CD Summary

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HUMAN PAPILLOMAVIRUS VACCINE: A POTENT ALLY IN CERVICAL CANCER PREVENTION

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 Glaxo-SmithKline 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]

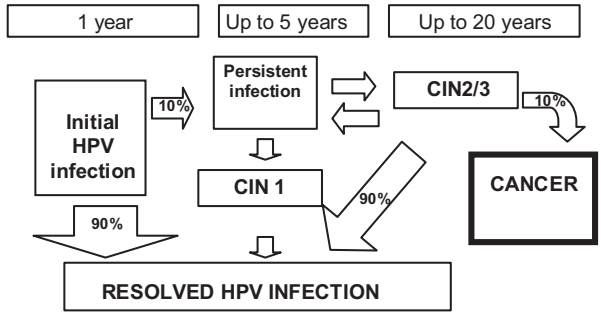
HPV VACCINE EFFECTIVENESS

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

Natural History of HPV Infection and Cervical Cancer



*VFC provides vaccines at no cost to providers who agree to immunize eligible children from birth through age 18. Eligibility categories include: Medicaid, no health insurance, Alaskan Native, and American Indian. In certain federally qualified clinics, underinsured children are also eligible to receive vaccine at no cost.

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available for eligible youth next month.

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.*

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HPV in Oregon: How Big is the Problem?

Incidence/Prevalence
- ~60,000 new infections each year, most asymptomatic
- 50–80% will acquire one or more sexually transmitted HPV infections in their lifetime
- ~200,000 people currently infected—including 15% of all persons aged 15–19

Cervical Cancer
- ~120 new cases and 40 deaths per year
- 11th most common cancer among Oregon women
- 3rd most common cancer among Latin-American women in Oregon

Burden
- ~23,000 abnormal Pap tests per year must be evaluated
- $30 billion estimated direct costs for abnormal Pap smears, genital warts and cervical cancer

HEP B RULE CHANGE

We are proposing a change in Oregon Administrative Rule (OAR) 333-18-0018 to require laboratories to submit sera that test positive for IgM antibody to hepatitis B core antigen (which indicates acute infection) to the Oregon State Public Health Laboratory (OSPHL).

Molecular subtyping has proved pivotal in assessing the relatedness of isolates of bacteria and viruses. OSPHL routinely performs pulsed field gel electrophoresis on isolates of *Salmonella, E. coli* O157, and *Shigella sonnei* in Oregon, allowing us to determine whether seemingly sporadic cases actually represent outbreaks. Similarly, CDC has employed viral sequencing to trace outbreaks of hepatitis A and hepatitis C. For these reasons, OAR 333-18-0018 currently requires the submission of selected specimens and isolates to OSPHL. With the proposed change, OSPHL will receive sera from patients with acute hepatitis B and forward them to CDC for sequencing.

We invite your comments at a hearing at 10 a.m. on November 22, 2006, Room 135, Portland State Office Building, 800 NE Oregon St., Portland; by calling 971-673-1111; or by e-mailing *ohd.acdp@state.or.us*.