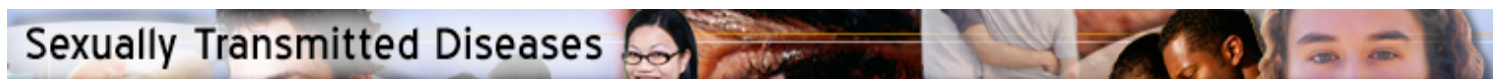


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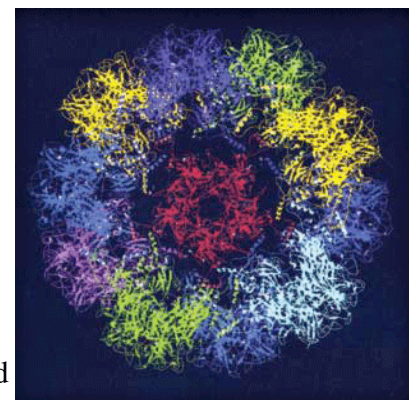
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HPV and HPV Vaccine - Information for Healthcare Providers

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Overview

[HPV infection](#) is the most common sexually transmitted infection (STI) in the United States (U.S.), with approximately 20 million Americans currently infected. Each year, an additional 6.2 million people become newly infected.¹ As many as half of those infected with HPV are adolescents and young adults, ages 15-24 years.²



While most HPV infections are asymptomatic and transient, HPV is of clinical and public health importance because persistent infection with certain oncogenic types can lead to cervical cancer. Cervical cancer is one of the most common cancers in women worldwide. Certain oncogenic types also have been associated with other, less common anogenital cancers. Moreover, non-oncogenic HPV types can cause genital warts and, rarely, respiratory tract warts in children.

On June 8, 2006, an HPV vaccine was licensed by the [Food and Drug Administration](#) (FDA) for use in females, ages 9-26 years. Another HPV vaccine is in the final stages of clinical testing, but not yet licensed. These vaccines offer a promising new approach to the prevention of HPV and associated conditions.

Genital HPV Infection

Over 30 types of HPV infect mucosal surfaces, including the anogenital epithelium (i.e., cervix, vagina, vulva, rectum, urethra, penis, and anus).

Genital HPV can be divided into “high-risk” (i.e., oncogenic or cancer-associated) types, and “low-risk” (i.e., non-oncogenic) types.

- HPV 16 and 18 are the most common high-risk types found in cervical cancer
- HPV 6 and 11 are the most common low-risk types found in genital and respiratory tract warts

Natural history of HPV

Over half of sexually active women and men are infected with HPV at some point in their lives.³ Approximately 90% of women with HPV infection become HPV-negative within two years.⁴ The gradual development of an effective immune response is thought to be the likely mechanism for HPV DNA clearance. However, it is also possible that the virus remains in a non-detectable dormant state and then reactivates many years later.

Many women with transient HPV infections may develop mild cytologic (Pap test) abnormalities that spontaneously regress.

About 10% of women infected with HPV develop persistent HPV infection. Women with persistent high-risk HPV infection are at greatest risk for developing high-grade cervical cancer precursor lesions (cervical intra-epithelial neoplasia or CIN 2,3) and cancer.

HPV-Associated Disease

Persistent infection with high-risk types of HPV is associated with almost all cervical cancers. The age-adjusted incidence rate for invasive cervical cancer in the U.S. was 8.7 per 100,000 women in 2002 (most recent year for which data are available).⁵ In that same year, 3,952 women died from this disease in the U.S.

Persistent infection with high-risk types of HPV is also associated with cancers of the vulva, vagina, penis and anus. However, these cancers are considerably less common than cervical cancer.

Genital HPV infection with low-risk types of HPV is associated with genital warts in men and women. About 1% of sexually active adults in the U.S. have visible genital warts at any point in time.²

Very rarely, [perinatal transmission](#) of low-risk HPV infections can result in respiratory tract warts in infants and children, a condition known as recurrent respiratory papillomatosis (RRP).

Prevention of Cervical Cancer

Cervical cancer once claimed the lives of more American women than any other type of cancer. But over the last 40 years, widespread cervical cancer screening using the Pap test and treatment of pre-cancerous cervical abnormalities have resulted in a marked reduction in cervical cancer incidence and mortality in the U.S.⁶ New technologies, such as liquid-based cytology and an HPV DNA test, are now commercially available and approved for use in women for cervical cancer screening and management, although they are not recommended by all professional associations.

Today, as many as 82% of women in the U.S. have been screened with a Pap test in the past three years.⁷ Despite this, U.S. screening programs are not reaching all women in the U.S. It is estimated that half of the women diagnosed with cervical cancer have never been screened for cervical cancer, and an additional 10% have not been screened in the previous 5 years.^{5,8} Cervical cancer disproportionately affects women of lower socioeconomic status, without regular access to health care, who are uninsured, and who are recent immigrants.^{6, 9}

HPV Vaccine

- A quadrivalent HPV vaccine (manufactured by Merck) has recently been licensed by the Food and Drug Administration (FDA) for females, ages 9-26 years. The vaccine protects against four types of HPV (6,11,16,18), including two that cause 70% of cervical cancers and two that cause 90% of genital warts. The vaccine has been tested in over 11,000 females (ages 9-26 years).
- This vaccine is prophylactic and made from non-infectious HPV-like particles (VLP), composed of the L1 major capsid protein. There is no thimerosal or mercury contained in the vaccine.
- The vaccine should be delivered through a series of three intra-muscular injections over a six-month period (at

- 0, 2, and 6 months).
- Clinical trials in females (ages 16-26 years) have demonstrated 100% efficacy in preventing cervical precancers caused by the targeted HPV types. The vaccine has also been found to be almost 100% effective in preventing vulvar and vaginal precancers and genital warts caused by the targeted HPV types. The vaccine has no therapeutic effect on HPV-related disease; it does not protect from disease due to HPV types already acquired.
 - Efficacy studies for the vaccine in males (ages 9-15 years) are ongoing. Data will be available in the next few years.
 - The vaccine appears to be safe and there are no serious side effects. Adverse reactions are mainly injection site pain. This reaction is common but mild.
 - The duration of protection is unclear. Current studies indicate the vaccine is effective for five years. There is no evidence of waning immunity during that time period. This information will be updated as additional data regarding immunity become available.
 - The [CDC Advisory Committee on Immunization Practices](#) (ACIP) is considering recommendations for use of the quadrivalent vaccine in females. The proposed recommendations are to provide routine vaccination for 11-12 year-old girls and catch-up vaccination for 13-26 year-old females. An ACIP vote is expected June 29, 2006.
 - Ideally, the vaccine would be administered before onset of sexual activity. However, females who are sexually active may also benefit from vaccination. Those who have not been infected with any vaccine HPV type would receive the full benefit of vaccination. Those who have already been infected with one or more HPV type would still get protection from the vaccine types they have not yet acquired. Few young women are infected with all four vaccine HPV types (6,11,16,18).
 - While it is possible that vaccination of males with the quadrivalent vaccine may offer direct health benefits to males and indirect health benefits to females (through herd immunity), there are not yet data to confirm this. No efficacy data are available for use in males. This information will be available in the future.
 - The retail price of the vaccine is \$120 per dose (\$360 for full series).
 - If the ACIP recommends the vaccine for routine use, federal health programs such as [Vaccines for Children \(VFC\)](#) will cover the HPV vaccine for persons less than 19 years of age who are VFC eligible.
 - Although an effective HPV vaccine is a major advance in approaches to the prevention of genital HPV and associated diseases, it will not replace other prevention strategies since vaccines will not work for all genital HPV types.
 - Vaccinated women will still need regular cervical cancer screening since the vaccine will NOT provide protection against all types of HPV that cause cervical cancer, and since some women may not receive the full vaccine series (or they may not receive them at appropriate intervals).
 - Vaccinated women should still practice protective sexual behaviors (e.g., abstinence, monogamy, limiting the number of sex partners, and/or using condoms, which is associated with lower rates of genital warts and cervical cancer¹⁰), since the vaccine will *not* prevent all HPV types—nor will it prevent other STIs.
 - A bivalent HPV vaccine (being developed by GlaxoSmithKline) is in the final stages of testing in females and may be available soon. This vaccine would protect against the two types of HPV (16,18) that cause 70% of cervical cancers.


Additional Sources of Information

www.cdc.gov/ncidod

www.cancer.org

www.fda.gov/bbs/topics/NEWS/2006/NEW01385.html

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