

January 2015 | Fact Sheet

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

Vaccination rates have remained mostly static for the 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 only for girls and young women and were subsequently broadened to include 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

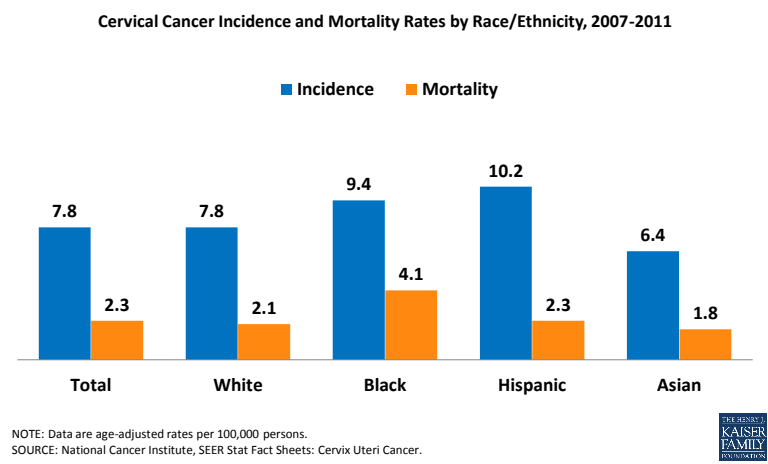
HPV infection in the U.S. is widespread; there are more than 14 million new infections annually, and it is estimated that 50% of sexually active men and women will get HPV at some point in their lives.² Almost 50% of new infections occur in women ages 15-24.³ There are more than 150 strains of HPV, and while most cases of HPV infection usually resolve on their own, there are more than 40 strains that can cause cancer.⁴ In particular, HPV is related to almost 100% of cervical cancer cases, with two strains (16 and 18) related to approximately 70% of cervical cancer cases.^{5, 6} While cervical cancer is the main concern with HPV, the infection affects both women and men and is also known to cause oral, anal, vulvar, vaginal and penile cancers, as well as genital warts.⁷

CERVICAL CANCER

In the U.S., it is estimated that over 12,000 new cases and more than 4,000 deaths from cervical cancer will occur in 2014.⁸ 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.⁹ Cervical cancer is usually treatable, especially when detected early through routine screening with Pap tests. Guidelines by the U.S. Preventive Services Task Force recommend that most women ages 21 to 65 receive a Pap test once every three years.¹⁰ In recent years, some professional associations and committees have recommended screening certain populations of women with a test for high-risk HPV DNA, but this recommendation continues to be debated.¹¹

- Despite widespread availability of pap testing, disparities in cervical cancer incidence and mortality rates by race persist. Black women have the highest mortality rates of the disease (**Figure 1**).^{12, 13} More than half of cervical cancer cases are detected in women who have

Figure 1
Racial and Ethnic Disparities in Cervical Cancer



never been screened or have not been screened as frequently as recommended in guidelines.¹⁴

- One notable paradox however, is that Black women also have the highest rates of recent pap testing to screen for the disease (78%, compared to 73% of White women), yet experience the highest mortality rate.¹⁵ Limited access to treatment and diagnosis at later stages of disease progression, as well as cost, lack of physician referral, and cultural barriers may account for some of the disproportionate impact of cervical cancer on Black women.¹⁶

THROAT CANCER

- Approximately 12,000 cases of throat cancer (oropharyngeal) occur annually in the U.S, about two-thirds of which are associated with oral HPV infection, making it the second most common HPV-related cancer.¹⁷ However, it's important to note that smoking and alcohol use are also risk factors.¹⁸ Diagnoses of oropharyngeal cancer are higher among men (6.2 men per 100,000) than women (1.4 women per 100,000).¹⁹ Research suggests that HPV vaccines can help protect against throat cancer, since many are associated with HPV 16, one of the strains that the vaccines prevent.

ANAL CANCER

- HPV is also responsible for the vast majority (93%) of the 4,700 annual cases of anal cancer in the U.S.²⁰ Most cases of anal cancer are among women but among men, men who have sex with men are at higher risk.²¹ HPV strains 16 and 18 as well as a history of cervical cancer, and suppressed immune systems are all risk factors for anal cancer.

HPV VACCINES

Currently, there are three 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 2006.²² Gardasil has been approved by the FDA for use in males and females ages 9-26. In December 2014, Gardasil 9 was approved by the FDA.²³ This new vaccine protects against 9 strains of HPV: the four strains approved in the previous Gardasil vaccine, as well as 31, 33, 45, 52, and 58.
- GlaxoSmithKline's vaccine, Cervarix®, was approved by the FDA in 2009 and protects against HPV strains 16 and 18. Cervarix can only be administered to females and has been approved for females ages 10-25.^{24, 25}
- The federal Advisory Committee on Immunization Practices (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.²⁶ The vaccine is recommended for use in men ages 22-26 if they have not been previously vaccinated, are immunocompromised, or engage in sexual activity with other men.²⁷ ACIP recommended the vaccine for females in 2006 and added the recommendation for males in 2011. ACIP has not yet recommended the new HPV vaccine.
- These recommendations are designed to promote vaccination before the initiation of sexual activity and exposure to HPV, when the vaccine is most effective.²⁸ 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

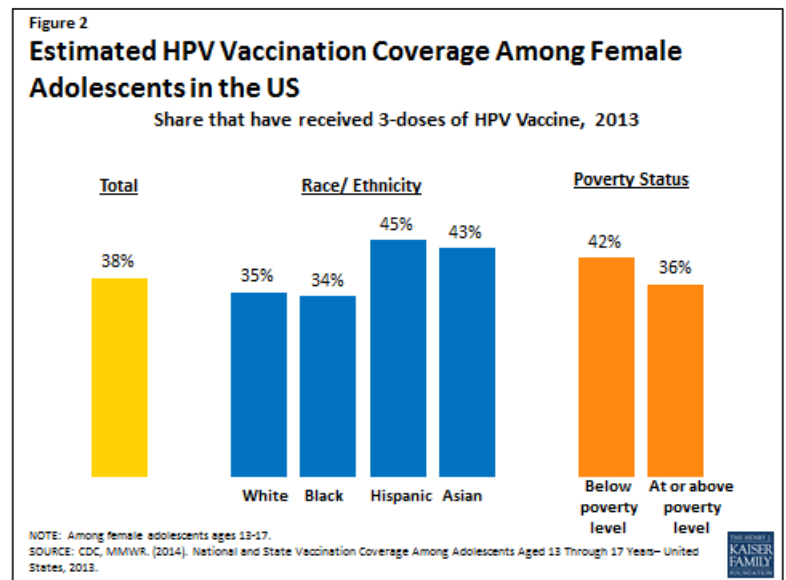
does not treat existing HPV infections.²⁹ Additionally, the vaccine elicits a higher immune response from adolescents ages 11 to 12 than in older teens.³⁰

- While the recommendation does not include women above age 26, some evidence supports providing HPV vaccines to adult women on a case-by-case basis.^{31,32} Cost effectiveness of providing the vaccine to women over age 26 tends to decrease because women over the age of 26 are more likely to have been exposed to the specific serotypes and have fewer sexual partners and hence less risk of exposure. However, other countries, such as Australia, recommend the HPV vaccine for women through age 45.
- All three vaccines prevent infection of HPV strains 16 and 18, which are associated with the majority of cervical cancer, anal cancer, and throat cancer (HPV 16) cases. Gardasil also prevents infection of strains 6 and 11, which are associated with 90% of genital warts cases and other HPV-associated ano-genital diseases.^{33, 34, 35} The five additional strains included in Gardasil 9 cause approximately 20% of cervical cancers.
- These vaccines are currently administered in 3 doses over 6 months, but research is under way to determine whether 2 doses may be sufficient to provide protection.^{36,37}
- Current research suggests the vaccine protection is long-lasting: more than 8 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 recipients will need a booster.^{38, 39}

OUTREACH AND UTILIZATION

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

- Just over one-third (37.6%) of adolescent girls aged 13-17 received all 3 doses of the vaccine in 2013. Hispanics, Asians, and girls whose families live below the poverty line were more likely to receive three doses compared to whites, African Americans, and girls whose families live above the poverty line (**Figure 2**).⁴⁰ The vaccination rates for adolescents in 2013 are only slightly higher than in 2012.
- HPV vaccination rates significantly increased in four states between 2012 and 2013 –IL, MS, NM and SC - due to a combination of initiatives including: increased public awareness, campaigns by professional and advocacy organizations, peer to peer education for physicians, and general health initiatives (**Figure 3**).⁴¹
- Prevalence of HPV has decreased significantly since the vaccine was made available, falling from 11.5% to 5.1% among girls ages 14 to 19 between 2003-2006 and 2007-2010. In 2007-2010, approximately one-third of this group had received at least one-dose of the vaccine.⁴²



- Vaccination rates among boys and young men are much lower than for girls (14% in 2013), but have been increasing since the recommendation was issued in 2011.⁴³ The vaccination rate for males ages 13 to 17 was 7% in 2012 and 1.3% in 2011.⁴⁴
- Presently, 21 states and D.C. have laws that either require HPV vaccination for school entry, provide funding to cover the costs of the vaccines, or support public education about HPV and the vaccine (**Figure 4**). D.C. and Virginia require the vaccine for girls to enter the sixth grade, but allow parents to opt out of the requirement due to medical, moral, or religious opposition.⁴⁵
- Slow vaccine uptake has been due to multiple factors.⁴⁶ Reasons cited by parents for not vaccinating or not planning to vaccinate their adolescent include: lack of knowledge about the vaccine, belief that the vaccine is not necessary, concerns about safety of the vaccine and side effects, it was not recommended to them, and their adolescent is not sexually active.⁴⁷ Studies have not found a link between vaccination and earlier sexual initiation. There have been relatively few adverse events reported after HPV vaccination, similar to those reported after meningococcal and Tdap vaccinations.⁴⁸ Commonly reported symptoms include injection-site reactions such as pain, redness and swelling, as well as dizziness, fainting, nausea, and headache.^{49,50}
- Missed opportunities by providers to recommend the HPV vaccine significantly contributes to the low vaccination rates.⁵¹ More than 1 in 10 parents of adolescent girls and 1 in 5 parents of adolescent boys said the vaccine was not recommended to them.⁵² More training may encourage providers to recommend the vaccine more frequently and more effectively to parents.

VACCINE FINANCING

The 3 doses of the HPV vaccine cost \$130 per injection (\$390 for entire series).⁵³

PRIVATE INSURANCE

- The majority of people in the target age group for the HPV vaccine have private insurance. The federal Affordable Care Act (ACA) requires all new private insurance plans to cover recommended preventive services without consumer cost-sharing. The HPV vaccines for the recommended age groups of males and

Figure 3

HPV Vaccination Rates of Adolescent Girls ages 13-17, by State

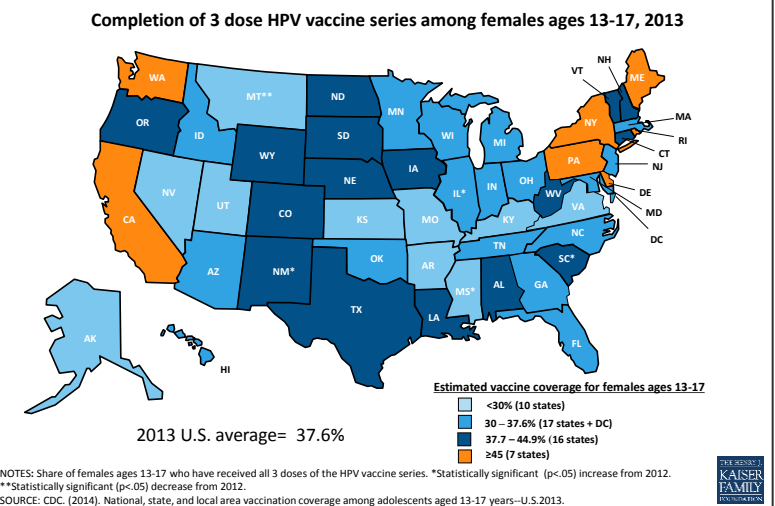
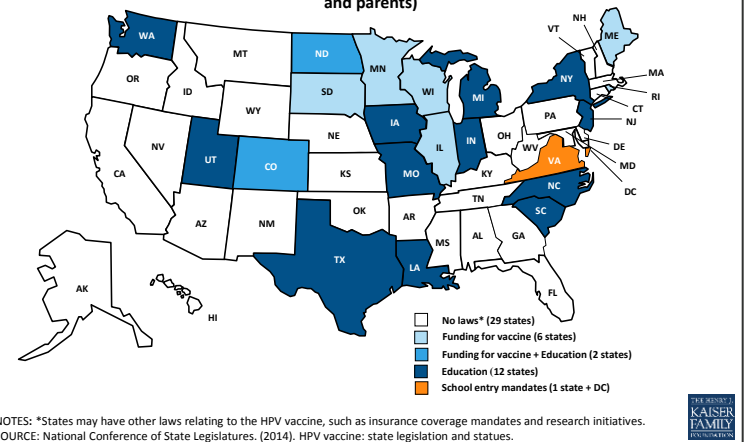


Figure 4

HPV Vaccination Policies- Mandates, Education, and Funding

State laws requiring HPV vaccinations for school entry, providing funding to cover the cost of the vaccine, or requiring public education (including for school children and parents)



females, Pap tests, and HPV testing for women are all covered under this policy.⁵⁴ Because Gardasil 9 is not yet recommended by ACIP, private and public payors are not required to cover it.

- Individuals who obtain insurance through the new health exchanges are also covered for the HPV vaccine, Pap Tests, and HPV DNA testing without cost-sharing.

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.⁵⁵ Almost half (41%) of all children's vaccines are paid for by the VFC program.⁵⁶
- **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 the VFC program.⁵⁷
- **Medicaid** – The VFC pays for vaccinations for all children through age 18 with Medicaid. Women and men ages 19 and 20 with Medicaid are eligible for Medicaid coverage of all ACIP-recommended vaccines as an Early and Periodic Screening Diagnosis and Treatment program (EPSDT) service.⁵⁸ Adults who are newly eligible for Medicaid as a result of the ACA expansion are covered for the vaccine as well as pap tests without cost-sharing in states that expand coverage. For adults 21 and older who qualify for Medicaid through other eligibility pathways, vaccine coverage is an optional benefit and is decided on a state-by-state basis. As of 2010, at least 37 states reported covering the vaccine for women.⁵⁹
- **Children's Health Insurance Program (CHIP)** – State CHIP programs that are separate from their Medicaid programs must cover ACIP-recommended vaccines for beneficiaries since they are not eligible for coverage under the federal VFC.⁶⁰
- 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.⁶¹

HPV VACCINES GLOBALLY

HPV vaccines are unique in their ability to prevent cancer. In developing nations, where 80-85% of the 275,000 annual deaths from cervical cancer occur, the vaccine has an enormous potential to save thousands of lives.⁶² However, access to the vaccine is limited mostly to affluent populations in developed countries.⁶³ Vaccination rates hover around 17% in most European countries, although Great Britain and Portugal have vaccination rates of approximately 80%.⁶⁴ In 2013, Merck and GlaxoSmithKline were awarded UNICEF contracts to provide the Gardasil and Cervarix vaccines to people in developing countries at significantly reduced prices.^{65, 66} As a result, the GAVI alliance, an international vaccine coalition connecting the public and private sectors in order to provide low-income and poor children with vaccines, is expected to support HPV vaccination in 28 countries by the end of 2017.

The HPV vaccine has been available in the U.S. for several years and uptake is rising. There are, however, still a number of financing, public acceptance, and delivery system challenges that must be addressed to enable widespread uptake of this important advance in cancer prevention.

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