



Oregon Public Health Division Office of Family Health Immunization Program 7/27/06 Updated 3/8/07

Human Papilloma Virus (HPV) Vaccine Frequently Asked Questions

1. What is HPV?

The Human Papilloma viruses are a diverse group of over 100 types, not all of which are sexually transmitted. Approximately 60% of strains (cutaneous) are relatively harmless, causing most common skin warts. The remaining strains (mucosal) can be divided into high and low risk groups. The four strains of HPV found in Gardasil® are very common, and are spread through all types of sexual contact with an infected partner. While most HPV infections resolve without treatment within one year, some go on to cause genital warts, precancerous cervical changes that cause abnormal Pap smears, and cervical cancer. Strains 16 and 18 in the vaccine are responsible for 70% of cervical cancers and most abnormal Pap smears worldwide, while strains 6 and 11 are responsible for 90% of genital warts as well as 9% to 12% of low-grade abnormal Pap smears.

HPV infections can be asymptomatic or sub-clinical in their manifestation, which means that most people are unaware of their infection and often under-diagnosed.

2. What HPV vaccines are available?

GARDASIL® is the only HPV vaccine currently available in the United States. It is a safe non-infectious recombinant, quadrivalent vaccine remarkably effective in preventing infections with Human Papillomavirus

¹ HPV can be spread though sexual intercourse (vaginal and anal), genital-to-genital, hand-to-genital, and oral-to genital contact. The infection can cause few or no symptoms, which means that most people don't know if they are infected.

types 6,11,16, and 18. The vaccine is administered in a series of three shots given over a six-month period. No serious side effects, beyond brief soreness at the injection site, have been detected. Current studies are being done on the vaccine in males. Merck intends to seek licensure for males in the next several years.

According to clinical trials, GARDASIL® produces a stronger immune response in youths ages 10-15 than women ages 16-23 years, and while vaccination before onset of sexual activity is best, HPV vaccine can provide some protection for women who have already become sexually active. In clinical trials, women who were already infected with one or more vaccine-related HPV types were protected from clinical disease caused by the remaining HPV vaccine types.

Because the new vaccine does not prevent approximately 30% of cervical cancers, other cancer prevention measures such as Pap smears remain critically important.

There is a second HPV vaccine, CERVERIX®, under study. The vaccine is a bivalent vaccine that protects against HPV types 16 and 18. The vaccine manufacture GlaxoSmithKline, hopes to have the vaccine approved by the FDA in a no so distant future.

Important facts to keep in mind about GARDASIL®:

- ➤ It <u>will not</u> prevent transmission of HIV or other sexually transmitted diseases.
- ➤ 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, but it will not prevent or treat infections with other types of HPV.
- ➤ It will not eliminate the need for regular Pap screening.

3. What are the ACIP recommendations for GARDASIL®?

Gardasil® was approved in June by the U.S. Food and Drug Administration. The vaccine is manufactured by Merck and is licensed for use in females ages 9-26 years. The federal Advisory Committee on Immunization Practices (ACIP) encourages providers to vaccinate females at the routine 11-12 year old pre-adolescent visit with their physician, and 13-26 year old females who have not been previously vaccinated. Providers are also encouraged to vaccinate down to age 9 when possible.

For more information about the ACIP recommendations and upcoming ACIP meetings, visit www.cdc.gov/nip/acip/.

4. What is the Impact of HPV in Oregon?

Each year, up to 50,000 adult women in the State of Oregon have abnormal Pap smears from HPV infection of the cervix. During 2002 in Oregon, 126 women developed invasive cervical cancer and 45 died of the disease. Nationally, approximately 11,150 women develop invasive cervical cancer and 3,670 die of the disease each year. While some cervical abnormalities lead to cervical cancer, most do not, yet every cervical Pap smear requires additional medical evaluation and treatment at a national cost of \$4,000,000,000 per year.

In order to prevent any unnecessary deaths from cervical cancer, early administration of HPV vaccine is ideal. The vaccine is most effective when given prior to the first sexual activity. In Oregon, 43% of all high school girls report having already had sexual intercourse. Of

Cervical cancer in Oregon women

- –11th most common cancer among women
- -3rd most common cancer among Latina women
- −120 new cases per year
- -40 deaths per year
- •23,000 abnormal Pap smears per year
- •~\$30 million / year

those, nearly 1 in 7 had their first sexual intercourse by age 13. Oregon State Public Health urges physicians and families to have girls and young women immunized as early as possible. The Society for Adolescent Medicine strongly supports linking vaccination to preventive health care visits during early, middle and late adolescence. These visits present an important opportunity for young women to be vaccinated against HPV and other vaccine preventable disease, as well as time to discuss and learn about healthy choices and risk reduction.

Recent data regarding HPV supports postponing sexual activity as means to reduce cervical cancer risk. For those already sexually active, condom use provides protection against HIV and other sexually transmitted diseases and may offer some protection against HPV infection, abnormal Pap smears and cervical cancer if used regularly. After becoming sexually active, all women—even those vaccinated against HPV—should continue to have routine Pap smears to screen for and treat precursors to cervical cancer.