

The HPV Vaccine: Access and Use in the U.S.

The FDA has approved two vaccines that protect young people against infection by certain strains of the human papillomavirus (HPV), the most common sexually transmitted infection (STI) in the United States.¹ The vaccines were originally recommended just for use in girls and young women, but recently the recommendations have been broadened to include vaccinations for boys and young men. This factsheet discusses HPV and related cancers, use of the HPV vaccines for both females and males, and insurance coverage and access to the vaccines.

HPV and Cancer

There are more than 100 strains of HPV, and while most cases of HPV infection usually resolve on their own, there are more than 40 strains that can cause cancer. Overall, HPV is related to almost 100% of cervical cancer cases.² Cervical cancer is the main concern with HPV, but the disease is also known to cause oral, anal, vulvar, vaginal and penile cancers, as well as genital warts.¹

- HPV infection in the U.S. is widespread; there are more than 6 million new infections annually, and it is estimated that 50% of sexually active men and women will get HPV at some point in their lives.³ The highest rates are seen among women ages 20-24, with a prevalence rate of 45%.⁴
- In the U.S., it is estimated that over 12,000 new cases and 4,290 deaths from cervical cancer will occur in 2011.⁵ In 2008, over 529,000 new cases of cervical cancer and 275,000 deaths attributed to cervical cancer occurred worldwide, with 86% of the cases in developing countries.⁶
- Cervical cancer is usually treatable, especially when detected early; regular screening with Pap tests is critical for early detection. Draft guidelines by the U.S. Preventive Services Task Force recommend that women ages 21 to 65 receive a Pap test once every three years.⁷
- Despite widespread availability of Pap testing, disparities in cervical cancer incidence, screening, and mortality rates by race and insurance status persist. African-American women have the highest mortality rates of the disease (Figure 1).^{5,8}

- However, African American women also have the highest rates of recent pap testing to screen for the disease (80%, compared to 75% of White women and 65% of Asian women).⁹ Limited access to treatment and early detection, as well as cost, lack of physician referral, and cultural barriers may account for some of these disparities.¹⁰
- Men are at a much lower risk than women for developing an HPV related cancer and suffer from less than 25% of reported cases.¹¹

HPV Vaccines

Currently, there are two HPV vaccines available in the U.S., varying slightly in protection, cost, and target population.

- Gardasil®, produced by Merck, prevents infection of four strains of HPV—6, 11, 16, and 18—and was approved by the FDA in 2006 for females and in 2009 for males.³
- GlaxoSmithKline's vaccine, Cervarix®, was approved by the FDA in 2009 and protects against HPV strains 16 and 18. Unlike Gardasil, Cervarix can only be administered to females and does not protect against genital warts.^{12,13}
- HPV strains 16 and 18 are associated with 70% of cervical cancer cases, while strains 6 and 11 are associated with 90% of genital warts cases.¹ Both vaccines have been shown to protect against vulvar and vaginal cancers, and Gardasil also protects against HPV-associated anogenital diseases.^{14,15,16}
- The primary benefits of vaccinating men include protection against genital warts, anal cancer, and preventing transmission of HPV to sexual partners.¹⁸
- Both vaccines are currently administered in 3 doses over 6 months, but research is under way as to whether 2 doses may be sufficient to provide protection.¹⁷
- Current research suggests the vaccine protection is long-lasting: 6 years of follow-up data indicate the vaccines are still effective and there is no evidence of waning protection, although it is still unknown if women will need a booster.¹⁸
- In the U.S., Gardasil has been approved by the FDA for use in males and females ages 9-26 and Cervarix has been approved for females ages 10-25.³

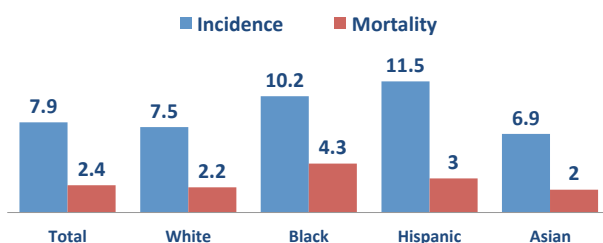
Immunization Recommendations

- The federal Advisory Committee on Immunization Practices (ACIP) recommended use of the HPV vaccine for females in 2006, and added the recommendation for males in 2011.
- ACIP recommends that all girls and boys get vaccinated at age 11 or 12, and that girls and women ages 13-26 and boys and men ages 13-21 be given a "catch-up" vaccination.¹⁸ The vaccine is recommended for "permissive use" in men ages 22-26.¹⁹
- These recommendations are designed to promote vaccination before the initiation of sexual activity and exposure to HPV, when the vaccine is most effective.¹⁸ Those already infected with HPV can benefit from the vaccine because it can prevent infection against HPV strains they may not have contracted, but the vaccine does not treat existing HPV infections.¹⁸

Figure 1

Incidence and Mortality Rates of Cervical Cancer in U.S., 2007

Incidence and Mortality by Race/Ethnicity, 2007



Note: Rates are per 100,000 persons and are age-adjusted to the 2000 U.S. standard population.
Sources: CDC, US Cancer Statistics: An Interactive Atlas.

Vaccine Financing

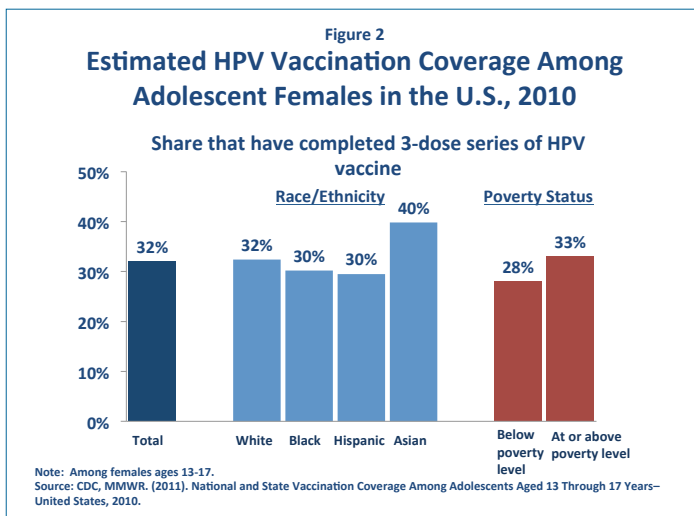
The 3 doses of the HPV vaccine cost \$130 per injection (\$390 for entire series).¹⁸

Private Insurance

- The majority of people in the target age group for the HPV vaccine have private insurance. As a result of the federal Affordable Care Act (ACA), all new private insurance plans must cover HPV vaccines as well as Pap tests for the recommended populations without consumer cost-sharing because they are recommended by ACIP.²⁰

Public Financing

- **Vaccines for Children (VFC) Program** – This federally-financed program pays for vaccines recommended by ACIP for children ages 18 and under who are either Medicaid-eligible, uninsured, American Indian or Alaska Native, or underinsured.²¹ Almost half (41%) of all children's vaccines are paid for by the VFC program.²²
- **Immunization Grant Program (Section 317)** – Through this federal program, the CDC awards federal grants to state, local, and territorial public health agencies to aid with vaccine costs. Funds can help extend coverage to children who do not qualify for VFC program.²³
- **Medicaid** – The VFC pays for vaccinations for all children through age 18 with Medicaid. Women and men ages 19 and 20 also are eligible for Medicaid coverage of all ACIP-recommended vaccines as a Medicaid Early and Periodic Screening Diagnosis and Treatment program (EPSDT) service.²⁴ For adults 21 and older on Medicaid, vaccine coverage is an optional benefit and is decided on a state-by-state basis. As of 2009, at least 28 states reported covering the vaccine for adults.²⁵
- **State Children's Health Insurance Program (SCHIP)** – States with SCHIP programs that are separate from their Medicaid programs must cover ACIP-recommended vaccines for beneficiaries. However, they must use state funds because children enrolled in these programs are not eligible for coverage under the federal VFC.²⁶
- There is currently no source of public funding for vaccines for uninsured adults age 21 and older. For uninsured, low-income adults, Merck and GlaxoSmithKline have established assistance programs to provide free vaccines.²¹



Outreach and Utilization

Awareness of the vaccine has grown, but take-up has been limited.

- In 2008, 87% of women 18 to 64 reported they had heard of the HPV vaccine, primarily through the mass media.²⁷ Although 35 million doses have been distributed, only 32% of adolescent girls aged 13-17 received all 3 doses of the vaccine in 2010, and there are disparities by race/ethnicity and income (Figure 2).²⁸
- Since 2006, 41 states, including D.C., have introduced legislation that would require, fund or educate the public about HPV and the vaccine, and 20 states have enacted legislation. Only D.C. and Virginia require the vaccine for girls to enter the sixth grade.²⁹ Both states allow parents to opt out of the requirement due to medical, moral, or religious opposition.¹⁹

HPV vaccines are unique in their ability to prevent cancer. In developing nations, where cervical cancer is a leading cause of cancer death among women, the vaccine has an enormous potential to save thousands of lives. However, access to the vaccine is limited mostly to affluent populations in developed countries.⁴ The recent addition of males to the vaccine's intended population will increase the reach of the vaccine in protecting both women and men against cancer. Despite these advances, there are still a number of financing, public acceptance, and delivery system challenges that must be met to ensure widespread uptake of this important preventive health achievement.

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The Henry J. Kaiser Family Foundation: 2400 Sand Hill Road, Menlo Park, CA 94025 (650) 854-9400 Facsimile: (650) 854-4800

Washington, D.C. Office: 1330 G Street, N.W., Washington, D.C. 20005 (202) 347-5270 Facsimile: (202) 347-5274 www.kff.org

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