

The HPV Vaccine:

What Health Care Providers Need to Know

What are the Main Messages About Human Papillomavirus Vaccine (HPV)

for Your Patients?

- » Preventing cervical cancer is the most important benefit of HPV vaccine.
- » HPV vaccines are now licensed for both males and females.
- » Three doses of HPV vaccine over six months are needed.
- » Routine Pap screening for cervical cancer remains important regardless of vaccination against HPV.
- » The vaccine is safe.

Cervical Cancer in the United States: What is the Risk?

Early diagnosis via Pap screening and follow-up treatment has significantly reduced death from cervical cancer in the United States. Despite this, in 2009, an estimated 11,270 women were diagnosed with cervical cancer, and 4,070 women died from it. More than half of women with cervical cancer have not had a recent Pap test.

What is HPV?

There are more than 100 different types of HPV; over a third of these infect genital epithelial cells (skin and mucous membranes). Genital HPV types are subdivided into high-risk types that can cause cancer and low-risk types that can cause warts. Nearly all cervical cancers are caused by high-risk HPV. Types 16 and 18 account for about 70 percent of cervical cancers in the United States and about 40 percent of vulvar and vaginal cancers. The high-risk HPV types 16 and 18 also have been associated with oropharyngeal cancers and anal cancer in both genders and penile cancer in men. Low-risk types 6 and 11 account for about 90 percent of genital warts in men and women. The vast majority of HPV infections are asymptomatic and resolve without causing disease.

How is HPV Transmitted?

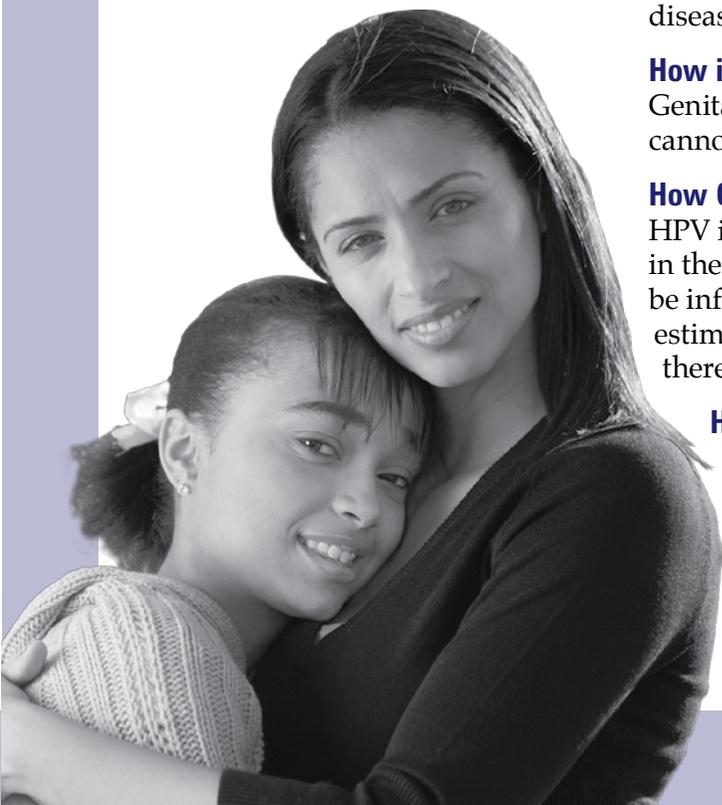
Genital HPV is transmitted sexually through genital contact and cannot be entirely prevented by condom use.

How Common is HPV Infection?

HPV is among the most common sexually transmitted infections in the United States. Well over half of sexually active people will be infected with genital HPV at some point in their lives. An estimated 20 million men and women are currently infected, and there are about 6.2 million new infections each year.

How Many HPV Vaccines are There?

There are currently two HPV vaccines. Gardasil®, produced by Merck, is a quadrivalent vaccine against HPV types 6, 11, 16, and 18 and licensed for use in females and males ages 9 through 26 years. Cervarix®, developed by GlaxoSmithKline, is a bivalent vaccine against HPV types 16 and 18 licensed for females ages 10 through 25 years. Neither vaccine contains the preservative thimerosal.



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How is HPV Vaccine Administered?

The HPV vaccines are given intramuscularly as a 0.5 mL dose in a three-dose series. The second dose is given one to two months after the first dose. The third dose is given six months after the first dose.

What if a Patient Cannot Complete the Series on Schedule?

If the vaccine series is interrupted, administer the next dose when possible. It is not necessary to restart the series, even if a significant amount of time has passed. Whenever possible, the same HPV vaccine product should be used for all doses in the series.

How Safe is HPV Vaccine?

The Centers for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA) have reviewed clinical trials and postlicensure data and consider HPV vaccines safe and effective. Both HPV vaccines have been associated with local injection-site reactions, especially pain. Syncope is more common among adolescents and young adults. To prevent syncopal injury, consider observing patients for 15 minutes after vaccination. Studies continue to monitor HPV vaccine safety. Adverse events after vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS), maintained by the FDA and CDC. To receive a VAERS reporting form, call (800) 822-7967 or report online at www.vaers.hhs.gov.

How Effective is HPV Vaccine?

In clinical studies, HPV vaccines have been over 90 percent effective in preventing infection and precancerous lesions in women caused by high-risk HPV types 16 and 18. The vaccine will not prevent disease in women who already have been infected by the specific HPV types included in the vaccine.

The vaccine has no value in eliminating pre-existing HPV infection or in treating HPV disease.

Can it Prevent Genital Warts?

The quadrivalent HPV vaccine Gardasil® also offers protection against genital warts for both males and females. Efficacy is close to 90% in males and close to 100% in females in protecting against genital warts caused by HPV types 6 and 11.

How Long Does Immunity Last?

The duration of immunity is not known; current studies have demonstrated protection up to six years. It is not yet known if booster doses will be needed in the future.

Who Should Get HPV Vaccine?

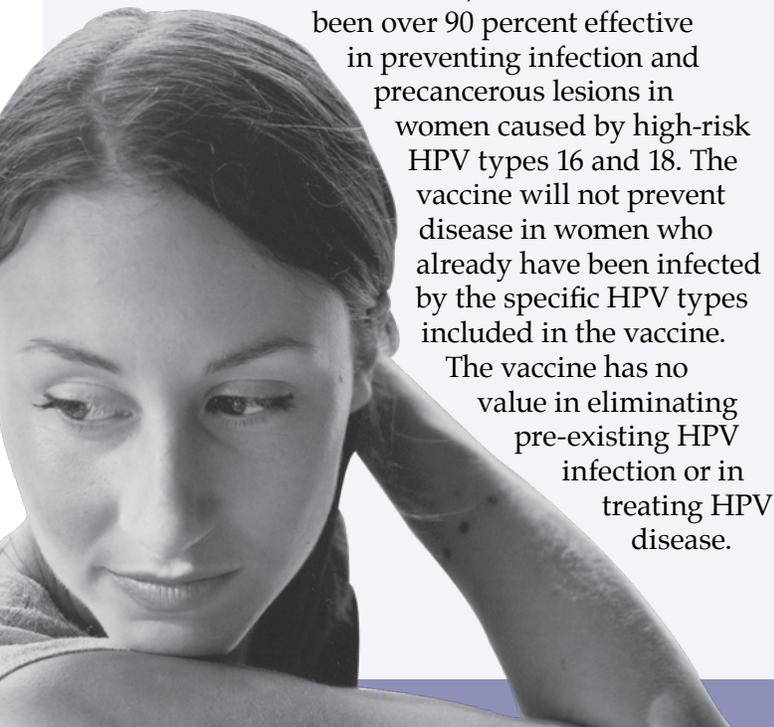
The federal Advisory Committee on Immunization Practices (ACIP) recommends three doses of HPV vaccine:

- » Routinely for females 11 or 12 years, though physicians may vaccinate girls starting at age 9.
- » Routinely for females 13 through 26 years, if not yet vaccinated or not yet completed the vaccine series.
- » Males 9 through 26 years may be vaccinated with the quadrivalent HPV vaccine only.

Patients not infected with HPV types included in the HPV vaccine benefit most from vaccination. Although HPV vaccines cannot treat prior HPV infection, sexually active patients are unlikely to have been exposed to all HPV types covered by the vaccines. Therefore, sexually active patients can still benefit from the vaccine for the virus type(s) in the vaccine they have not yet acquired.

Who Should not be Immunized with HPV Vaccine?

Do not vaccinate individuals with a history of immediate hypersensitivity (e.g., anaphylaxis) to any component of the HPV vaccines. This includes hypersensitivity to yeast (in the quadrivalent vaccine only) and history of anaphylaxis to latex (in the bivalent vaccine pre-filled syringes only; not in single dose vials). Defer immunization during pregnancy or moderate to severe illness until the illness improves.



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Should Pregnant Women Receive HPV Vaccine?

HPV vaccination is not recommended during pregnancy. The vaccine has not been associated casually with adverse outcomes of pregnancy or adverse events to the developing fetus; however, data are limited. If a woman begins the vaccine series and then becomes pregnant, the series should be suspended until after the pregnancy. No treatment is recommended for women who receive one or more doses of the HPV vaccine while pregnant. Exposures to HPV vaccine during pregnancy should be reported to the manufacturer's pregnancy registry at (800) 986-8999 (Gardasil®) or (888) 452-9622 (Cervarix®) so that the vaccines can continue to be assessed for safety.

Is HPV Vaccine Required for Entry into Grade School or College?

No. Regardless, providers are encouraged to provide a routine medical visit for children 11 or 12 years old and to urge parents to vaccinate their children according to ACIP recommendations.

Does the HPV Vaccine Replace Pap Screening?

No. It is important that women continue to receive routine Pap screening. Because the HPV types targeted by the vaccine account for 70 percent of cervical cancer, the cancer risk is significantly decreased, but not eliminated.

Is HPV Testing Needed with HPV Vaccine?

No. There is no role for serologic or DNA testing for the HPV virus before or after administering the HPV vaccine. Even after infection with one type of HPV, immunization can still protect against other types covered by the vaccine.

Are HPV Vaccines Covered by Health Plans or Other Programs?

The Vaccines for Children (VFC) program covers both licensed HPV vaccines for eligible girls 9 through 18 years and covers the quadrivalent HPV vaccine only for eligible boys 9 through 18 years.

The VFC program serves children and adolescents up to and including 18 years of age who are either uninsured, Medi-Cal eligible, Native American, or Alaska Native. Eligible children and adolescents can also get VFC vaccines through federally qualified health centers or rural health centers if their private health insurance does not cover the vaccine.

By law, California's managed care plans must cover all ACIP-recommended vaccines for children. Co-payments may apply for those visits. Most health plans cover the vaccine for girls, but some may not cover the vaccine for adult women or males. Please check with the specific health plan for more information.

How Can I Participate in the VFC Program?

VFC has more than 4,000 enrolled provider sites in California. Any medical practice providing vaccinations to low-income children meeting VFC eligibility may choose to become a VFC provider. To learn more about California's VFC program, including how to become a VFC provider, visit www.EZIZ.org or call the VFC program office toll-free at (877) 243-8832.

Are There Patient Information Materials Available?

Fact sheets on the HPV vaccine produced by CDC can be accessed at www.HpvVaccineCa.org. A Vaccine Information Statement is required to be given to patients, parents, or guardians. The most up-to-date version is available at www.cdc.gov/vaccines/pubs/vis/default.htm.



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Additional resources can be found at:

California Department of Public Health

www.HpvVaccineCa.org

Advisory Committee on Immunization Practices (ACIP)

www.cdc.gov/vaccines/recs/acip/default.htm

American Cancer Society

www.cancer.org

American Social Health Association, HPV Resources

www.ashastd.org/learn/learn_hpv.cfm

California Medical Association Foundation: Cervical Cancer and HPV Project

www.calmedfoundation.org/projects/HPV/index.aspx

Centers for Disease Control and Prevention, HPV Vaccine Fact Sheet

www.cdc.gov/std/hpv

Food and Drug Administration

www.fda.gov

National Cancer Institute

www.cancer.gov/cancertopics/types/cervical

National STD/HIV Prevention Training Center

www.stdhivtraining.org

Vaccine Information Statements in Multiple Languages (Immunization Action Coalition)

www.immunize.org/vis

Vaccines for Children (VFC) Program in California

www.EZIZ.org

Medical Literature

ACIP Provisional Recommendations for HPV Vaccine. December 2009. <http://www.cdc.gov/vaccines/recs/provisional/downloads/hpv-vac-dec2009-508.pdf>

Baseman JG, Koutsky LA. The epidemiology of human papillomavirus infections. *J Clin Virol.* 2005;32 (Suppl 1):S16-24.

Paavonen J, Naud P, Salmerón J, et al. for the HPV PATRICIA Study Group. Efficacy of human papillomavirus (HPV)-16/18 AS04-adjuvanted vaccine against cervical infection and precancer caused by oncogenic HPV types (PATRICIA): final analysis of a double-blind, randomised study in young women. *Lancet.* 2009 Jul 25;374(9686):301-14. Epub 2009 Jul 6.

FUTURE II Study Group. Quadrivalent vaccine against human papillomavirus to prevent high-grade cervical lesions. *N Engl J Med.* 2007 May 10;356(19):1915-27.

GlaxoSmithKline Vaccine HPV-007 Study Group. Sustained efficacy and immunogenicity of the human papillomavirus (HPV)-16/18 AS04-adjuvanted vaccine: Analysis of a randomised placebo-controlled trial up to 6.4 years. *Lancet Dec 2009; 374(9706):1975-1985.*

Markowitz LE, Dunne EF, Saraiya M, Lawson HW, Chesson H, Unger ER; Centers for Disease Control and Prevention (CDC); Advisory Committee on Immunization Practices (ACIP). Quadrivalent Human Papillomavirus Vaccine: Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR Recomm Rep.* 2007 Mar 23;56(RR-2):1-24.

Slade AB et al. Postlicensure safety surveillance for Quadrivalent Human Papillomavirus Recombinant Vaccine. *JAMA.* 2009; 302(7): 750-757

Winder DM et al.. Sensitive HPV detection in oropharyngeal cancers. *BMC Cancer Dec 15, 2009; 9(1): 440.*



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