

The HPV Vaccine:

What Health Care Providers Need to Know

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

for Your Patients?

- » Preventing cancer is the most important benefit of HPV vaccine.
- » HPV vaccines are licensed for both males and females.
- » Three doses of HPV vaccine over six months are needed.
- » Giving HPV vaccine at age 11-12 years ensures strong protection well in advance.
- » HPV vaccines are safe.

What is HPV?

There are more than 150 different types of HPV; over 40 can infect the skin or mucous membranes of the genitals. HPV types are subdivided into high-risk types that can cause cancer and low-risk types that can cause warts. The vast majority of HPV infections resolve without ever causing symptoms or disease, but persistent HPV infections can lead to cancer.¹

What cancers are related to HPV infections?

Infection with high-risk HPV types 16 and 18 account for approximately 70% of cervical cancers in the United States.^{2,3,4} Five more types (31, 33, 45, 52, and 58) account for an additional 15% of cervical cancers.² Even though Pap screening can aid in early diagnosis, each year about 12,000 women in the United States are diagnosed with cervical cancer and more than 4,000 die from it. More than half of women with cervical cancer have not had a recent Pap test.⁵

HPV is thought to be responsible for more than 90% of anal cancers; about 70% of vaginal, vulvar and oropharyngeal cancers; and more than 60% of penile cancers.⁶ HPV infections are associated with over 12,000 cancers in men and over 20,000 cancers in women each year.⁶

How is HPV Transmitted?

HPV can be transmitted sexually and cannot be entirely prevented by condom use.

How Common is HPV Infection?

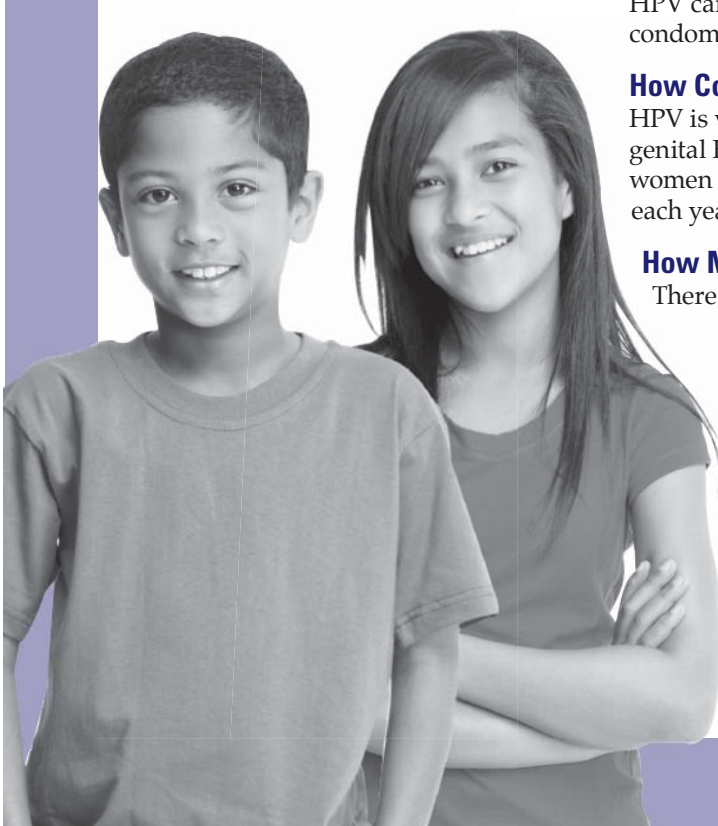
HPV is very common. Nearly all sexually active people will be infected with genital HPV at some point in their lives. An estimated 79 million men and women are currently infected, and there are about 14 million new infections each year.⁷

How Many HPV Vaccines are There?

There are currently three licensed HPV vaccines:

- » Gardasil^{®9} (HPV9; Merck), HPV types: those in HPV4 + types 31, 33, 45, 52, and 58
Indications: Prevention of vaginal, vulvar, anal, and cervical precancers and cancers, and genital warts.²
- » Gardasil[®] (HPV4; Merck), HPV types: 6, 11, 16, and 18
Indications: Prevention of vaginal, vulvar, anal, and cervical precancers and cancers, and genital warts.^{8,9}
- » Cervarix[®] (HPV2; GlaxoSmithKline), HPV types: 16 and 18
Indications: Prevention of cervical precancers and cancers.⁴

None of the HPV vaccines contain the preservative thimerosal.⁴



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Who Should Get HPV Vaccine?

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

- » Routinely for females and males 11 or 12 years, though physicians may vaccinate starting at age 9.
- » Routinely for females 13 through 26 years and males 13 through 21 years, if not yet vaccinated or not yet completed the vaccine series.
- » For gay men, other men who have sex with men, and men with compromised immune systems who are 22 through 26 years, if not yet vaccinated or not yet completed the series.
- » Other males through age 26 years may also be vaccinated.

All HPV vaccines are licensed for use in females, but HPV4 and HPV9 are also licensed for use in males. 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, immunization can still protect sexually active patients against HPV virus type(s) in the vaccine with which they have not been infected.

Providers should give a strong recommendation for the HPV vaccine series along with the other vaccines for preteen girls and boys.¹⁶

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 and four months after the second dose.

What are Ways to Ensure Patients Complete the Series on Schedule?

Patient reminder and recall systems help notify patients of scheduled appointments and contact patients who have missed appointments and need to reschedule. Reminder postcards, phone calls, and text messages may be helpful in getting patients to complete the series.

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.

May An Individual Receive Multiple HPV Vaccines?

Females: A dose of any HPV vaccine may be used for protection against HPV types 16 and 18 when providers

- » do not know which vaccine the patient previously received,
- » do not have available the formulation used for prior doses,
- » are transitioning to HPV9 from other formulations.²

Males: HPV9 may be used to complete a series regardless of the formulation used for preceding doses.²

How Safe is HPV Vaccine?

The Centers for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA) have reviewed clinical trials and post-licensure data and consider HPV vaccines to be safe and effective. All HPV vaccines have been associated with local injection-site reactions, especially pain. Syncope is more common among adolescents and young adults. To prevent injury after fainting, 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% effective in preventing infection and precancerous lesions in females caused by high-risk HPV types 16 and 18.¹⁰

Even though HPV vaccination rates among adolescents are low, HPV vaccine-type infections in adolescent females have decreased by 56% since HPV vaccine introduction in 2006.¹¹ In Australia, where HPV vaccination coverage is over 70%, HPV vaccine has reduced the number of cases of high-grade cervical lesions in young women.¹⁵ Prevalence of HPV vaccine-related infections in vaccine-eligible females have also decreased by over 75%.¹⁵

Vaccination prevents infection with the HPV types included in the vaccine to which a vaccinated person is naïve. Vaccination does not eliminate or treat preexisting HPV infection or disease.

Can it Prevent Genital Warts?

Yes. HPV4 and HPV9 also offer 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.^{2,8} In Australia, the incidence of genital warts has declined by more than 90% in women younger than 21 years and more than 80% in males older than 21 years since HPV vaccine was introduced.¹⁵

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Can it Prevent Anal and Vaginal Cancers?

Yes. The FDA approved HPV4 in 2010 and HPV9 in 2014 to help prevent anal cancer. The vaccines may be up to 78% effective in preventing anal cancer associated with the vaccine-related HPV types. HPV4 and HPV9 may be up to 100% effective in preventing vulvar and vaginal cancer associated with the vaccine-related HPV types.^{2,3,4}

How Long Does Immunity Last?

Studies suggest that vaccine protection is long-lasting and available evidence indicates protection for at least 8-10 years, with no evidence of waning immunity.

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 HPV4 and HPV9) and history of anaphylaxis to latex (in pre-filled syringes of HPV2; not in single-dose vials of HPV2).^{1,2,4} Defer immunization during moderate to severe illness until improvement.¹

Should Pregnant Women Receive HPV Vaccine?

No. HPV vaccination is not recommended during pregnancy. The vaccine has not been associated causally 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 pregnancy. Pregnancy testing is not needed before vaccination. No treatment is recommended for women who receive one or more doses of the HPV vaccine while pregnant. Exposures to HPV9 vaccine during pregnancy should be reported to the manufacturer's pregnancy registry at (800) 986-8999 (Merck) so that the vaccine can continue to be assessed for safety.

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

No. Regardless, providers should recommend HPV vaccine during routine medical visits for children 11 years of age or older, and urge parents to vaccinate their children according to national recommendations. The healthcare provider recommendation is the single best predictor of vaccination against HPV.

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 vaccines account for approximately 70-85% of cervical cancer, the cancer risk is significantly decreased but not eliminated.^{2,7}

Is HPV Testing Needed for Immunization?

No. Serologic or DNA testing for the HPV virus isn't needed to make decisions about administering 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?

Yes. The Vaccines for Children (VFC) program includes HPV vaccines for eligible females and males 9 through 18 years. The VFC program serves children and adolescents 0-18 years of age who are uninsured, Medi-Cal eligible, Native American, or Alaska Native. Many children and adolescents whose private health insurance does not cover immunizations can get VFC vaccines through federally qualified health centers or rural health centers. By law, most health plans must cover all ACIP-recommended vaccines. Please check with the specific health plan for more information.

How May 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 and CDPH can be accessed at www.EZIZ.org. A Vaccine Information Statement is required to be given to patients, parents, or guardians before the vaccine is administered. The most up-to-date version is available at www.cdc.gov/vaccines/hcp/vis/index.html.



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Additional resources can be found at:

California Department of Public Health

www.getimmunizedca.org

Advisory Committee on Immunization Practices (ACIP)

www.cdc.gov/vaccines/acip/index.html

American Cancer Society

www.cancer.org

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

Tips and Timesavers for Talking to Parents About HPV Vaccine

www.cdc.gov/std/hpv

Medical Literature

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