In June 2006, the U.S. Food and Drug Administration (FDA) approved Gardasil®, a new vaccine against the human papillomavirus (HPV) types that cause the majority of cervical cancers and genital warts. A rival vaccine made by GlaxoSmithKline may be considered for licensure by FDA within the next year. This is welcome news in the fight against cervical cancer, which affects an estimated 9,700 women in the United States annually, and causes 2,700 deaths. This CD Summary provides an overview of HPV, describes the scope of the problem in Oregon, and outlines vaccine recommendations.

**THE SKINNY ON HPV**

The human papillomaviruses comprise more than 100 different strains, about 40 of which can be transmitted through sexual contact. Of those 40, a small number cause most of the disease: HPV types 16 and 18 are responsible for 70% of all cervical malignancies. HPV types 6 and 11 are responsible for 90% of genital warts, or condyloma acuminata.¹

HPV incidence and prevalence are astonishingly high—although most infections are not persistent. An estimated 50–80% of all persons will acquire sexually transmitted HPV in their lifetime. Luckily, about 90% of those infected clear their infections within 2 years.² Women who develop persistent infections are at greatest risk for developing cervical cancer (see figure).

**HPV BURDEN IN OREGON**

An estimated 60,000 Oregonians contract HPV infections each year; most are asymptomatic. Approximately 200,000 people in Oregon are currently infected with HPV, including 15% of all persons aged 15–19. During 2003, 116 cases of invasive cervical cancer were diagnosed in Oregon, and 43 women died of the disease.

**THE PAP TEST**

To date, prevention of cervical cancer has relied on the use of the Pap test to detect pre-cancerous “cervical intraepithelial neoplasia” which can be treated before it progresses to cancer. In fact, widespread use of the Pap test during the past five decades precisely coincides with steep declines in cervical cancer incidence and mortality. The direct medical costs of HPV, including Pap test screening and evaluation and treatment of cervical dysplasia, genital warts, and cervical cancer, amounted to about $30 million per year in Oregon ($3 billion in the US) during 2000, and some invasive cancers continue to occur.³

**HPV VACCINE EFFECTIVENESS**

HPV vaccine consists of an empty viral capsid devoid of nucleic acid. It is given in a series of three injections, at 0, 2, and 6 months. Clinical trials indicate that the vaccine is extremely effective in preventing incident and persistent infection and clinical disease caused by HPV types 6, 11, 16 and 18. No cases of HPV 16- or 18-related dysplasia or adenocarcinoma in situ were noted in 8,487 vaccine recipients after 2–4 years, while 53 cases were observed in 8,460 placebo recipients. Similarly, a single HPV 6-, 11-, 16-, 18-related genital wart was observed in 7,897 vaccine recipients, while 98 were observed in 7,899 placebo recipients.⁴ In another published trial, no HPV 6-, 11-, 16-, 18-related genital warts or dysplasia were observed in 266 vaccine recipients followed for up to 36 months; while 4 of 263 placebo recipients developed warts, and 7 developed dysplasia.⁵ Gardasil® is not effective for treatment for existing dysplasia or genital warts. The vaccine is not licensed for use in boys or men; these studies are ongoing. Duration of immunity beyond 5 years is not yet known.

**VACCINE RECOMMENDATIONS**

The Advisory Committee on Immunization Practices (ACIP) recommends that girls aged 11–12 years be routinely given the 3-dose series of HPV vaccination. The catalog price of Gardasil® is now $120 per dose. Gardasil® is licensed for use in girls aged as young as 9 years and can be given to previously unvaccinated girls and women aged 13–26 years. The Oregon Vaccines for Children (VFC) program expects to make the vaccine
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THE BOTTOM LINE

Routine immunization of young women against HPV should prevent most cervical cancer in the US. However, regular Pap tests will remain a necessity in all sexually active women regardless of HPV vaccination, because the vaccine does not prevent persistent infection with oncogenic HPV types other than 16 or 18.

Remember that HPV vaccination of early adolescents does not prevent other sexually transmitted diseases or pregnancy. Parents and health care providers should continue to encourage young adults to postpone sexual activity as a means to prevent HPV, other sexually transmitted diseases (STD), and pregnancy. For those already sexually active, condom use provides protection against HIV and other STDs and may provide some protection against HPV.

RESOURCES

The Centers for Disease Control and Prevention’s website has detailed information regarding HPV and the newly licensed vaccine for both clinicians and their patients at: http://www.cdc.gov/nip/vaccine/hpv/default.htm.

REFERENCES