

THE HUMAN PAPILLOMAVIRUS (HPV), CERVICAL CANCER AND THE HPV VACCINE

$FREQUENTLY ASKED \ QUESTIONS \cdot SEPTEMBER \ 2007$

GENERAL OVERVIEW OF HPV, CERVICAL CANCER AND THE HPV VACCINE

1. WHAT IS HUMAN PAPILLOMAVIRUS (HPV)?

Human Papillomavirus (HPV) is the name of a group of viruses, many of which are spread through skin to skin contact, particularly during sexual activity. HPV has been linked to both cervical cancer and genital warts. There are approximately 120 types of HPV, but two types (strains 16 and 18) are responsible for approximately 70% of all cases of cervical cancer.

HPV is the most common sexually transmitted infection in the United States with an estimated 6.2 million people newly infected each year. It is estimated that a quarter of teenage girls and half of women in their early 20s have the virus. It is important to note that there is currently no cure or treatment for HPV and oftentimes there are no symptoms. According to the American Cancer Society, the infection usually disappears without any treatment and any abnormal cell growth or warts caused by HPV can be treated effectively. It is important to note that HPV is *not* the same as HIV or Herpes (Herpes simplex virus or HSV)¹.

2. HOW IS HPV ASSOCIATED WITH CERVICAL CANCER?

Approximately a dozen strains of HPV can infect a woman's cervix (lower part of the womb) and cause the cells to change.ⁱⁱ While most cases of HPV infection are resolved on their own, certain strains can lead to cervical cancer if not treated over time.ⁱⁱⁱ The strains most associated with cervical cancer are 16 and 18.

According to the Center for Disease Control and Prevention (CDC)^{iv}, about 40 types of HPV can infect the genital areas of men and women. These types also have been linked to other less common genital cancers— including cancers of the anus, vagina, and vulva (area around the opening of the vagina). Other types of HPV can cause warts in the genital areas of men and women.

3. How common is cervical cancer and how does it impact Latinas?

According to the American Cancer Society, there are approximately 10,000 cases and 3,700 deaths from cervical cancer in the U.S. per year.^v The incidence of cervical cancer for Latina women in the United States is almost twice as high as non-Latina white women. Latina women have the 2^{nd}



highest mortality rate from cervical cancer (after black women), although mortality for Latina women is higher in communities along the Texas-Mexico border.^{vi} This is largely due to Latina women's low rates of routine gynecological care, particularly pap smears and cervical cancer screening. These low rates are caused by lack of insurance, fear associated with their immigration status, embarrassment, lack of knowledge, and limited English proficiency.^{vii} About 85% of women who die from cervical cancer never had a pap smear.

4. WHAT IS THE HPV VACCINE?

In June 2006, the federal Food and Drug Administration (FDA) approved the first vaccine, Gardasil[®], manufactured by Merck & Company, developed to prevent cervical cancer and genital warts caused by four strains of HPV; two strains (strains 16 and 18) that are responsible for 70% of cervical cancer incidences and two strains (strains 6 and 11) which are responsible for 90% of genital warts caused by HPV. Subsequently, the CDC's Advisory Committee on Immunization Practices (ACIP) recommended that the vaccine be administered to all girls ages 11-12, and approved it for administration to women from 9 to 26 years old.

The vaccine requires a three-shot regimen over the course of 6 months and is quite costly at approximately \$120 per shot, for a total of \$360 for the series. Administrative charges tacked on by the doctor may increase the cost, and anecdotal reports indicate that some women have paid as much as \$700 for the three-shot series.

5. WHAT'S IN THE VACCINE? HOW DOES IT WORK?

The vaccine is made from non-infectious HPV-like particles that trigger an antibody response that prevents recipients from contracting HPV strains 6, 11, 16, and 18. It is important to note that, according to the FDA, because the vaccine only contains a protein, and not the actual virus, the vaccine will not cause HPV.^{viii}

6. How Do I Access the HPV VACCINE?

Many gynecologists or pediatricians have the vaccine available, although recent reports indicate that some doctors are not stocking the vaccine because of its hefty price tag. Publicly funded access to the HPV vaccine varies state-to-state, although all low-income adolescents between the ages of 9 through 19 who are either uninsured, Medicaid-eligible, American Indian, or Alaska Native, have access to the vaccine through the federal Vaccines for Children (VFC) Program. For women over the age of 19 with private health insurance, 96% of private plans cover the vaccine; for women who are uninsured and Medicaid-eligible, it is imperative that they verify if their state has chosen to provide optional vaccine coverage. Additional publicly-funded or Merck-funded programs may be available to provide vaccine access for low-income women, but these programs are not universally available nationwide.

7. WHEN SHOULD I GET THE VACCINE?

The HPV vaccine is approved by the FDA for use by girls and women ages 9 to 26. It is ideal to obtain the shots prior to the onset of sexual activity, but women who are sexually active are still recommended to receive the vaccine up to age 26. The FDA has not approved the vaccine for use in



women over the age of 26, and it is not recommended for women who are pregnant. Also, women who already have HPV can still benefit from the vaccine because it targets particular strains that the woman may not have contracted. However, the HPV vaccine *does not treat* existing HPV infections.

8. I ONLY HAVE SEX WITH OTHER WOMEN; DO I NEED TO RECEIVE THE VACCINE?

Yes! Lesbian and bisexual women are also at risk of acquiring HPV. According to research conducted by National Network for Immunization Information, cervical pre-cancers and cancerous changes have been found in women who exclusively have sex with women.^{ix} Lesbian and bisexual women oftentimes practice oral sex, genital to genital sex, vaginal finger penetration, and/or sharing of sex toys^x; all which could contribute to the transmission of HPV. In addition, women who have sex with women face barriers to preventive reproductive health services, including encountering health providers with negative or judgmental attitudes, and misperceptions about the diversity of their health needs.^{xi}

9. WHAT DOES THIS NEW APPROVAL OF THE HPV VACCINE MEAN FOR LATINAS?

While cheered in the medical community as a breakthrough for women's health, the HPV vaccine is still out of reach for many women with its price tag of over \$360 for the recommended three-shot regimen. Barriers to accessing the HPV vaccine are compounded for Latina and immigrant women, who may have limited English proficiency, may be without health insurance and/or may be undocumented. Latina women are less likely to receive adequate reproductive health care services and often forgo critical pap smears and screenings that could provide early detection of abnormal pre-cancerous cells that can lead to cervical cancer. More than half of all U.S. women diagnosed with cervical cancer have not had a pap smear in the last three years. Researchers have found that Latina women were more likely than other women to be diagnosed with cervical cancer at an advanced stage, largely because of the lack of education about the importance of pap smears and their link to early detection of pre-cancerous cells. The lack of education is often a result of poverty, language barriers and cultural stigma around discussing issues of sex and sexuality in the Latino community.

10. How should the HPV VACCINE BE PROVIDED?

NLIRH advocates a standard of care that will provide Latinas with all the possible options for preventing cervical cancer. This standard of care includes: regular HPV and cervical cancer screenings during gynecological visits, comprehensive sexuality information, affordable access to reproductive health technologies such as the HPV vaccine, and accurate information on preventing HPV and other sexually transmitted infections. NLIRH supports Latina's full access to new reproductive technologies when they are coupled with unbiased information and implementation that is free from coercive policies and practices. Additionally, policy makers should advance legislation that provides universal access to the vaccine through public funding such as Title X, Medicaid and the State Children's Health Insurance Program (SCHIP), and private insurance coverage requirements for girls and women ages 9 to 26 years old.



11. I DON'T WANT TO GET THE VACCINE; ARE THERE OTHER WAYS TO PREVENT HPV?

HPV is very common, and both women and men are carriers of the virus. There is still much to be studied about HPV, but according to the CDC, the only way to prevent contracting HPV is to abstain from all sexual activity.^{xii} HPV could be spread from skin-to-skin contact, and recent studies have found HPV under the fingernails of men. While utilizing condoms during sex can reduce the transmission of HPV, it does not provide full protection because areas not covered by a condom can be exposed to the virus.^{xiii} However, condom use is highly encouraged because of protection against other sexually-transmitted infections.

The best way to prevent developing cervical cancer is to obtain regular pap smears—ideally, once a year beginning with the initiation of sexual activity. Pap smears are the most effective way to screen for the pre-cancerous cells that can lead to cervical cancer. For women over 30, there is a HPV test that can be used along with the pap smear as part of routine cervical cancer screening.^{xiv}

Additional studies have shown that maintaining a healthy lifestyle with a diet rich in fruits and vegetables can help reduce the risk of developing cervical cancer.^{xv} Furthermore, women who do not smoke are less at risk than those who smoke. According to the American Cancer Society, tobacco by-products have been discovered in the cervical mucus of women who smoke, leading to the damage of DNA cells in the cervix.^{xvi} This exposes women to the risk of developing cervical cancer at a rate twice as high as non-smokers.^{xvii}

ADDRESSING THE CONTROVERSY: WHY HAS THE HPV VACCINE BECOME SO POLITICAL?

1. WHAT ABOUT BOYS? WHY CAN'T THEY BE VACCINATED?

The studies are currently being conducted on boys to see if the vaccine will be effective. While boys cannot get cervical cancer and HPV remains symptom-less, they can transmit it to their partners. It is more difficult to track boys and cervical cancer because to participate in the study, researchers must track their sexual partners and their incidence of cervical cancer.

HPV impacts boys in a different way. According to the New England Journal of Medicine, a team of researchers at Johns Hopkins University confirmed that infection with HPV via oral sex is by far the leading cause of throat cancer, which strikes 11,000 American men and women each year.^{xviii} HPV is also a major cause of anal cancer and genital warts, both of which affect either sex; HPV is also linked to penile cancer in boys and men. It is not clear whether the HPV vaccine could prevent anal, penile or throat cancer or if it will be effective for boys, but research and data are forthcoming.

2. WHAT KIND OF SIDE EFFECTS HAVE THEY FOUND?

According to the CDC^{xix}, the most common side effect is soreness at the injection site. The CDC, working with the FDA, will continue to monitor the safety of the vaccine after it is in general use. Despite rumors that have been circulating, there is no thimerosal or mercury in the HPV vaccine. It is made up of proteins from the outer coat of the virus (HPV). There is no infectious material in this



vaccine. In addition, claims of three deaths associated with the vaccine have proven unrelated and an FDA spokesperson states that the deaths occurred independently of the vaccine.^{xx}

3. DID THEY REALLY TEST THE VACCINE ENOUGH TO KNOW ABOUT LONG TERM SIDE EFFECTS?

According to Merck & Co., Gardasil[®] has been studied for more than a decade in more than 25,000 individuals, including 1,124 adolescent girls ages 9 to 15.^{xxi} These studies have shown no serious side effects. The most likely long term effect might be the necessity for a booster (similar to the Tetanus vaccine) after five years, although this is not a conclusive finding.

4. WHAT ABOUT THE CONTROVERSY WITH MERCK AND THEIR LOBBYING? ARE THEY JUST TRYING TO MAKE MONEY?

Our pharmaceutical industry is for-profit, which means that companies invest a lot of money in research on new technologies. Many of those technologies do not turn into effective medicines, and so when one technology does prove effective (and is approved by the FDA) the company has to make up its losses on all the experimental research, as well as make a profit. This results in high prices for medicines. High prices often result in new reproductive technology becoming out of reach for many women in our community.

Merck led a strong campaign to make the vaccine mandatory in public schools, and ended up having to rescind its push for state legislation due to the controversy. While pharmaceutical lobbying is controversial, the matter of the fact is that this vaccine is an important tool to fight a deadly form of cancer, and we need legislation to help increase access to it.

5. What about the history of abuses against women of color? How do we know this isn't just another form of genocide against our community?

History has demonstrated that women of color were often coerced into sterilization and were used as guinea pigs in contraception trials. Many of these coercive practices were in place until the 1970's and were seen as part of a wide-spread eugenics movement that discriminated against people of color. This history has led many Latinas to mistrust the medical system and to be suspect of new medical policies that infringe upon their reproductive self-determination. However, legislative mandate proposals, ethical standards and clinical research procedures have evolved through the establishment of the Office for Human Research Protections. In addition, vaccine approval by the FDA is a very strenuous process and all vaccines must be thoroughly tested before deemed safe and effective. This vaccine has been recommended for use by *all* girls and women up to the age of 26 (with some limited exceptions), and efforts to expand access to the vaccine should be embraced. The somber reality is that cervical cancer disproportionately impacts women of color; Latina women have the highest rates of cervical cancer (almost twice the rate of non-Latina white women), followed by Black women and Asian Pacific Islander women. Black women are most likely to die from cervical cancer, followed by Latina women. This is due to the tremendous health disparities that exist in our country that are perpetuated by race, class, socio-economic status, English-language proficiency and immigration status. The HPV vaccine could help reduce some of the disparities that exist for women with cervical cancer, and would serve as a tool to protect the fertility of women of color by



preventing cancer treatment surgeries such as hysterectomies. However, access to the vaccine remains a challenge. Unless states take action to expand access to the vaccine for low-income and uninsured women, the cervical cancer disparities in this country will continue.

6. Why do the girls need to get it so young? And what about women older than 26?

The HPV vaccine has proven most effective for girls who receive it prior to onset of sexual activity. According to the CDC^{xxii}, nationwide, 6.2% of high school students had sexual intercourse for the first time before age of 13; for Latinas, the rate is 3.6%. By the time students reach the 12th grade, 46.8% will have had sexual intercourse, including 44.4% of Latinas. Sexual activity increases the likelihood of exposure to HPV, so the vaccine is recommended for administration to girls 11-12 years of age, and girls as young as 9 years old can receive it.

Regarding women over the age of 26, research on the vaccine's safety and efficacy is currently being conducted. Another pharmaceutical company, GlaxoSmithKline, is currently testing a cervical cancer vaccine on women up to age 55. However, at this time, the Gardasil[®] vaccine is approved by the FDA for girls and women only between 9 to 26 years of age.

7. Does the vaccine promote promiscuity?

No! Although religious and conservative groups have purported that the vaccine would promote promiscuity and that encouraging wide-spread vaccination goes against their "abstinence-only" message, the general public (including parents, health care providers, and sexual health advocates) have largely rejected that message.^{xxiii} Studies have shown that young people do not abstain from sexual activity due to fear of contracting HPV (the vaccine does not protect against other sexually transmitted infections) and there has been no scientific evidence that the HPV vaccine will promote sexual activity.

8. IF I PLAN ON ABSTAINING FROM SEX UNTIL I MARRY, DO I STILL NEED THIS VACCINE?

Yes. While abstaining from sexual intercourse is one of the best methods to prevent contracting HPV, it can be misleading. Individuals that abstain from intercourse but engage in other forms of sexual activity, such as fondling and other forms of intimate partner contact, can still be exposed to the virus through skin-to-skin contact. In addition, individuals who have abstained from sexual activity may marry a spouse or commit to a life partner that has been exposed to HPV through previous sexual activity.

For more information on Cervical Cancer, HPV and the vaccine, visit the National Latina Institute for Reproductive Health at <u>www.latinainstitute.org</u>

Additional Resources: Center for Disease Control and Prevention (CDC): <u>www.cdc.gov</u> American Cancer Society: <u>www.cancer.org</u>

ⁱ Centers for Disease Control and Prevention (CDC), "HPV Vaccine Questions and Answers", August 2006. ⁱⁱ Ibid.



NATIONAL LATINA INSTITUTE FOR REPRODUCTIVE HEALTH

ⁱⁱⁱ Henry J. Kaiser Family Foundation, "Fact Sheet: HPV Vaccine: Implementation and Financing Policy", January 2007.

^v American Cancer Society, "Detailed Guide: Cervical Cancer", October 2005.

- viii Food and Drug Administration, "Product Approval Information- Licensing Action, Gardasil® Questions and Answers", June 8, 2006.
- ^{ix} National Network for Immunization Information, "HPV Vaccines: HPV Infection in Women who have sex with Women", March 1, 2007.

^x Ibid.

^{xi} Ibid.

xii Centers for Disease Control and Prevention (CDC).

xiii Ibid.

xiv Ibid, "HPV. Common Infection. Common Reality" Brochure.

^{xv} Singh, VN and Gaby, SK., "Premalignant Lesions: Role of antioxidant vitamins and beta-carotene in risk reduction and prevention of malignant transformation", *American Journal of Clinical Nutrition*, Volume 53, 386S-390S, 1991.

^{xvi} American Cancer Society, "What are the Risk Factors for Cervical Cancer?", August 2006.

^{xvii} Ibid.

- xviii Mundell, E.J., "Experts Debate Giving HPV Vaccine to Boys", MedicineNet.com, May 18, 2007.
- xix Centers for Disease Control and Prevention (CDC).
- ^{xx} Food and Drug Administration, www.fda.gov.
- xxi Merck & Co. Product News, "CDC Finalizes Advisory Panel Recommendations for Gardasil®, Merck's Cervical Cancer Vaccine", March 22, 2007.
- xxii Centers for Disease Control and Prevention (CDC), Youth Risk Behavior Surveillance, US, 2005.

xxiii Gibbs, Nancy. "Defusing the War over the 'Promiscuity' Vaccine", Time, June 21, 2006.

^{iv} Centers for Disease Control and Prevention (CDC).

^{vi} Byrd, Chavez and Wilson, "Barriers and Facilitators of Cervical Cancer Screening Among Hispanic Women", *Ethnicity & Disease*, Volume 17, Winter 2007.

vii Ibid.