found to be a good value. Both the routine vaccination of 12-year-olds and the "catch-up" vaccination of adolescents remained cost effective only at high levels of vaccine coverage, Dr. Kim and Dr. Goldie noted.

The model predicted less success for HPV vaccination programs if it turns out that immunity is not lifelong but lasts only 10 years. In that case, continued screening and booster vaccines will be necessary and will add substantially to costs.

In an editorial comment accompanying this report, Dr. Charlotte J. Haug, editor-in-chief of the Journal of the Norwegian Medical Association, Oslo, called the Harvard researchers' model "well done and ambitious."

"There has been pressure on policy makers worldwide to introduce the HPV vaccine in national or statewide vaccination programs. How can policy makers make rational choices about the introduction of medical interventions that might do good in the future, but for which evidence is insufficient, especially since we will not know for many years whether the intervention will work or—in the worst case—do harm?" she asked (N. Engl. J. Med. 2008;359:861-2).

One answer is to "develop mathematical models of the natural history of the disease in question, introduce various intervention strategies, and use cost-effectiveness analysis to estimate the costs and health benefits associated with each clinical intervention," as the investigators have done.

However, their model and its predictions are only as accurate as the assumptions on which the model is based, Dr. Haug noted. Also, data are limited on several factors: incidence; mortality and quality of life associated with noncervical HPV-related cancers; the long-term efficacy of the vaccine; and the efficacy of the vaccine against noncervical cancers.

The researchers did not report any potential conflicts of interest. ■

Sildenafil Cuts Adverse Sexual Effects of SRIs

BY MARY ANN MOON
Contributing Writer

Sildenafil reduced the adverse sexual effects related to treatment with serotonin reuptake inhibitors in women who had major depression in remission in a randomized trial of 98 women.

"These findings are important not only because women experience major depressive disorder at nearly double the rate of men and because they experience greater resulting sexual dysfunction than men, but also because [they established] that selective phosphodiesterase type 5 inhibitors are effective" for reducing adverse sexual effects in women, Dr. H. George Nurnberg of the department of psychiatry, University of New Mexico Health Sciences Center, Albuquerque, and his associates said in a report in JAMA.

The researchers compared sildenafil with placebo in an 8-week randomized clinical trial with 98 premenopausal women who had major depressive disorder in remission. The participants in the study, which was supported by Pfizer Inc., reported persistent sexual dysfunction and had been taking selective or nonselective SRIs for a mean of 27 months.

Treatment efficacy was assessed using four measures: the Clinical Global Impressions Scale adapted for sexual function, the Sexual Function Questionnaire, the Arizona Sexual Experience Scale (female version), and the University of New Mexico Sexual Function Inventory (female version).

At the end of treatment, women in the sildenafil group reported a greater ability to reach orgasm and to experience orgasm satisfaction than did those in the placebo group. They also were more likely to report improvements in arousal, vaginal lubrication, and orgasm delay, the last of which "is considered a central feature of SRI-associated sexual dysfunction," the investigators said.

"Clinically, 73% of women taking placebo, compared with 28% of women taking sildenafil, reported no improvement with treatment," Dr. Nurnberg and his associates said (JAMA 2008;300:395-404).

There were no serious adverse events. The most common minor adverse events were headache (affecting 43% of the sildenafil group and 27% of the placebo group), flushing (24% vs. 0%), dyspepsia (12% vs. 0%), nasal congestion (37% vs. 6%), and transient visual disturbances (14% vs. 2%).

Treating the sexual dysfunction that affects up to 70% of women treated with SRIs should encourage patients to adhere to antidepressant therapy and thus improve outcomes, the researchers added.

Dr. Nurnberg has received research support from, has been a paid consultant for, and has been on speakers bureaus for various pharmaceutical companies that manufacture antidepressants. ■