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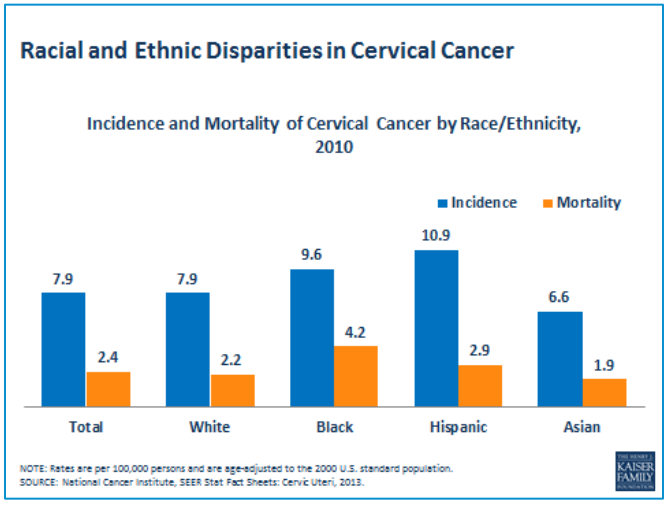
The HPV Vaccine: Access and Use in the U.S.

Vaccination rates have remained stagnant 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 the recommendations 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] While cervical cancer is the main concern with HPV, the disease is also known to cause oral, anal, vulvar, vaginal and penile cancers, as well as genital warts.[3]

- 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.[4] Almost 50% of new infections occur in women ages 15-24.[5]
- 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.[6] 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.[7]
- Cervical cancer is usually treatable, especially when detected early; regular screening with Pap tests is critical for early detection. Guidelines by the U.S. Preventive Services Task Force recommend that women ages 21 to 65 receive a Pap test once every three years.[8]
- 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).[9, 10]
- However, African American women also have the highest rates of recent pap testing to screen for the disease (81%, compared to 77% of White women and 70% of Asian women).[11] 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.[12]



- Men are at a much lower risk than women for developing an HPV related cancer and suffer from less than 25% of reported cases.[13] However, men who have sex with men (MSM) are 17 times more likely to develop anal cancer when compared with men who have sex with only women.[14]

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.[15]
- 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.[16,17]
- 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.[18] Both vaccines have been shown to protect against vulvar and vaginal cancers, and Gardasil also protects against HPV-associated anogenital diseases.[19,20,21]
- The primary benefits of vaccinating men include protection against genital warts, anal cancer, and preventing transmission of HPV to sexual partners.[22]
- 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.[23,24]
- 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. [25]
- 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.[26]
- Effectiveness of HPV vaccines have been supported by recent studies examining prevalence of cervical abnormalities among young women who have been vaccinated compared to those who have not been vaccinated.[27]

Immunization Recommendations

- The federal Advisory Committee on Immunization Practices (ACIP) recommended use of the 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.[28] The vaccine is recommended for use in men ages 22-26 if they have not been previously vaccinated or are immunocompromised.[29]
- These recommendations are designed to promote vaccination before the initiation of sexual activity and exposure to HPV, when the vaccine is most effective.[30] 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.[31]

Vaccine Financing

The 3 doses of the HPV vaccine cost $130 per injection ($390 for entire series).[32]

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 HPV vaccines as well as Pap tests for the recommended populations without consumer cost-sharing because they are recommended by ACIP.[33]
- Starting in January 2014, individuals who obtain insurance through the new health exchanges or who will be newly eligible for Medicaid in those states that expand coverage will also be covered for the HPV vaccine and Pap Tests without cost-sharing.

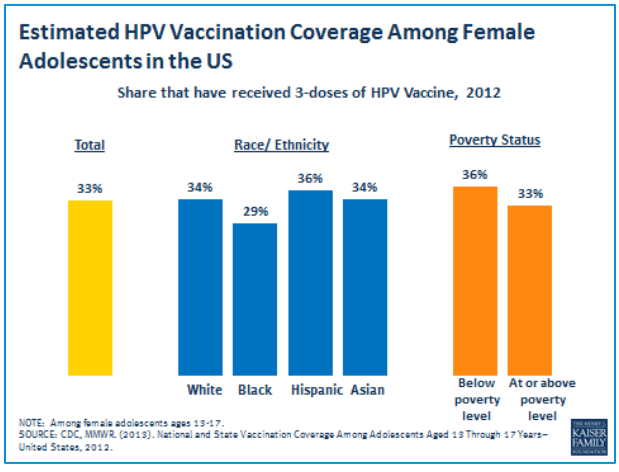
Public Financing

- **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.[34] Almost half (41%) of all children's vaccines are paid for by the VFC program.[35]
- **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.[36]
- **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.[37] For adults 21 and older on Medicaid, 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 adults.[38]
- **Children's Health Insurance Program** (CHIP) – States with CHIP 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.[39]
- 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.[40]

Outreach and Utilization

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

- Just over one-third (33.4%) of adolescent girls aged 13-17 received all 3 doses of the vaccine in 2012. Hispanics 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).[41]



- Prevalence of HPV decreased significantly since the vaccine was made available, falling by 56% to 5.1% among girls ages 14-19 between 2003-2006 and 2007-2010. In 2010, approximately half of this group had received at least one-dose of the vaccine, but high vaccine effectiveness and vaccination prior to sexual initiation has contributed to this decline.[42]
- Vaccination rates among boys and young men are much lower (7% in 2012), but have been increasing since the recommendation was issued in 2011.[43]
- Presently, 23 states and D.C. have laws that either require HPV vaccinations, provide funding to cover the costs of the vaccines, or support public education about HPV and the vaccine. 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.[44]
- Slow vaccine uptake has been due to multiple factors, including early concerns surrounding vaccine safety, fears that teens may engage in risky sexual activity earlier due to the vaccine, and inadequate provider recommendation.[45] The vaccine has been proven safe and studies have not found a link between vaccination and earlier sexual initiation.[46] More training and may encourage providers to recommend the vaccine more frequently.

HPV Vaccines Globally

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.[47] Despite availability, vaccination rates hover around 17% in most European countries; Great Britain and Portugal have vaccination rates of approximately 80%.[48] In 2013, Merck and GlaxoSmithKline were awarded the UNICEF contracts to provide the Gardasil and Cervarix vaccines to people in developing countries at significantly reduced prices.[49,50] As a result, the GAVI alliance is expected to support HPV vaccination in 28 countries by the end of 2017.

Despite the fact that an HPV vaccine has been available in the U.S. for several years, 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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