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### HPV Vaccine: Implementation and Financing Policy in the U.S.

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 (STI) in the United States.<sup>1</sup> This factsheet provides background information on HPV and the vaccine and highlights issues around financing, delivery, public and provider education, and access to care.

#### HPV and Cervical Cancer

HPV infection is widespread in the United States. A recent CDC study found that approximately one in four women ages 14–59 in the U.S. have HPV (27%). The burden is highest among women ages 20–24 with a prevalence rate of 45%, but remains at a substantial rate of 20% even among women ages 50–59.<sup>2</sup>

- There are more than 100 strains of HPV, with over 30 types that can cause cervical cancer and genital warts.<sup>1</sup> While most cases of HPV infection usually resolve on their own, certain strains can lead to cervical cancer. HPV is the major cause of cervical cancer.
- In 2007, over 555,000 new cases of cervical cancer and 260,000 deaths attributed to cervical cancer were estimated to have occurred worldwide, mostly in developing countries. In the U.S., cervical cancer is relatively rare, but it was estimated that over 11,000 new cases and about 3,700 deaths from cervical cancer occurred in 2007.<sup>3</sup>
- 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.<sup>4,5</sup> 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.<sup>6</sup>
- Treatment costs associated with HPV were estimated to total nearly \$3 billion in 2000, with the majority resulting from spending on follow-up care from abnormal Pap test results.<sup>7</sup>

#### 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 cervical cancer cases, while strains 6 and 11 are associated with 90% of genital warts cases.<sup>8</sup>
- Gardasil has also been shown to protect against vulvar and vaginal cancers, as well as HPV-associated anogenital diseases.<sup>9,10</sup>
- The vaccine is administered in 3 doses at 0, 2, and 6 month intervals. Although the vaccine has been shown to be effective for up to five years,<sup>11</sup> it is still unknown whether women will need a booster and if so, at what time interval following the initial dose.

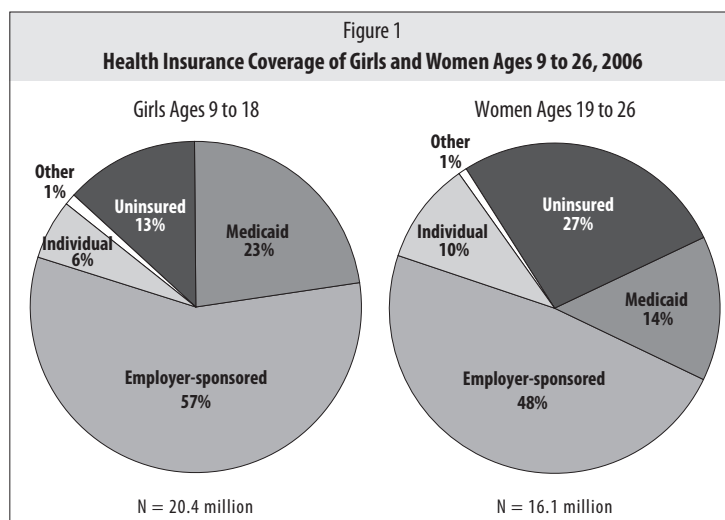
- In the U.S., the vaccine has been approved by the FDA for use in girls and women ages 9 to 26. The federal Advisory Committee on Immunization Practices (ACIP) has recommended that all girls be vaccinated at age 11 or 12, and that girls and women ages 13 to 26 be given a “catch-up” vaccination.<sup>12</sup>
- These age recommendations are designed to promote vaccination before onset of sexual activity when the vaccine is most effective. The CDC also recommends that the vaccine be administered to those who are already sexually active between ages 9 to 26.
- 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 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.<sup>13</sup>
- GlaxoSmithKline has also developed a vaccine against HPV, Cervarix®, targeted at strains 16 and 18, which is currently under FDA review.<sup>14</sup>

#### Vaccine Financing

The 3-dose HPV vaccine is expensive, costing \$120 per injection (\$360 for entire series). Many, but not all, private and public sector payers cover the vaccine, but policies vary regarding the age of the coverage, the reimbursement levels paid by different payers, and the out-of-pocket costs faced by health care consumers.

##### Private Insurance

- Most girls and women in the target age group for the HPV vaccine have private insurance. However, over one in ten (13%) girls ages 9 to 18 and one in four (27%) women ages 19 to 26 are uninsured (Figure 1).



Source: Kaiser Family Foundation analysis of March 2007 Current Population Survey, U.S. Census Bureau, 2007. Note: “Other” indicates other forms of public insurance, including VA and Medicare. Percentages may not add to 100 due to rounding.

- Private insurers typically follow ACIP guidelines and are likely to cover the vaccine. Several major insurers have begun covering the vaccine in at least some of their plans.

### Public Financing

- Vaccines for Children (VFC) Program—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.<sup>15</sup>
- 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.<sup>16</sup>
- Medicaid—The VFC pays for vaccinations for all children through age 18 with Medicaid. Young women ages 19 and 20 also are eligible for Medicaid coverage of all ACIP-recommended vaccines as a basic Medicaid Early and Periodic Screening Diagnosis and Treatment program (EPSDT) service, sharing the cost of purchase at the usual Medicaid matching rate.<sup>17</sup> For adults 21 and older on Medicaid, however, vaccine coverage is an optional benefit and is decided on a state-by-state basis.<sup>18</sup>
- 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.
- Several states including AK, IL, LA, MA, ME, NH, SD and WA have created pools that offer free or low-cost vaccines for girls who may not qualify for other assistance.<sup>19</sup>

There is currently no source of public funding for vaccines for uninsured adults age 21 and older. Merck has established a vaccine assistance program for uninsured women 19 to 26 years old. To qualify, women must meet certain criteria, including incomes below 200% of the federal poverty level and no insurance.<sup>20</sup> However, some uninsured women in this age group may not qualify for assistance based on where they receive care. For example, some public clinics do not qualify for the program.<sup>21</sup>

### Implementation Challenges

#### Consent and Mandates

Mandatory requirements associated with school entrance have been among the most effective methods for assuring that vaccines reach the largest share of the population.<sup>22</sup> State policymakers have jurisdiction over the vaccines that children must obtain to meet school entrance requirements.

- Of the 27 states and DC that took action to require HPV vaccination for school entry in 2007, only Virginia has enacted the requirement. Washington D.C.'s City Council has passed a similar mandate that still needs Congressional approval to be implemented. Legislators in at least 41 states and DC have introduced legislation to study, fund, or educate the public about the HPV vaccine. So far, 19 states have enacted such legislation.<sup>19</sup>
- 17 states have proposed laws requiring insurers to cover the cost of the HPV vaccine, but only five states (Colorado, Illinois, Nevada, New Mexico, and Rhode Island) have passed such a law and individuals in self-funded plans are exempt from these rules.<sup>19</sup>
- Every state allows parents to opt out of vaccine requirements due to a medical, moral or religious opposition to mandatory vaccination for children.<sup>23</sup>

- There has been increasing attention to parental concern about general vaccine safety, and some family practitioners and pediatricians report encountering some parents who refuse certain vaccinations for their children.<sup>24</sup>

### Public Outreach and Awareness

Public knowledge of HPV and cervical cancer will likely influence whether girls and women obtain the HPV vaccine, 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 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.<sup>25</sup>
- Research suggests that knowledge about HPV incidence and transmission as well as physician recommendations are important factors that influence parental acceptability of the HPV vaccine.<sup>26</sup>

In the U.S., this 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. A recent CDC survey found that only 10% of women ages 18 to 26 had received the HPV vaccine as of summer 2007.<sup>27</sup> While the federal government has recommended universal vaccination for girls and young women in the U.S., there are still financing, public acceptability and awareness as well as other delivery system challenges that must be met to ensure widespread uptake of this new advance in women's health.

### Endnotes

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