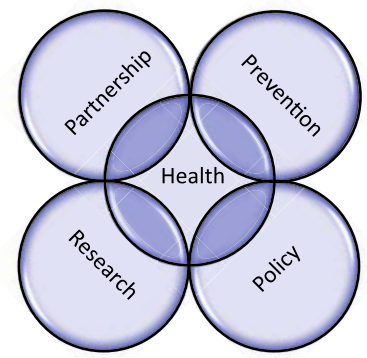


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The HPV Vaccine: A Look at Both Sides of the Debate

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Research Brief

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EXECUTIVE SUMMARY

The most common sexually transmitted disease (STD) in the United States is genital human papillomavirus (HPV), the predominant cause of genital warts and cervical cancer.¹ About half of all sexually active men and women will be infected with genital HPV at some time during their lives,² and the majority of these infections will occur in young women between the ages of 14 and 24.³

Racial and ethnic minority women, especially African Americans, are at greatest risk for developing HPV and are most negatively impacted by HPV-associated diseases. For example, African American women are more likely to die from cervical cancer than any other racial/ethnic group.⁴ Such disparities suggest the need to increase knowledge of HPV and cervical cancer prevention in African American women using a multi-level approach, which involves public and private institutions, health practitioners, government officials, and policymakers.

In June 2006, a vaccine was approved by the United States Food and Drug Administration (FDA) to immunize 9-26 year old females against infection with four HPV types—6, 11, 16, and 18. During development, clinical trials demonstrated that the vaccine was safe and highly effective. This vaccine has the potential to greatly reduce HPV and cervical cancer disparities. Since the introduction of the vaccine, legislators from multiple states have worked to introduce vaccine-related legislation regarding mandated use, vaccine funding, or public education about HPV and the vaccine. However, this legislation has stirred some heated debate, largely because of the vaccine's recommended use in young girls to prevent infection with an STD.⁵

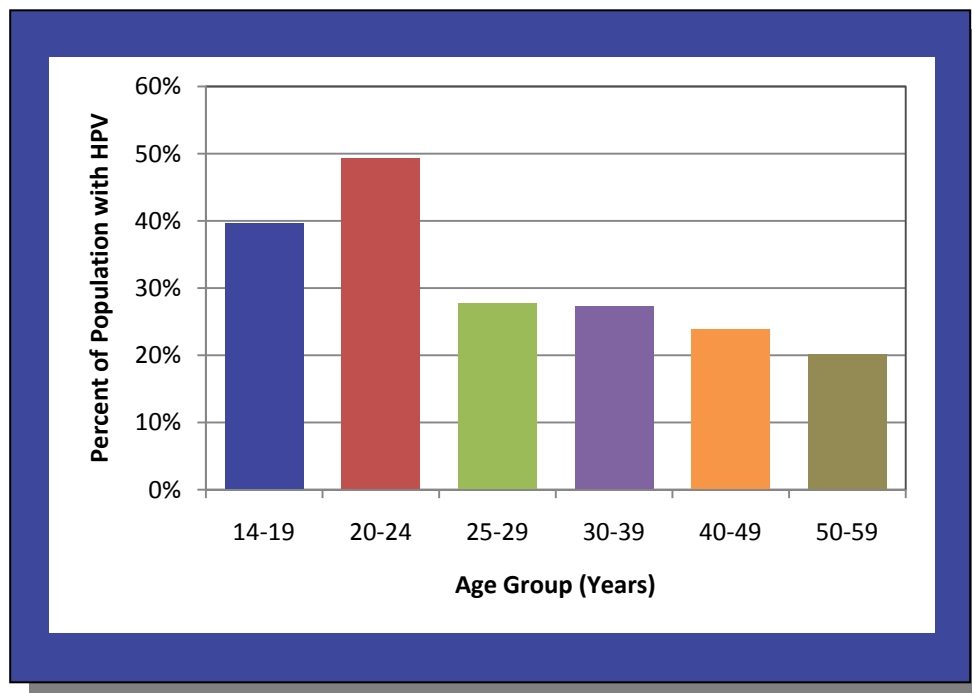
Research is currently being conducted to identify the long-term effects of the HPV vaccine. Additionally, health care practitioners are conducting community studies to help them understand and address the public's knowledge, attitudes, and beliefs about HPV and its vaccine. The University of North Texas Health Science Center at Fort Worth will conduct such research locally. A study is under way to examine how female caregivers of African American girls obtain HPV information; whether they trust this information; how they feel about their ability to act on it; and what they believe to be the risks associated with HPV and the HPV vaccine. The results of this study will be used to develop a culturally-competent educational campaign targeted at African American women to increase the acceptability of the vaccine and help eliminate disparities in cervical cancer incidence and mortality.

HUMAN PAPILLOMAVIRUS

Human papillomavirus (HPV), the primary cause of genital warts and cervical cancer, is the most common sexually transmitted disease (STD) in the United States. It is estimated that about 20 million Americans have HPV at any given time, with 6.2 million Americans acquiring the disease each year. About half of all sexually active men and women will be infected with genital HPV at some time during their lives.²

Although men and women can both acquire HPV, it is harder to detect in men, so most of the HPV prevalence data are limited to women. For females, infection with genital HPV most commonly occurs at an early age, close to the time of sexual debut. According to 2003-2004 data collected in the National Health and Nutrition Examination Survey (NHANES), HPV is most common among sexually active females in the 20-24 year old age group, followed closely by those in the 14-19 year old age group. (See Figure 1.) These data show higher prevalence rates of HPV in non-Hispanic African American women (39.2%) than in their white (24.2%) or Mexican-American (24.3%) counterparts, suggesting that there are significant disparities in HPV infection and treatment.³

Figure 1. Prevalence of HPV Infection among Sexually Active U. S. Females Aged 14-59 Years³



HPV Infection

There are about 100 types of HPV (identified by number of discovery), and more than 40 of these infect the genital area.⁶ Genital types of HPV have been further classified as high-risk and low-risk types, based on the cancer risk associated with the HPV type. Other types of HPV are associated with the development of non-genital warts.

Genital HPV is transmitted through genital contact, usually through vaginal or anal sex. Intercourse is thought to be necessary for infection of the cervix, but other types of skin-to-skin contact can facilitate transmission of HPV to other anogenital sites.⁷ HPV infects the basal layer of the epidermis (directly beneath the outermost layer of skin) usually through a small tear or abrasion in the skin, which may be produced during sexual

activity. The outer skin cell location of infection helps to shield the virus from the host immune response,⁶ but 90% of infections are cleared by the body's immune system.²

When the host's immune system does not rid the body of HPV, the virus inserts its DNA into the host cell and begins to replicate within the cells. As a result, the virus produces two proteins, which alter cellular development. These proteins disrupt the cell cycle and, among other things, cause unhealthy cells to replicate, potentially leading to the formation of pre-cancerous lesions.⁸ It is important to note, however, that this is relatively rare, occurring in only about 10% of high-risk type HPV infections.²

HPV Symptoms

Most genital HPV infections, both low-risk and high-risk types, clear the body without presenting any clinical symptoms. In some cases, however, infection with HPV causes genital warts or pre-cancerous lesions. Development of anogenital warts takes an average of 2-3 months after infection occurs. The warts appear as groups of small bumps or growths in the genital area or anus. Genital warts can be treated or may disappear without treatment. They are benign and will not turn into cancer.² It is estimated that 1% of sexually active people in the U.S. have genital warts.⁶

Infections with high-risk types of HPV may cause more serious problems, such as low-grade cell abnormalities. If these infections are persistent, they may lead to high-grade cell abnormalities, which are more likely than low-grade abnormalities to progress to cervical and other anogenital cancers.

Cervical Cancer

According to the Centers for Disease Control and Prevention (CDC), about 10% of women infected with high-risk HPV will develop persistent infections that put them at increased risk for cervical and other anogenital cancers.² In fact, high-risk HPV types are detected in more than 95% of cervical cancer cases and in 50-70% of many other anogenital cancer cases.⁹ (See Table 1.)

Table 1. Types of Cancers Associated with HPV Infection⁹

Type of Cancer	Percent of Cases Associated with Oncogenic HPV Types
Cervical	≥95%
Anal	>70%
Vulvar	>50%
Vaginal	50%
Penile	50%

Of the cancers associated with HPV, cervical cancer is by far the most common and the most deadly. (See Table 2.) Worldwide, cervical cancer is the second most common cancer among women,¹⁰ and in the United States, cervical cancer ranks about twelfth.¹¹ Since the 1950s, there has been a dramatic decline in the incidence rates (75%) and mortality rates (70%) for cervical cancer in the United States and other developed nations,⁶ largely due to the use of routine cervical cancer screening with the Papanicolaou test, also known as the Pap test.¹² In fact, about half of women diagnosed with cervical cancer in the United States had not had a Pap test in the preceding three years.⁶ Ongoing, preventive healthcare is critical to prohibiting the progression of cellular abnormalities to cervical cancer.¹ However, there have been no improvements in cervical cancer morbidity and mortality over the past 20 years, primarily because healthcare providers have reached the limits of what the tests can do and because not all females get screened for cervical cancer.¹³

**Table 2. Age Adjusted Incidence and Mortality Rates for Selected Anogenital Cancers
United States, 2002-2004¹⁴**

Type of Cancer	Incidence	Mortality
Cervical	8.3	2.5
Anal	1.5	0.2
Vulvar	2.3	0.5
Vaginal	0.7	0.2
Penile	0.8	0.2

The identified link between HPV and cervical cancer may help improve cervical cancer prevention efforts. Studies have found a direct association between cervical cancer and infection with high-risk HPV types, though HPV infection is not sufficient to cause all cervical cancers. Almost all cervical cancers (up to 99.7% in some studies) have been found to be linked to HPV, and researchers suspect that HPV may be a facilitating factor in the remaining 0.3% of cases, but the link cannot be proven.¹³

Persistent infection with high-risk types of HPV is the most important risk factor for developing cervical cancer.⁷ Because of this, most of the other risk factors for cervical cancer are the same as those for HPV—unprotected sex, multiple sexual partners, and early sexual debut. Other risk factors include cigarette smoking, alcohol consumption, having an uncircumcised male partner, having more than three pregnancies, long-term oral contraceptive use, and infection with other STDs.⁷ Furthermore, low socioeconomic position seems to increase the likelihood of developing and dying from cervical cancer.¹² According to the American Cancer Society, at least 80% of all cervical cancer cases and deaths occur in underserved, resource-poor populations of women.¹

Despite improvements in cervical cancer incidence and outcomes since the 1950s, distinct racial/ethnic disparities persist, leaving minority women carrying the bulk of the cervical cancer burden. Data from the CDC’s National Program of Cancer Registries show that Hispanic and Black women are 1.5-2 times more likely to develop and to die from cervical cancer than White women. (See Table 3.)

**Table 3. Cervical Cancer Incidence and Mortality Rates per 100,000 Females
United States, 2002-2004¹⁴**

Race/Ethnicity	Incidence	Mortality
All Races	8.3	2.5
White	7.8	2.2
Black	11.6	4.7
Hispanic	13.0	3.1

Similar disparities in cervical cancer incidence and mortality exist when considering data at the state and local level. (See Table 4.) In Texas, women of all racial/ethnic groups have a higher incidence and mortality from cervical cancer compared to white women. This may suggest that women are not receiving appropriate primary care and screening. In Tarrant County, while the incidence and mortality rates are slightly lower than the national rates, the racial/ethnic disparities are significantly more pronounced. This may indicate that while White women are receiving the preventive care they need, Black and Hispanic women are not.

**Table 4. Cervical Cancer Incidence and Mortality Rates per 100,000 Females
Texas and Tarrant County, 2001-2005¹⁵**

	Texas		Tarrant County, TX		Dallas County, TX	
Race/Ethnicity	Incidence	Mortality	Incidence	Mortality	Incidence	Mortality
All Races	10.1	3.2	8.1	2.4	10.8	3.3
White	8.1	2.6	6.3	1.9	8.1	2.2
Black	12.1	5.8	10.1	4.7	13.9	5.7
Hispanic	15.1	4.3	15.0	3.2	18.3	5.0

HPV Diagnosis

The presence of asymptomatic HPV infections can only be detected by HPV DNA testing. Consequently, the majority of asymptomatic cases go undiagnosed. The majority of diagnosed HPV cases are identified by the presence of the most common symptoms—genital warts and cell abnormalities, or pre-cancerous lesions. Genital warts are often diagnosed by direct visual examination. Cervical cell abnormalities may be detected during a routine Pap test. This procedure collects cervical cells and examines them using a microscope to look for squamous epithelial cell changes. If abnormal cervical cells are observed, a follow-up HPV test may be done to test for the presence of high-risk HPV DNA, which is associated with the development of cervical cancer.¹⁶

Treatment of HPV and HPV Symptoms

There is no cure for HPV. Therefore, while most new HPV infections clear naturally from the body, while the infection lasts, up to a lifetime among those who develop a persistent HPV infection, patients can spread the disease to other sexual partners and are susceptible to developing genital warts and/or pre-cancerous lesions.⁶

Treatment options are available for these HPV symptoms, but they are likely to recur until the HPV infection is cleared from the body. Genital wart treatments involve lesion removal via cryotherapy, electrocautery, laser therapy, surgical excision, or topical medication.

Similar treatment options are used to remove pre-cancerous lesions caused by HPV. Cervical cancer and other HPV-associated cancers that may progress from these lesions are usually treatable, especially if detected early through regular screening. The American Cancer Society, the U.S. Preventive Services Task Force, and the American College of Obstetricians and Gynecologists all recommend that women begin cervical cancer screening (Pap tests) within 3 years of onset of sexual activity or by age 21.⁶

Prevention of HPV

The surest way to prevent HPV infection is by abstaining from sexual activity. If a female does engage in sexual activity, it is best to limit the number of sexual partners or maintain a monogamous relationship with a partner who is not infected with HPV.² Studies have also shown that the use of condoms is helpful, but not 100% effective in preventing HPV infection.⁶ Finally, a vaccine has been developed for use in females to protect against infection with four high-risk types of HPV. Getting vaccinated before the onset of sexual activity will help prevent HPV infection in females.^{17, 18}

THE HPV VACCINE

A quadrivalent vaccine, Gardasil, has been developed to prevent infection with four types of HPV—types 6, 11, 16, and 18. Gardasil is produced by Merck and was approved for use by the United States Food and Drug Administration (FDA) on June 8, 2006.⁶ The vaccine consists of virus-like particles, which are essentially empty shells of protein that do not contain any viral DNA. The vaccine is not a live or attenuated virus. When the vaccine is injected, it stimulates an immune response and causes the formation of antibodies that will protect against infection with the four viruses types.¹⁹

Clinical trials have demonstrated that Gardasil is highly effective (almost 100%) at preventing infection with low-risk HPV types 6 and 11, which are associated with about 90% of genital wart cases, and high-risk HPV types 16 and 18, which are associated with about 70% of cervical cancer cases.^{6, 20} HPV-16 is the most prevalent HPV type associated with high-grade lesions and is the type most likely to persist and cause further health problems.¹

Efficacy studies for Gardasil were performed in groups of females aged 16-23 and 16-26 years. Efficacy data were collected through five years of follow-up and results showed that women were still protected against HPV at the end of the study period.²⁰ Studies are ongoing to investigate long-term efficacy. It is unknown whether women will require a booster shot after a certain number of years. Immunogenicity studies, which measure the immune response elicited by the vaccine, included males and females aged 9-15 and were compared to data from the efficacy studies for females aged 16-26.⁶ These studies found that vaccination produced higher antibody titers than those produced from a natural infection with HPV.⁶ Safety studies have also demonstrated that Gardasil is safe in females aged 9-26 and males aged 9-15.⁶ The most common side effect of the vaccine is soreness at the site of injection.²¹

Although safety and immunogenicity studies of Gardasil have included males, the vaccine is not currently approved for use in this population. Gardasil does not protect against types of HPV other than 6, 11, 16, and 18; nor will it provide protection against an established infection of one of these four HPV types. It is important to note that **vaccination does not replace the need for routine Pap tests**, as it does not protect against all types of high-risk HPV that can cause cervical cancer.

GlaxoSmithKline has also developed a bivalent HPV vaccine called Cervarix. This vaccine protects against high-risk HPV types 16 and 18. Cervarix has not yet been licensed by the FDA for use in the United States.

HPV Vaccine Recommendations

Gardasil is approved for use in girls and women between the ages of 9 and 26 years, as this is the population for which efficacy, safety, and immunogenicity studies of the vaccine have been conducted. The Advisory Committee on Immunization Practices recommends routine vaccination of females aged 11-12 years with three doses of quadrivalent HPV vaccine and catch-up vaccination of females aged 13-26 years.⁶ The rationale for vaccinating girls at a young age is to establish immunity to the HPV types before the onset of sexual activity.²¹ The three doses of vaccine should be given over a period of six months, with the second and third doses administered about 2 and 6 months, respectively, after the first dose.⁶ It is not known how effective protection will be if all three doses are not received. The vaccine is not recommended for pregnant women. There is no need to be screened for HPV infection before getting the vaccine.

The Centers for Disease Control and Prevention released the HPV Vaccine Information Statement in September 2006 and revised it in February 2007.²² In January 2007, the American Academy of Pediatrics

(AAP) added the HPV vaccine to the recommended 2007 childhood immunization schedule for the United States.²³ In early 2007, the American Cancer Society (ACS) published its “Guideline for Human Papillomavirus (HPV) Vaccine Use to Prevent Cervical Cancer and Its Precursors,” proposing recommendations almost identical to those given by ACIP.¹ Both AAP and ACS advocate the same vaccine recommendations as ACIP, with the exception of recommending catch-up vaccinations for girls between 13 and 18 years of age, rather than for girls between 13 and 26 years of age.²³ The AAP and ACS both state that there is not enough evidence of efficacy and benefit to women above the age of 18 to recommend the vaccine for this population.^{1, 23}

Paying for the HPV Vaccine

The cost of each dose of Gardasil is \$120, for a total of \$360 for the entire series. Most major insurance companies will cover the costs of ACIP-recommended vaccines, such as Gardasil.²⁴ There are also some public financing options available for people without private insurance. The federally financed Vaccines for Children (VFC) pays for ACIP-approved vaccines for children who are Medicaid-eligible, uninsured or underinsured, or American Indian or Alaska Native.²⁴ Over 45,000 sites in the United States provide VFC vaccines, including hospitals, private and public clinics, and schools.²⁵ Children and teens whose private health insurance will not cover the vaccine may also get VFC vaccines through Federally Qualified Health Centers and Rural Health Centers.²⁵ The Immunization Grant Program helps to finance vaccines for children who do not qualify for VFC.²⁴ Furthermore, in states where the State Children’s Health Insurance Program (SCHIP) is separate from Medicaid, SCHIP must cover ACIP-recommended vaccines using state funds.²⁴

Through VFC, states may choose to provide adult vaccine coverage, but there is currently no nation-wide public funding to provide vaccines for uninsured adults.²⁴ To help fill this gap, Merck has created a vaccine assistance program for 19-26 year old, uninsured, low-income women who receive care from private physicians’ offices that distribute other Merck products.²⁴ This program, however, is underused because these groups of women tend to seek care in public clinics and therefore do not qualify.

THE HPV VACCINE DEBATE: TO MANDATE OR NOT TO MANDATE?

Almost immediately after FDA licensure of Gardasil and the release of the ACIP recommendations regarding vaccination, health officials, state legislatures, and the public began debating the appropriateness of mandating the vaccine for young girls. Although state governments have the authority to require vaccination for school entrance (except when it interferes with religious beliefs), the use of this authority is often controversial, regardless of the vaccine in question. However, the HPV vaccine has stirred particularly heated debate, largely because of the vaccine’s recommended use in young girls to prevent infection with an STD.⁵

Knowledge about the HPV Vaccine

Opponents of the mandate say that there is not enough evidence regarding duration of protection, safety, and potential effects on future fertility to enforce widespread use of the HPV vaccine.²⁶ Many of these individuals support use of the vaccine, but question the rush to mandate it, pointing out that vaccines are generally introduced gradually and mandates are enacted over a period of years. For example, it took over five years to mandate the chicken pox vaccine, longer for the Hepatitis B vaccine, and the meningitis and pertussis vaccines are not yet mandated.¹ Mandate opponents recommend waiting for the results of on-going vaccine studies before making any decisions about the vaccine.

On the other hand, many proponents of the mandate feel that sufficient evidence has been gathered to warrant a mandate. They cite the successes of other vaccines, such as the Hepatitis A vaccine, which was mandated in some states as early as one year after it was licensed.^{27, 28}

Cost-Benefit Assessments

Opponents of the vaccine believe that the cost-benefit ratio for mandatory vaccination is too high.^{29, 30} Since cervical cancer is not the major killer among Americans that it is in developing nations, some suggest that governmental funding in the United States would be better spent on diseases with higher prevalence. Furthermore, mandate opponents point out that HPV infection can be prevented without vaccination (i.e., with abstinence or condom use) and that cervical cancer can be prevented with regular Pap tests. These preventive measures are relatively inexpensive and are already routinely recommended by health care professionals.

On the other hand, advocates of the mandate point out that spending money on the HPV vaccine now could result in large savings down the road. As more people receive the vaccine, the population as a whole receives indirect protection against the virus. This is a concept that health professionals refer to as herd immunity. As more individuals gain immunity from a disease, the number of potential hosts for the agent that causes the disease decreases. When the number of potential hosts becomes small enough, the disease-causing agent has nowhere to live and can eventually be wiped out of a population. Thus, both those who have immunity (i.e., were vaccinated) and those who do not have immunity are protected from the disease.³¹ Herd immunity campaigns have been used to eradicate diseases, such as polio and smallpox, in America.^{32, 33}

Analysts have suggested that taking into account the effects of herd immunity significantly decreases the overall cost-benefit ratio associated with vaccinations.^{34, 35} In a recent study, Kim and Goldie found that, assuming that the vaccine confers life-long immunity (an assumption which has not yet been proven) and that widespread coverage is achieved among 12-year-old girls, the cost-effectiveness ratio of the HPV vaccine was \$43,600 per quality-adjusted life year (QALY) gained, compared with current screening practice.³⁶ Generally, any intervention that costs less than \$50,000/QALY is considered to be cost-effective, so these data support the use of the HPV vaccine, if the assumptions hold true. However, Kim and Goldie found that the cost-effectiveness ratio increases significantly as the age for HPV vaccination increases. Furthermore, if we find that HPV vaccine protection wanes after 10 years, the cost-effectiveness ratio increases to more than \$140,000/QALY.³⁷ It is important to note that this study used population estimates to estimate the cost-effectiveness of the vaccine. It will be decades before scientists can begin to measure the observable impact of HPV vaccination on cervical cancer rates.

Reducing HPV and Cervical Cancer Disparities

Proponents of mandating the HPV vaccine claim that mandates are the best way to eliminate disparities in HPV and cervical cancer and to reduce the economic burden of these diseases.²⁶ They suggest that, whereas a mandate would not only require, but also provide funding for, all girls to get the vaccine, a voluntary or “opt-in” system could exclude some children from receiving the vaccine.²⁶ Children from low-income, uninsured, or underinsured families would likely be excluded due to a lack of funding. Even if these children are eligible to receive the vaccine from sources such as Medicaid or VFC, these families are often less likely to receive preventive care, especially for their adolescent children, than higher income families. Children of uneducated parents and/or those in medically underserved communities would also be less likely to receive the vaccine with an “opt-in” system for vaccination. Thus, suggest supporters of the mandate, anything short of a

mandate could serve to increase, rather than decrease, HPV and cervical cancer disparities in incidence and prevalence.²⁶

Others suggest that targeted educational campaigns and outreach could help to reduce disparities without a vaccine mandate. In an unpublished study, Goldie and colleagues found that GlaxoSmithKline's HPV vaccine, Cervarix, produced relatively small improvements at the population level when compared to current screenings. But if the vaccine is targeted to low-income, historically underscreened communities, it has great potential to reduce cervical cancer disparities.¹

Impact on Sexual Behavior

Finally, some opponents of the mandate are concerned that HPV vaccination of adolescents will lead to an increase in premarital sex and unsafe sexual behavior.¹ If that is true, HPV vaccination could inadvertently increase young women's risk of acquiring other STDs. These concerns are based on the assumption that adolescents abstain from sex for fear of HPV infection.

Data from the National Survey of Family Growth, however, indicate that only 10% of male and 7% of female adolescents who have never had sex cite "don't want STD" as the main reason for not having sex.³⁸ This same survey showed that 24% of girls report sexual activity by the age of 15, 40% by the age of 16, and 70% by the age of 18.³⁸ Similarly, the Youth Risk Behavioral Surveillance System (YRBSS) found that in 2007, 47.8% of high school students reported ever having sex, 7.1% reported initiating sex before the age of 13, and 14.9% reported having sex with 4 or more partners—all risk factors for HPV infection.³⁹

Proponents of the vaccine point to these data to show that young people in the United States are already engaging in sexual behaviors that put them at risk for HPV and that fear of getting an STD is not a major factor in a teenager's decision about whether or not to have sex. Thus, they say, the risk that a young woman will get HPV if she is not vaccinated is significantly greater than the risk that she will initiate sexual activity because she is vaccinated. Requiring girls to obtain the HPV vaccine before entering middle school is arguably the best way to reduce their risk of HPV infection.

HPV VACCINE LEGISLATION

Amidst these debates, 42 states and the District of Columbia introduced bills relating to Gardasil and/or cervical cancer between its licensure in 2006 and August 2008. (See Table 5.) Twenty-four of these states and Washington, DC, introduced legislation to mandate the vaccine for girls entering middle school,⁴⁰ but Virginia and the District of Columbia are the only places where vaccine mandates are currently approved.⁵ In 2008, Virginia's state legislature introduced a bill to remove the HPV vaccine requirement for middle school entry.⁴⁰

Although Texas Governor Rick Perry issued an executive order to mandate the HPV vaccine in Texas in 2007, the Texas House of Representatives issued a bill to ban the mandate. A Senate version of the bill, however, provided that the ban would expire in four years, so lawmakers can revisit the issue at a later date. The next Texas Legislature meets in 2009 and could vote to take up the issue then.⁴¹

Table 5. State Legislation Relating to the HPV Vaccine⁴⁰

HPV Vaccine Legislation	States
Introduced legislation to educate the public about HPV and/or the HPV vaccine; and/or introduced legislation to further study the issues surrounding the HPV vaccine	AZ, CO, CT, HI, FL, IL, IN, IA, KS, KY, LA, MD, MI, MO, MN, NE, NJ, NY, NC, ND, PA, TN, TX, WI, UT, WA,
Enacted public education legislation	CO, IN, IA, MD, MN, NJ, NC, ND, TX, UT, WA,
Introduced legislation to fund and/or require insurance companies to fund the HPV vaccine	AZ, CA, CO, CT, FL, GA, HI, IL, IA, KY, LA, ME, MA, MS, NV, NJ, NM, NY, OR, PA, RI, SD, TX, VT, VA,
Enacted HPV vaccine funding legislation	CA, CO, IL, IA, ME, NV, NM, NY, RI, SD,
Introduced legislation to mandate the HPV vaccine for middle school entry	CA, CO, CT, DC, FL, GA, IL, KS, KY, MD, MA, MI, MO, MN, MS, NM, NY, OH, OK, SC, TX, VT, VA, WV
Approved mandates	DC, VA

POLICY RECOMMENDATIONS

Regardless of whether or not the HPV vaccine is mandated, most public health organizations as well as the American Academy of Pediatrics, the American Cancer Society, and the U.S. Preventive Services Task Force agree that the vaccine should be recommended for young girls entering middle school, as widespread use of the HPV vaccine would serve as a major influence to eliminate disparities in cervical cancer. The following policy recommendations are provided to encourage widespread use of the HPV vaccine:

- ***Increase awareness of HPV and cervical cancer prevention.*** Multi-level educational campaigns are needed to inform the public about HPV infection, cervical cancer, and the HPV vaccine. Specifically, current sexual education curricula may be expanded to incorporate discussions of HPV and cervical cancer prevention, including abstinence, safe sex practices, and the HPV vaccine. Educational efforts are also needed for parents so that they can make informed decisions about protecting their children from HPV infection and cervical cancer. These efforts must include information regarding vaccine and Pap test coverage by private, state, and federal insurance programs to decrease the chance that children who are eligible for vaccine coverage go without it.
- ***Increase access to the HPV vaccine and cervical cancer screening.*** The HPV vaccine is currently expensive enough to exclude use by uninsured and low-income populations. It is recommended that changes to existing programs and new programs be considered throughout the United States to provide the HPV vaccine to those at highest risk of developing cervical cancer, including the uninsured and medically underserved. The changes must improve access to the HPV vaccine, Pap tests, and cervical cancer treatment in order to reduce disparities in access, quality of care, and health outcomes among minority women. Improving access includes, but is not limited to, covering the costs associated with screening, preventive and palliative care—it must also include improving access to services. For example, medical buses could be used to provide the HPV vaccine and cervical cancer screening in medically underserved populations.
- ***Collaborate with local, grassroots organizations.*** Issues associated with HPV and cervical cancer prevention and screening vary across communities. Thus, it is critical that state and national

organizations partner with local, grassroots organizations to increase awareness of HPV and cervical cancer and to improve access to prevention, screening and treatment. For example, local public health agencies may be awarded grants to assess local knowledge of the HPV vaccine and design culturally-sensitive programs to increase awareness.

- ***Provide resources to support HPV and cervical cancer prevention strategies.*** Although many states have passed legislation to promote HPV and cervical cancer educational campaigns and HPV vaccine funding, these states have not all allocated resources to make this happen. For example, although the Texas Department of State Health Services (DSHS) was charged with creating a strategic plan to “eliminate mortality from cervical cancer by 2015,”⁴² the plan is currently unfunded, reducing the likelihood that the State will be able to meet the goals laid out in the plan. Of even greater concern, Virginia and Washington, DC, the only two areas which currently mandate the HPV vaccine, have not enacted legislation to allocate funding toward HPV vaccination or to require insurance companies to cover the vaccine. This may leave some families without a way to pay for the vaccine and thus without a way to enroll their daughters in school.

FUTURE RESEARCH

Although Gardasil has been found to be safe, effective, and beneficial in young girls and women, there is still much to be learned about the vaccine. For example, the vaccine is currently only licensed for use in females between 9 and 26 years of age. Efficacy studies are underway to determine the vaccine’s effectiveness in preventing HPV infection in males. If proven effective, vaccinating males has the potential to not only prevent genital warts, head and neck cancers, and rare anogenital cancers in males, but also to provide indirect benefits to girls and women by preventing the transmission of HPV.²⁰ Efficacy research involving females of different ages may be useful, as well.

The long-term impact of the vaccine is also unclear. Investigators do not know how long the vaccine confers protection against HPV or whether booster shots are needed to maintain protection. Studies are currently being conducted to evaluate the long-term efficacy and safety of the vaccine. Future studies should also be conducted to identify the impact of Gardasil on the anogenital and head and neck cancers associated with HPV. Studies should be conducted to collect data on reproductive toxicity and co-administration with other vaccines.¹ Alternative dosing schedules, as well as the protection conferred from sub-optimal doses (i.e., receiving less than 3 doses), may also need to be studied.

In addition to studying the vaccine itself, it is critical for medical and public health practitioners to understand and address the knowledge, beliefs, and attitudes associated with the vaccine. For example, because it is important for women to continue getting regular Pap tests, even after HPV vaccination, it will be useful to study the impact of vaccine use on screening behaviors. Parents’ beliefs about the vaccine should also be taken into consideration, as they are responsible for deciding whether or not their daughters get vaccinated. Investigators at the University of North Texas Health Science Center are collaborating with the Fort Worth Public Health Department and Tarrant County Public Health to study what is known about HPV and the HPV vaccine among female caregivers of African American girls. This exploratory study will also identify the trusted sources from which these women obtain health information. This information will be used to help create an educational campaign that would encourage HPV vaccination in this high-risk community.

CONCLUSION

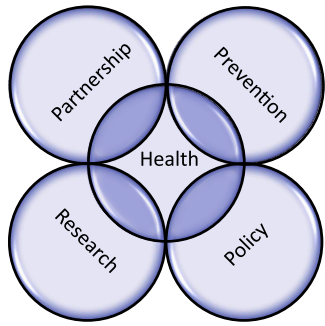
The HPV vaccine is the first vaccine introduced with the potential to prevent cancer and help erase the racial/ethnic and socioeconomic disparities related to cervical cancer. Use of the vaccine will protect girls and women from the types of HPV that cause most cases of genital warts and cervical cancer. However, the vaccine has stirred much debate, and many people are wary of vaccinating young girls against a sexually transmitted disease to which they may not be exposed. Concentrated education efforts are needed to inform the public about the prevalence of and risks associated with HPV, as well as the advantages and disadvantages of vaccination. Research, such as that being recently underway at the University of North Texas Health Science Center, is needed to identify the best ways to provide such education, especially in high-risk populations. Such research, along with local and state policy changes, could encourage widespread use of the HPV vaccine. This could in turn save thousands of lives in the United States each year and help to reduce the disparities associated with cervical cancer.

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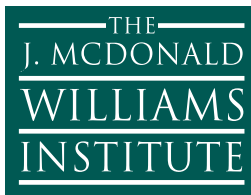
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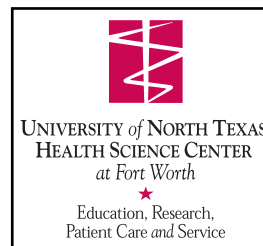
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