October 2018 | Fact Sheet

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

The human papillomavirus (HPV) vaccine is the first and only vaccination that helps protect women and men from getting many different types of cancer that are associated with different HPV strains. The vaccine protects young people against infection from certain strains of HPV, the most common sexually transmitted infection (STI) in the United States. Since HPV vaccines were first introduced in the U.S. in 2006 there have been changes in the range of protection they offer and the dosing regimen. Furthermore, 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

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. HPV is the most common STI in the U.S. and is often acquired soon after initiating sexual activity.[1] Currently about 79 million Americans are infected with HPV and there are more than 14 million new infections annually.[2] More than 43% of American adults ages 18-59 are infected with genital HPV, with higher rates among men (45%) than women (40%).[3] HPV-related cancers have increased significantly in the past 15 years—in 2015, 43,000 people developed an HPV-related cancer compared to 30,000 in 1999. While HPV-related cervical and vaginal cancer rates have decreased in recent years, rates for oropharyngeal and anal HPV-related cancers have increased.[4]

Cervical Cancer

HPV is related to almost 100% of cervical cancer cases, with two strains (16 and 18) responsible for approximately 70% of cervical cancer cases.[5] Most cases of cervical cancer occur in women in developing countries, but it remains a challenge in the U.S. In the U.S., it is estimated that over 13,240 new cervical cancer cases will be diagnosed in 2018. While cervical cancer is usually treatable, especially when detected early, more than 4,170 deaths from cervical cancer will occur in 2018.[6] Guidelines by the U.S. Preventive Services Task Force (USPSTF) recommend that most women ages 21 to 65 receive a Pap test once every three years and recommends that women over 30 get a high-risk HPV test every 5 years.[7]

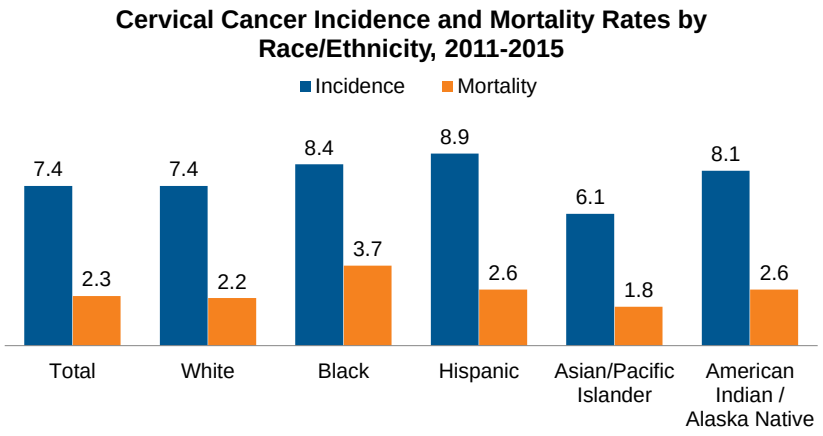
U.S. Preventive Services Task Force Cervical Cancer Screening Recommendation

The USPSTF recommends screening for cervical cancer in women age 21 to 29 years with cytology (pap smear) every 3 years, and for women 30 to 65 a screening with cytology alone every 3 years, or a high risk human papillomavirus (hrHPV) test every 5 years, or cytology in combination with a hrHPV every 5 years.

- Overall, cervical cancer rates have fallen. Between 1999 to 2015, cervical cancer rates decreased by 1.6% a year, a continued trend since the 1950s as a result of cancer screenings.[8] Cervical cancer is the most common HPV-related cancer among women.[9]

Figure 1

Racial and Ethnic Disparities in Cervical Cancer



NOTE: Data are age-adjusted rates per 100,000 women.
SOURCE: National Cancer Institute. SEER Stat Fact Sheets: Cervix Uteri Cancer. Accessed August 2018.

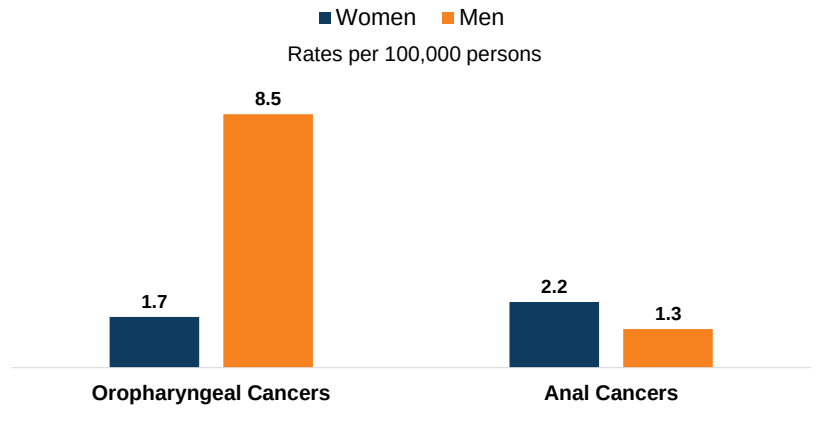
- Despite widespread availability of pap testing, disparities in cervical cancer incidence and mortality rates by race persist. Black women have the highest mortality rates of the disease **(Figure 1)**. More than half of cervical cancer cases are detected in women who have never been screened or have not been screened as frequently as recommended in guidelines.[10]
- One notable paradox however, is that Black women also have the highest rates of recent pap testing to screen for the disease (75%, compared to 69% of White women), yet experience the highest mortality rate.[11] 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.[12]

Oropharyngeal and Anal Cancers

- Approximately 18,226 cases of oropharyngeal (throat) cancer occur annually in the U.S, most (70%) of which are probably caused by HPV.[13] Oropharyngeal cancers are now the most common HPV-associated cancer, surpassing cervical cancer. However, it's important to note that smoking and alcohol use are also risk factors.

Figure 2

Rates of Oropharyngeal and Anal Cancers Among Women and Men, 2015



NOTES: Rates per 100,000 persons in 2015.
SOURCE: CDC. (2018). Trends in Human Papillomavirus—Associated Cancers—United States, 1999-2015. *MMWR 67(33)*.

Oropharyngeal cancers are more common among men than women (**Figure 2)**.[14] 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 protect against.[15]

- HPV is also responsible for the majority (91%) of the 8,580 annual cases of anal cancer in the U.S.[16] Most cases of anal cancer are among women, but men who have sex with men are also at higher risk.[17] HPV strains 16 and 18, as well as a history of cervical cancer, and suppressed immune systems are all risk factors for anal cancer. Like oropharyngeal cancer, there has been an increase in the rate of anal cancers in the past 15 years.[18]

HPV Vaccines

Beginning in 2017, Gardasil®9 is the only HPV vaccine available in the U.S.

- The FDA first approved first-generation Gardasil®, produced by Merck, in 2006, which prevented infection of four strains of HPV – 6, 11, 16, and 18. In December 2014, Gardasil®9 was approved by the FDA. This 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.[19]
- These strains are associated with the majority of cervical cancer, anal cancer, and throat cancer cases as well as most genital warts cases and some other HPV-associated ano-genital diseases. [20]
- Gardasil®9 has been approved by the FDA for use in males and females ages 9-26.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.[21] 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.
- In October 2018, the FDA approved Gardasil®9 for women and men ages 27 to 45. A study that followed women ages 27 through 45 for three and a half years found that the original vaccine, Gardasil®, was 88% effective in preventing genital warts, vulvar and vaginal precancerous lesions, cervical precancerous lesions, and HPV-related cervical cancers.[22]
- ACIP now recommends that 11-14 year olds receive two doses of the HPV vaccine over 6 months, instead of the original recommendation of three doses. Teens and young adults who initiate vaccination at age 15 through 26 should continue to receive three doses over six months.[23]
- These recommendations are designed to promote immunization when the vaccine is most effective – before the initiation of sexual activity and exposure to HPV. Those already infected with HPV also 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. Additionally, the vaccine elicits a higher immune response from adolescents ages 11 to 12 than in older teens.[24]
- 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. 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. [25] There is some evidence that suggests there may be benefits to immunizing men over the age of 26, particularly high risk populations such as men who have sex with men, but more research is needed.[26]

- Current research suggests the vaccine protection is long-lasting: more than 10 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.[27]

Outreach and Utilization

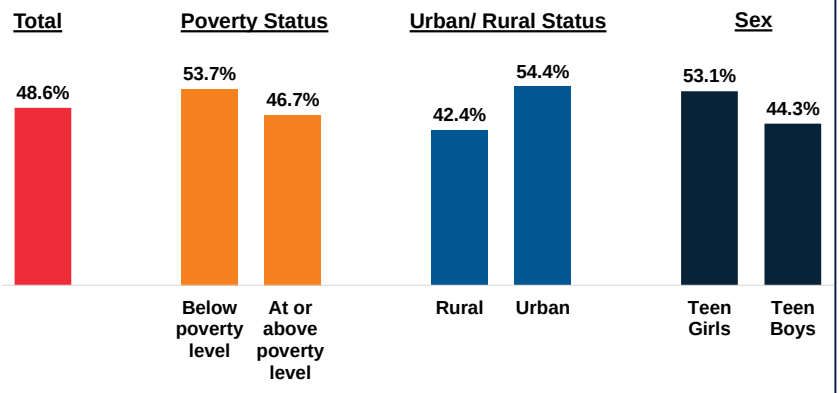
Awareness of the importance of the HPV vaccine has grown, and take-up has been increasing since it entered the market.

- In 2017, almost half of adolescents aged 13-17 were up-to-date with their HPV vaccinations (HPV UTD) **(Figure 3).**[28] Adolescents whose families live below the poverty line and those living in urban areas were more likely to be HPV UTD compared to adolescents whose families live above the poverty line or live in rural areas. HPV vaccination rates among teen boys are lower than for girls (44% vs. 53% HPV UTD in 2017), but they have been rapidly rising since 2011.[29]
- Some people begin the vaccine series but do not complete it. In 2017, 69% of adolescent girls and 63% of boys received at least one dose of the HPV vaccine.[30]

Figure 3

Estimated HPV Vaccination Coverage Among Adolescents in the US

Share that are HPV Up-to-Date (UTD), 2017



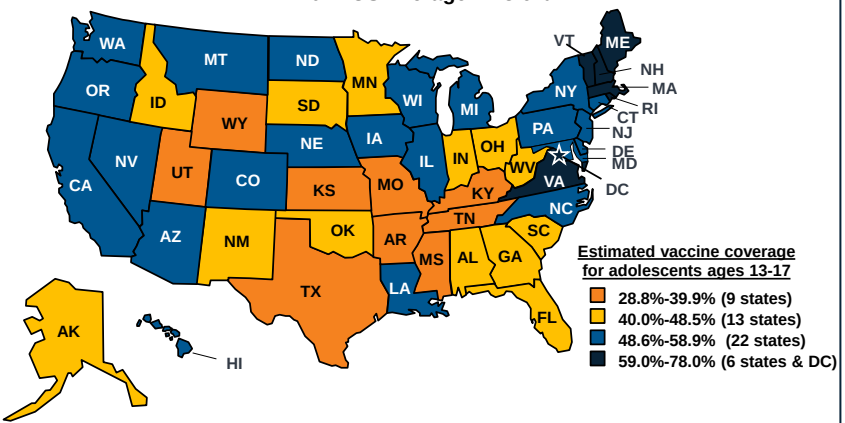
NOTE: Among adolescents ages 13-17. HPV UTD includes those with ≥3 doses, and those with 2 doses when the first HPV Vaccine dose was initiated before age 15 years and time between the first and the second dose was at least 5 months minus 4 days.
SOURCE: CDC. (2018). National, Regional, State, Selected Local Area Vaccination Coverage Among Adolescents Aged 13-17 Years—United States, 2017. *MMRW* 67(33).

Figure 4

HPV Vaccination Rates of Adolescents, by State

Adolescents ages 13-17 with HPV Up-To-Date (UTD) Vaccination Series, 2017

2017 US Average = 48.6%



NOTES: HPV UTD includes those with ≥3 doses, and those with 2 doses when the first HPV Vaccine dose was initiated before age 15 years and time between the first and the second dose was at least 5 months minus 4 days.
SOURCE: CDC. (2018). National, Regional, State, Selected Local Area Vaccination Coverage Among Adolescents Aged 13-17 Years—United States, 2017. *MMRW* 67(33).

- HPV vaccination rates vary by state, from 29% of adolescents being HPV UTD in Mississippi to 78% in D.C. **(Figure 4)**. Presently, two states and D.C. have laws that require HPV vaccination for school entry. D.C. and Virginia require the HPV vaccine for girls to enter the sixth grade, but allow parents to opt out of the requirement due to medical, moral, or religious opposition.[31] Rhode Island requires all seventh-grade students to be vaccinated.[32] State laws regarding HPV have been controversial because of concerns that HPV vaccinations may encourage risky sexual behaviors among teens. However, a recent study found that state laws regarding HPV vaccination and education are not associated with changes in adolescent sexual behaviors.[33]
- There have been relatively few adverse events reported after HPV. Commonly reported symptoms include injection-site reactions such as pain, redness and swelling, as well as dizziness, fainting, nausea, and headache.[34] A review of eight years of post-licensure follow-up studies of Gardasil® worldwide found no serious health risks associated with the vaccine.[35]
- Prevalence of HPV in the U.S. has decreased significantly since the vaccine was made available, falling from 11.5% to 4.3% among girls ages 14 to 19 between 2003-2006 and 2009-2012. In 2009-2012, half of this group had received at least one-dose of the vaccine.[36]

Vaccine Financing

There are multiple sources of private and public financing that assure that nearly all children and young adults in the U.S. have coverage for the HPV vaccine. Many of the financing entities base their coverage on the recommendations of the CDC's Advisory Community for Immunization Practices (ACIP) an independent body of experts that issues the immunization recommendations for the U.S. population.

- The Affordable Care Act (ACA) requires most private insurance plans to cover some recommended preventive services and ACIP recommended immunizations without consumer cost-sharing. Plans must cover the HPV vaccine for the recommended populations, pap tests, and HPV testing for women.

Public Financing

- **Medicaid** – The Vaccines for Children Program pays for vaccinations for all children through age 18 with Medicaid. Women and men ages 19 and 20 with Medicaid are covered for all ACIP-recommended vaccines as an Early and Periodic Screening Diagnosis and Treatment program (EPSDT) service.[37] Adults who qualified for Medicaid as a result of the ACA expansion are covered for the vaccine, HPV testing, as well as pap tests without cost-sharing in states that expanded 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 2015, at least 39 states and DC reported covering the vaccine for women.
- **Vaccines for Children (VFC) Program –** This federally-financed program pays for vaccines recommended by the ACIP for children ages 18 and under who are either Medicaid-eligible, uninsured, American Indian or Alaska Native, or underinsured. ACIP recommended VFC coverage for Gardasil 9 in February 2015 for males and females ages 9 through 18.

- **Immunization Grant Program (Section 317 of the Public Health Service Act)** –Provides grants to states and local agencies to help extend the availability of vaccines to uninsured adults in the United States. Merck has also established assistance programs to provide free vaccines to uninsured low-income adults in the United States.[38] These funds are often directed towards meeting the needs of priority populations, such as underinsured children and uninsured adults.[39]
- **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.[40]

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The HPV vaccine has been available in the U.S. for several years and uptake is rising. Since its introduction in 2006, the vaccine covers more strains of HPV, its use has been extended to males as well as females, the dosage has dropped from three to two shots, and the cost is fully covered by private insurance and public programs. With these improvements, the vaccine holds the promise to safely and dramatically reduce rate of and prevent many kinds of cancers that have long been responsible for the deaths of women and men across the United States and the world.

Endnotes

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