



## THE HPV VACCINE AND SCHOOL MANDATES: QUESTIONS AND ANSWERS

*MOIRA GAUL, M.P.H.*

### HPV

Q: What is HPV?

A: HPV, or human papilloma virus, is a virus that can cause abnormal tissue growth on different cell surfaces in and on the human body. There are over 100 types or strains of HPV that exist. HPVs causing warts which appear on outer skin layers, such as hands, are different than HPVs which grow on mucus covered surfaces found in the throat and genitals.<sup>1</sup> Over 30 HPV types are sexually transmitted.<sup>2</sup>

Q: Are some types of HPV more dangerous than others?

A: Yes, HPV types can be divided into two categories: high-risk or cancer associated/causing types and, low-risk or non-cancer causing types.<sup>3</sup>

Q: How is genital HPV infection associated with cervical cancer?

A: Sexually transmitted HPV has been shown to be present in virtually all cases of cervical cancer and is the leading cause of cervical cancer. High risk HPV types 16 and 18 cause 70 percent of cervical cancer cases.<sup>4</sup>

### Genital HPV

Q: How many people have genital HPV?

A: According to the Center for Disease Control and Prevention (CDC), about 20 million Americans are infected with HPV currently and approximately 6.2 million Americans become infected with HPV every year. An estimated half of those infected, or 10 million, are sexually active adolescents and young people aged 15 to 24 years.<sup>5</sup>

Q: How can a person get infected with HPV?

A: HPV transmission takes place during direct skin to skin contact, usually at the time of sexual intercourse (vaginal or anal sex). Transmission can also take place

through other routes which involve any genital contact, though much less frequently than during sexual intercourse.<sup>6</sup>

Q: How does a person know if they have infection with HPV?

A: Because HPV infections usually clear themselves without intervention in anywhere from six months to two years and because they don't often produce any symptoms, many people do not know that they are or were at one time infected. People who develop a "persistent infection" may develop genital warts, precancerous lesions, or cancer.<sup>7</sup> Most women are diagnosed with HPV based upon abnormal results of screening by regular Pap (Papanicolaou) tests. The Pap test is a procedure in which a sample of cells are scraped from the cervix and then examined microscopically.<sup>8</sup>

The CDC estimates that 10 percent of women with HPV develop persistent HPV infections. Persistent infection with high-risk HPV types places a woman at greatest risk for developing cervical lesions or precancer lesions, and cancer. Women with persistent low-risk HPV type infection may develop genital warts.<sup>9</sup>

Q: What are risk factors for HPV infection in women?

A: Women and girls who have not been sexually active are not at risk for genital HPV infection. Among sexually active females, the CDC cites the following risk factors as being strongly associated with acquisition of HPV infection: increasing number of sex partners, early age at first sexual intercourse (16 years or younger), male partner has (or has had) multiple sex partners, and young age (less than 25 years). Further, the risk of HPV infection is proportionately related to the number of sex partners a person has or has had.<sup>10</sup>

Q: How can a person be best protected from acquiring genital HPV?

A: Limiting sexual activity to the context of one faithful and monogamous long-term relationship with an uninfected individual is the single most effective method of preventing HPV infection. This statement is supported by the CDC which concluded in a 2004 report, "Because genital HPV infection is most common in men and women who have multiple sex partners, abstaining from sexual activity (i.e. refraining from any genital contact with another individual) is the surest way to prevent infection. For those who choose to be sexually active, monogamous relationship with an uninfected partner is the strategy most likely to prevent future genital HPV infections.

"The available scientific evidence is not sufficient to recommend condoms as a primary prevention strategy for the prevention of genital HPV infection..."<sup>11</sup>

For these reasons stated above the Family Research Council (FRC) takes the position that practicing abstinence until marriage and fidelity within marriage is the best form of prevention against HPV infection.

However, HPV infection can result from involuntary sexual activity, such as abuse or assault, and a woman may marry someone carrying HPV. Therefore, it is possible that even someone practicing abstinence and fidelity may benefit from HPV vaccines.

## **Cervical cancer and HPV**

Q: How many women are affected by cervical cancer?

A: Worldwide, cervical cancer is a significant cause of death in women. Currently, an estimated 500,000 cases of cervical cancer are diagnosed annually, and 230,000 deaths are attributed to cervical cancer. The disease burden is greatest in developing countries.<sup>12</sup>

The American Cancer Society estimated that in the U.S. in 2006, over 9,710 women will be diagnosed with cervical cancer and 3,700 will die from this disease.<sup>13</sup>

Q: What has been the principal method of preventing cervical cancer until now?

A: Screening via regular Pap tests has been vitally important for the detection and initiation of treatment for precancerous cervical lesions which are precursors to cervical cancer.

## **Gardasil**

Q: What is Gardasil?

A: Gardasil is a vaccine that protects against infection with four HPV types which are responsible for 70% of cervical cancers (types 16 and 18), and 90% of genital warts (types 6 and 11). The vaccine can only protect against infection by each of these four HPV types if a person has never been exposed to the HPV type before.<sup>14</sup>

Q: Will Gardasil fully protect a woman from ever developing cervical cancer?

A: No, Gardasil will not protect against other strains of HPV. Thirty percent of cervical cancers are due to infection with HPV types not included in the vaccine. For this reason, vaccination with Gardasil will not eliminate the need for regular Pap test screening.

Q: What else does Gardasil not protect against?

A: In addition to not protecting against other HPV types responsible for 30 percent of cervical cancer cases, the vaccine does not prevent about 10 percent of genital

warts.<sup>15</sup> Gardasil does not protect against other sexually transmitted diseases, including Human Immunodeficiency Virus or HIV, which causes AIDS.

Q: How is Gardasil given?

A: The vaccine is administered through a series of three injections over a six month period at 0, 2, and 6 months intervals.<sup>16</sup>

Q: When did Gardasil become available to the public?

A: On June 8, 2006, the Food and Drug Administration (FDA) licensed Gardasil as a vaccine to prevent cervical cancer and other diseases caused by genital HPV infection in women. On June 29 2006, the CDC's Advisory Committee on Immunization Practices (ACIP), recommended vaccine use in girls and women aged nine to 26, and recommended routine vaccination for 11 and 12 year old girls.<sup>17</sup>

Q: Does the Family Research Council oppose development and distribution of an HPV vaccine?

A: No, FRC believes that Gardasil and other HPV vaccines represent a tremendous advance in preventative medicine. FRC advocates for widespread availability and distribution of the vaccine to both girls and young women. Forms of primary prevention and medical advances in this area hold potential for helping to protect the health of millions of Americans and helping to preserve the lives of thousands of American women who currently die of cervical cancer each year as a result of HPV infection.

Q: Would vaccinating individuals against a sexually transmitted disease lead them to be more sexually active?

A: Not necessarily. If vaccination is handled properly, accompanied by medically accurate information and the right message, it could even have the opposite effect. Vaccination at the beginning of adolescence may provide a unique opportunity for both health care providers and parents to discuss with young people the full range of issues related to sexual health. FRC has recommended that policy-making bodies, such as the American Academy of Pediatrics, should develop and formalize clinical counseling interventions directed toward sexual risk avoidance (also known as abstinence) strategies for adolescents. Such strategies mirror the risk avoidance messages presented to adolescents regarding tobacco, alcohol, and drug usage, and youth violence prevention. The sexual risk avoidance/abstinence message is the best form of primary prevention youth can receive to prevent HPV infection, as well as the wide range of sexually transmitted diseases and associated physical, emotional, and social consequences. The adolescent sexual risk avoidance/abstinence strategy is also the best form of prevention to protect a female's future fertility.

## **Vaccine Efficacy and Safety**

Q: How well does Gardasil work in preventing infection with the four types of HPV?

A: To date in clinical trials, Gardasil has been shown to be close to 100 percent effective at protecting against infection with the four HPV types. Studies published by Merck and Co. yield results that protection against infection has been demonstrated for a period of five years.

It is not yet known how long vaccine-induced immunity or protection will last. Clinical trial study participants will continue to be followed and tested for HPV infection. With time it will be easier to determine if booster shots will be necessary.<sup>18</sup>

Q: How safe is Gardasil?

A: Gardasil has been tested in clinical trials of over 11,000 girls and women aged 16 to 26 years. Immune response studies have been conducted in girls and women aged nine to 26 years. Studies published by Merck and Co. to date have not shown the vaccine to cause significant serious adverse events in nonpregnant women when compared to a placebo.<sup>19 20</sup> Gardasil is not recommended for pregnant women.<sup>21</sup> Further trials need to be conducted to properly assess the safety of Gardasil in pregnant women and unborn infants. If a woman or adolescent has begun the vaccine series and learns that she is pregnant, she should not continue with further injections during pregnancy.

At time of injection, Gardasil can cause pain, swelling, itching, and redness at injection site, fever, nausea, and dizziness.<sup>22</sup>

## **Vaccination Costs and coverage**

Q: How much will the three injection vaccine series cost?

A: The private-sector cost of each injection is \$120, or \$360 for the series of three shots. Total costs for administration of vaccine doses may be higher.<sup>23</sup>

Q: What types of insurance will provide coverage for the vaccine?

A: Private insurers who generally follow ACIP guidelines are likely to cover the vaccine. The federally financed Vaccines for Children (VFC) program covers all ACIP recommended vaccinations for children 18 and under who are either on Medicaid, Medicaid-eligible, uninsured or underinsured or American Indian and Alaskan Native. State Children's Health Insurance Programs (SCHIP) vary in coverage dependent upon whether they are separately standing from State Medicaid programs.<sup>24</sup>

## **The issue of compulsory HPV vaccination for school entry**

Q: Why are some immunizations made mandatory for school entrance?

A: School-based immunization laws have been instituted since the 19<sup>th</sup> century to prevent the spread of highly communicable diseases such as smallpox and measles. Mandatory vaccination has been an effective way to prevent widespread infection in the school setting where disease exposure is increased and transmission is intensified due to large numbers of children gathered together for long periods of time.

Q: Does the federal government mandate vaccines for school attendance, or recommend that they be mandatory?

A: No. The Centers for Disease Control has recommended that vaccination for HPV be part of the routine standard of medical care, but takes no position on the issue of making it mandatory for school attendance. School vaccination mandates are adopted by state governments, not the federal government, and may vary from state to state.

Q: Is HPV the same as other diseases subject to school vaccination mandates?

A: No, unlike other communicable diseases such as measles, HPV is not spread through casual contact. Genital HPV is a sexually transmitted disease. A child cannot catch HPV from a classmate by sitting at the same table or drinking from the water fountain.

Q: Does FRC support mandatory HPV vaccination?

A: No. We feel that a mandate infringes on the right of parents to make decisions regarding their children's medical care. Since genital HPV is not spread by casual contact, but rather is a sexually transmitted infection, there is not sufficient public health justification to require vaccination for school attendance. It may also lead them to believe that the vaccine is the only available way to reduce the risk of cervical cancer, which is untrue.

Q: Is an opt-out policy enough to protect parental rights?

A: No, an opt-out policy would likely mislead parents to believe immunization with Gardasil is necessary to protect their child's health while in the school setting. Parents could feel pressured into going with the majority and not opting-out. In this sense the opt-out policy would be coercive and violate parent's rights to be the primary decision-maker regarding their children's health.

Q: Would FRC support a policy whereby schools promote the vaccine on an "opt-in" basis?

A: Yes, in contrast to opt-out policy, opt-in policies allow parents to make the decision concerning their child's level of risk and whether or not to vaccinate. Parents may freely consult and receive professional advice from a health care provider and then make an informed decision. Health care providers can assist

parents with an individualized risk assessment for a child, discuss possible risks of side effects from the vaccine with any pre-existing conditions, and help to facilitate discussion about the health risks associated with adolescent sexual activity. Additionally, an opt-in policy would allow parents to decide at what age their child should be vaccinated, and what age to discuss sexuality and sexual health with each child.

Some parents who conclude that their daughter is at low risk for contracting HPV may decide to allow her to make the decision for herself at age 18.

Q: What do medical experts and the public health community advise regarding mandates?

A: While the concern has not been unanimous, a large part of the medical community has either directly opposed or urged caution towards mandatory vaccination at this point in time. The vaccine community in general has not advocated for mandatory immunization. The following medical professionals and organizations have voiced opposition to HPV vaccination mandates: the Texas Medical Association; the Association of American Physicians and Surgeons; Dr Richard Zimmerman, M.D., former CDC ACIP member; Dr. Louis Cooper, M.D. past president of the American Academy of Pediatrics; and Dr. Keertie Shah, a virologist at John Hopkins Bloomberg School of Public Health who has conducted important research linking HPV infection to cervical cancer.

*Moira Gaul is director of women's and reproductive health in the Center for Human Life and Bioethics at the Family Research Council.*

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<sup>1</sup> National Cancer Institute, Dictionary of Cancer Terms. U.S. National Institutes of Health. [www.cancer.gov](http://www.cancer.gov) (February 6, 2007).

<sup>2</sup> National Cancer Institute Fact Sheet, Human Papillomaviruses and Cancer: Questions and Answers. p.1. U.S. National Institutes of Health, [www.cancer.gov](http://www.cancer.gov) (February 6, 2007).

<sup>3</sup> Human Papillomavirus: HPV Information for Clinicians, Centers for Disease Control and Prevention (November 2006): p. 1.

<sup>4</sup> Ibid, pp. 7,9

<sup>5</sup> Ibid, pp. 1,2

<sup>6</sup> Ibid, p. 3.

<sup>7</sup> Ibid, p. 5.

<sup>8</sup> National Cancer Institute Fact Sheet, Human Papillomaviruses and Cancer: Questions and Answers, p. 3. U.S. National Institutes of Health: [www.cancer.gov](http://www.cancer.gov) (February 6, 2007).

<sup>9</sup> Human Papillomavirus: HPV Information for Clinicians, Centers for Disease Control and Prevention. (November 2006): p. 5.

<sup>10</sup> Ibid, p. 3.

<sup>11</sup> Report to Congress 2004: Prevention of Genital Human Papillomavirus Infection, Centers for Disease Control and Prevention, Gerberding, J.L., M.D., M.P.H. (January 2004): pp. 3-4.

<sup>12</sup> Pan American Health Organization, World Health Organization. Press Release: Cervical Cancer is a Potential Epidemic, Yet Preventable Killer (December 20, 2004).

<sup>13</sup> National Cancer Society, *Cancer Facts and Figures*. Atlanta: American Cancer Society; 2006.

<sup>14</sup> Human Papillomavirus: HPV Information for Clinicians, Centers for Disease

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Control and Prevention, (November 2006): p. 9.

<sup>15</sup> Ibid.

<sup>16</sup> Ibid.

<sup>17</sup> Ibid.

<sup>18</sup> Ibid, p. 10

<sup>19</sup> Ibid.

<sup>20</sup> VRBPAC Background Document, Gardasil HPV Quadrivalent Vaccine, (May 18, 2006). VRBPAC Meeting. Merck and Co.

<sup>21</sup> Genital Warts and HPV Information at [www.gardasil.com](http://www.gardasil.com). Know the Link: Genital Warts and HPV. Important Information about Gardasil, (February 2, 2007)

<sup>22</sup> Ibid.

<sup>23</sup> Human Papillomavirus: HPV Information for Clinicians, Centers for Disease Control and Prevention, (November 2006): p. 10

<sup>24</sup> Fact Sheets: Women's Health Policy Facts. HPV Vaccine: Implementation and Financing Policy. The Henry J. Kaiser Family Foundation, (January 2007).