

Human Papillomavirus (HPV) Background Paper

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Human Papillomavirus (HPV) is among the most common sexually transmitted infections in the United States and the leading cause of cervical cancer. There are about 100 different strains of HPV; some are associated with cervical cancer, some with genital warts, vulvar or vaginal cancers. "More than 50% of all women will get HPV at some time in their life, most of whom will not know it because of asymptomatic strains" (CDC 2006). The greatest prevalence of HPV is among young women aged 15 to 24 (Koutsky, 1997). Those at greatest risk for HPV infection include females: younger than 25, with an increased number of sexual partners; having had the first sexual intercourse at 16 or younger; and /or sex with a male who has had multiple sexual partners.

Cervical cancer is the second leading type of cancer resulting in the death of women worldwide. This number is much smaller in the US than in other countries largely because of the Papanicolaou (Pap) test, a screening tool for precancerous lesions of the cervix. The American Cancer Society reports that, with early detection, cervical cancer is usually treatable. Even with early detection, the American Cancer Society estimated that a total of 9,710 women in the US would be diagnosed with cervical cancer in 2006, and 3,700 would die of the disease in 2006. The peak incidence of cervical cancer occurs in women older than 40 years who were exposed to HPV many years earlier. The overall death rate from cervical cancer among African-American women is close to six times higher than that among white women. Cervical cancer occurs "most often" in Hispanic women (~double the rate of non-Hispanic white women). (American Cancer Society, 2006)

Gardasil is reported to provide 100% protection against infection from HPV types 16 and 18, which are responsible for nearly 70% of all cervical cancers. It also protects against HPV types 6 and 11 that cause 90% of genital warts. Results of current studies indicate the duration of the protection lasts at least five years; it is unknown at this time whether boosters will be needed (CDC, 2006). The vaccine does not treat existing HPV infections, genital warts, precancers or cancers. GlaxoSmithKline is in the finishing stages of seeking FDA approval for their own vaccine.

The national Advisory Committee on Immunization Practices (ACIP) released their recommendation for routine vaccination of girls between the ages of 11 and 12 before they become sexually active. ACIP's recommendation, followed by what has been reported to be heavy lobbying on the part of Merck Pharmaceuticals, the producer of the vaccine, resulted in the introduction of legislation requiring vaccination in a number of states. The debate in states has centered--in part--around school vaccine requirements, which are determined by individual states. Some states grant regulatory bodies, like the Department of Health, the power to require vaccines, but the legislature must still provide funding. Some who support availability of the vaccine do not support a school mandate, citing concerns about the drug's cost, safety, and parents' rights to refuse. Still others expressed moral objections related to a vaccine mandate for a sexually transmitted disease. Financing is another concern: if states make the vaccine mandatory, they must

also address funding issues, including for Medicaid and SCHIP coverage and youth who are uninsured, and whether to require coverage by insurance plans. All of this has resulted in a desire for further discussion about whether or not to require the vaccine.

The cost for the three injections of Gardasil in the US is reported to be \$360. Most large health plans cover the costs of “recommended” vaccines. There may also be a period of “catch up” to extend coverage with new recommendations.

To date, legislators in at least **39 states and the District of Columbia** have introduced legislation to **require, fund** or **educate** the public about the HPV vaccine.

The Michigan Senate was the first to introduce legislation (S.B. 1416) in September of 2006 to require the HPV vaccine for girls entering sixth grade, but the bill did not pass. Ohio also considered legislation in late 2006 to require the vaccine (H.B. 703), which also failed. The New Hampshire Health Department announced in 2006 that it will provide the vaccine at no cost to girls under age 18. South Dakota's governor announced a similar plan in January 2007 that combines \$7.5 million in federal vaccine funds and \$1.7 million from the state's general fund.

In 2007 alone, at least **23 states and D.C.** introduced legislation to specifically **mandate** the HPV vaccine for school. On February 2, 2007, Texas became the first state to enact a mandate--by executive order from the governor--that all females entering the sixth grade receive the vaccine, with select exceptions. Legislators in Texas introduced H.B. 1098 to override the executive order and at the time of this report, the Governor has ten days to respond to the override. In March 2007, the Virginia legislature passed a school vaccine requirement and sent it to the governor for approval (S.B. 1230). The governor sent an amendment back to the legislature that gives parents more exemption rights. The legislature was scheduled to debate the governor's action during a special session in April; with no information on their action at the time of this report. The District of Columbia passed legislation on April 18, 2007, making it effective in fall 2009 that all girls entering the sixth grade must be vaccinated before entering school unless parent's elect to opt out. Utah enacted legislation establishing an awareness campaign.

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