

HPV Vaccine: Implementation and Financing Policy

In June 2006, the Food and Drug Administration (FDA) approved a new vaccine for young women and girls that protects against infection by certain strains of human papillomavirus (HPV), the most common sexually transmitted infection in the United States.¹ This fact sheet provides background information on HPV and the vaccine and highlights issues around financing, delivery, public and provider education, parental consent, and access to care.

HPV and Cervical Cancer

HPV infection is widespread in the United States. The Centers for Disease Control and Prevention (CDC) estimates that upwards of 80% of women in the U.S. are infected with HPV by age 50.²

- There are over 100 strains of HPV, with over 30 types that can cause cervical cancer and genital warts.³ While most cases of HPV infection resolve on their own, certain strains can lead to cervical cancer. HPV is the major cause of cervical cancer.
- In 2005, nearly 500,000 cases of cervical cancer worldwide were diagnosed, and 260,000 deaths were attributed to cervical cancer, mostly in developing countries. In the U.S. cervical cancer is relatively rare, but there are nearly 10,000 cases and 3,700 deaths from cervical cancer annually.⁴
- Cervical cancer is largely treatable, but regular screening through Pap tests is critical for early detection.
- Hispanic and African American women are approximately 1.5 times more likely to develop cervical cancer than white women, and are also more likely to die as a result.^{5,6} Limited access to treatment and early detection, as well as cost, lack of physician referral, and cultural barriers may account for some of this disparity.⁷
- Treatment costs associated with HPV were estimated to total nearly \$3 billion in 2000, with the majority due to the spending for follow-up care from abnormal Pap test results.⁸

HPV Vaccine

- The new vaccine, Gardasil® produced by Merck, prevents infection of four strains of HPV—6, 11, 16, and 18. Strains 16 and 18 are associated with 70% of all cases of cervical cancer and strains 6 and 11 are associated with 90% of genital warts cases.⁹
- The vaccine is administered in 3 doses at 0, 2, and 6 months intervals. It is unknown whether women will need a booster and if so, at what time interval following the initial dose.
- In the U.S., the vaccine has been approved by the FDA for use in girls and women ages 9 to 26. The federal Advisory Committee on Immunization Practices (ACIP) has recommended that all girls be vaccinated at age 11 or 12, and that girls and women ages 13 to 26 be given a “catch-up” vaccination.¹⁰

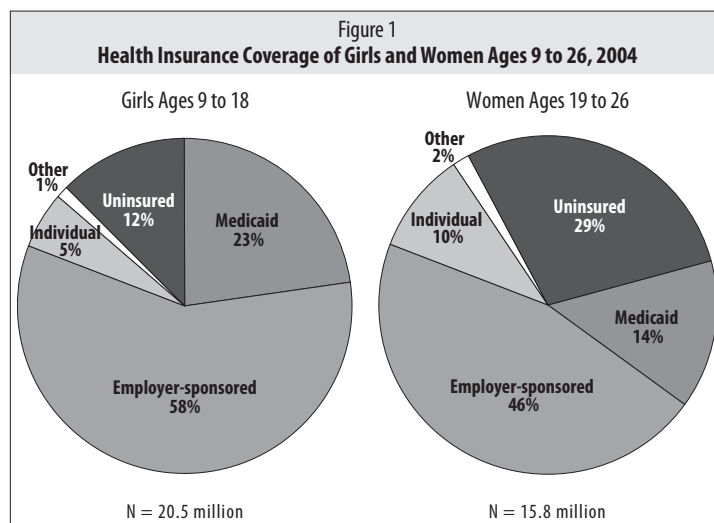
- These age recommendations are designed to promote vaccination before onset of sexual activity to maximize effectiveness. However, the vaccine should be administered to those who are already sexually active in the recommended age group.
- Women already infected with HPV can benefit from the vaccine because it can prevent infection of other HPV strains that they may not have contracted. Gardasil® does not treat existing HPV infections.
- Women will still need to get routine Pap tests because Gardasil® does not protect against all cancer-causing strains of HPV.
- Gardasil® has also been approved for use in the European Union, Australia, Canada, and several other countries.¹¹
- GlaxoSmithKline has also developed a vaccine against HPV, Cervarix®, targeted at strains 16 and 18, which is expected to be submitted to the FDA for review in 2007.¹²

Financing

The 3-dose HPV vaccine is expensive, costing \$120 per injection (\$360 for entire series). Many, but not all, private and public sector payors will cover the vaccine, but policies about who will be covered and what amount will be paid are still being determined.

Private Insurance

- Most girls and women in the target age group for the HPV vaccine have private insurance. However, one in ten (12%) girls ages 9 to 18 and three in ten (29%) women 19 to 26 are uninsured (Figure 1).
- Private insurers typically follow ACIP guidelines and are likely to cover the vaccine. Several major insurers have already begun covering the vaccine in at least some of their plans.



Source: Kaiser Family Foundation analysis of Urban Institute estimates from March 2005 Current Population Survey, U.S. Census Bureau. Note: “Other” indicates other forms of public insurance, including Medicare, CHAMPUS, and TriCare. Percentages may not add to 100 due to rounding.

Public Financing

- Vaccines for Children (VFC) – This federally financed program pays for vaccines approved by the ACIP for children ages 18 and under who are either Medicaid-eligible, uninsured, American Indian or Alaska Native, or underinsured; 41% of all children's vaccines are paid for by the VFC program.¹³
- 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.¹⁴
- Medicaid – The VFC must pay for vaccinations for all children through age 18 with Medicaid. For adults on Medicaid, however, vaccine coverage is an optional benefit and is decided on a state-by-state basis.¹⁵
- 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.
- New Hampshire has established a program that allows girls 18 and younger to get the vaccine for free through a pool that is financed by the federal government and private insurers.

There is no public source of funding for vaccines for uninsured adults at this time. Merck has established a vaccine assistance program for uninsured women 19 to 26 years old. To qualify, women must be low-income (below 200% of the federal poverty level), uninsured, and receive their care from private physician offices that already distribute other Merck products.¹⁶ However, many uninsured women in this age group seek care in public clinics, such as those funded by the federal Title X program, and would not qualify for assistance under the Merck program.¹⁷

Implementation Challenges

Consent and Mandates

Mandatory requirements associated with school entrance have been among the most effective method for assuring that vaccines reach the largest share of the population.¹⁸ State policymakers have jurisdiction over the vaccines that children must obtain to meet school entrance requirements.

- To date, no state requires that girls receive the HPV vaccine for school entry. Legislators in Michigan, California, and Kentucky have proposed such laws.¹⁹
- All states have policies that allow parents to opt out of vaccine requirements due to a medical, moral or religious opposition to mandatory vaccination for children.²⁰
- There has been increasing attention to parental concern about vaccine safety, and many family practitioners and pediatricians report encountering some parents who refuse to administer certain vaccinations to their children.²¹

Public Outreach and Awareness

Public knowledge of HPV and cervical cancer will likely influence whether girls and women obtain the HPV vaccination, and parents and providers will play a critical role in achieving high vaccination rates for the recommended age group of girls.

- Public awareness and knowledge about HPV is still very limited. Only 40% of women ages 18 to 75 have heard of HPV and of that group, less than half know that it is associated with cervical cancer.²²
- Research suggests that knowledge about HPV incidence and transmission as well as physician recommendation are important factors that influence parental acceptability of the HPV vaccine.²³
- The HPV vaccine requires 3 visits to a health care provider in a six-month period. Currently, there are no guidelines that require this level of medical visits for girls 11 and 12 years old. Some clinicians have recommended instituting a regular health care visit at this age.

In the U.S., this new vaccine has the potential to prevent many cases of cervical cancer and also reduce the cost and emotional burden for the millions of women who receive abnormal Pap test results attributable to HPV infection. In developing nations, where cervical cancer is a leading cause of cancer death among women, the vaccine has even more potential to save lives. While the federal government has recommended universal vaccination for girls and young women in the U.S., there are still financing, public awareness, and other delivery system challenges that must be met to ensure the widespread uptake of this new advance in women's health.

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