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# Gardasil: What Every Parent Should Know about the New HPV Vaccine





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to make a difference in their families, in their communities, and in their culture.

Recent history has clearly shown the influence that the "Values Voter" can have in the political process. FRC is committed to enabling and motivating individuals to bring about even more positive change in our nation and around the world. I invite you to use this pamphlet as a resource for educating yourself and others about some of the most pressing issues of our day.

FRC has a wide range of papers and publications. To learn more about other FRC publications and to find out more about our work, visit our website at www.frc.org or call I-800-225-4008. I look forward to working with you as we bring about a society that respects life and protects marriage.

President Family Research Council

THE HPV VACCINE: WHAT EVERY PARENT SHOULD KNOW BY MOIRA GAUL, M.P.H. SUGGESTED DONATION: \$1.50 © 2007 FAMILY RESEARCH COUNCIL ALL RIGHTS RESERVED. PRINTED IN THE UNITED STATES

## Gardasil: What Every Parent Should Know about the New HPV Vaccine by MOIRA GAUL, M.P.H.

## Q: What is HPV?

- A: HPV, or human papillomavirus, is a virus that can cause abnormal tissue growth in and on the human body. Over 30 HPV types are sexually transmitted. Some forms of HPV are more dangerous than others. While some types can lead to warts, others can cause cancer in certain body tissues.<sup>1</sup>.<sup>2</sup>
- Q: How is HPV infection associated with cervical cancer?
- A: Sexually transmitted HPV is the leading cause of cervical cancer, shown to be present in virtually all cases. High-risk HPV types 16 and 18 cause 70 percent of cervical cancer cases.<sup>3</sup>

#### Q: How many people have genital HPV?

A: According to the Centers for Disease Control and Prevention (CDC), about 20 million Americans are currently infected with genital HPV, and approximately 6.2 million Americans become infected every year. Virtually all of those infected with genital HPV have been sexually active; an estimated half, or 10 million, are adolescents and young people aged 15 to 24 years.<sup>4</sup> Younger women (under 25) are more vulnerable to infection,

MOIRA GAUL, M.P.H. is Director of Women's and Reproductive Health at the Family Research Council. Moira Gaul presented testimony to the Centers for Disease Control and Prevention Advisory Committee on Immunization Practices. She works on public policy concerning women's and children's health issues, including abstinence. and the more sexual partners a person has, the more likely he or she is to be infected with genital HPV.<sup>5</sup>



- Q: What is the best way to protect against genital HPV infection?
- A: According to the CDC, limiting sexual activity to the context of a "monogamous relationship" with an uninfected individual is the surest way of preventing future HPV infection.<sup>6</sup> Therefore, practicing sexual abstinence until marriage and fidelity within marriage are the best ways to avoid genital HPV infection.

However, in some cases HPV infection may result from involuntary sexual activity, such as abuse or assault, and/or if a woman marries someone who is carrying HPV. Therefore it is possible that even someone practicing abstinence and fidelity could benefit from vaccines designed to prevent HPV infection.

#### Q: What does Gardasil, an HPV vaccine, prevent? How much does it cost?

A: Gardasil has been shown to virtually prevent infection with two HPV strains, numbers 16 and 18, which cause 70 percent of cervical cancer cases and two HPV strains, 6 and 11, which cause 90 percent of genital warts.<sup>7</sup>

The vaccine is administered through a series of three injections over a six-month period at intervals of 0, 2, and 6 months. Compared to other vaccines, Gardasil is very expensive. The cost of each injection begins at \$120, or \$360 for the series of three shots, but total costs for administration may be much higher. Some private insurers and various public insurance programs, such as the Vaccines for Children Program and State Medicaid programs, will help to cover vaccine costs for eligible families.<sup>8</sup>

- Q: What else should I know about vaccination with Gardasil?
- A: Gardasil does not protect against other strains of HPV responsible for 30 percent of cervical cancers. For this reason, Gardasil will not eliminate the need for regular Pap test screening.<sup>9</sup> The vaccine does not protect



against any other sexually transmitted diseases, including Human Immunodeficiency Virus, or HIV, which causes AIDS.

### Q: Is Gardasil safe for my child?

A: Gardasil has been tested in clinical trials on over 11,000 girls and women aged 16 to 26 years. In addition, studies have been conducted in girls and women aged nine to 26 years to test for vaccine safety and to measure immune response. Studies to date have not shown the vaccine to cause significant serious adverse events in non-pregnant women when compared to a placebo.<sup>10,11</sup> (Gardasil is not recommended for pregnant women, and further studies must be conducted to accurately assess vaccine safety for pregnant moms and unborn babies).<sup>12</sup>

Side effects that have occurred are related to problems which take place when the vaccine is administered. These include fever, nausea, dizziness, and pain, as well as swelling, itching, and redness at the injection site.<sup>13</sup>

To date, Gardasil has been shown in clinical trials to be nearly 100 percent effective at protecting against infection with the four HPV types (6, 11, 16, and 18) for a period of five years. It is not yet known how long vaccine-induced immunity or protection will last. With time it will be easier to determine if booster shots will be necessary.<sup>14</sup>

- Q: What are some reasons why parents might choose to have their child/daughter vaccinated with Gardasil, or another HPV vaccine, if they are taught to practice abstinence-untilmarriage?
- A: Genital HPV infections are currently very prevalent in sexually active men, women, and

adolescents as indicated above. Studies examining immune system response to the vaccine have shown higher levels of immunity produced during adolescence than at older ages. Gardasil can only produce a protective immune response in a person who has not already been infected with the four genital HPV strains covered by the vaccine.

If choosing to have their child vaccinated, parents should request that providers present a clear, accurate, and unwavering message to their adolescent about the multitude of health benefits of abstaining from sexual behavior. Parents can also request that pro-



viders conduct 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 many health risks and consequences associated with adolescent sexual activity.

In this sense, vaccination during adolescence could provide a unique opportunity to reinforce a risk avoidance or abstinence message as the best form of prevention against HPV infection, as well as the many other negative outcomes associated with adolescent sexual activity.

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

#### Q: Should boys be vaccinated with Gardasil?

A: While previous studies have included testing young boys' immune response to Gardasil, clinical trials studying the effects in boys and men are not yet completed. Consequently the vaccine has not been licensed for use in boys and men by the Food and Drug Administration.

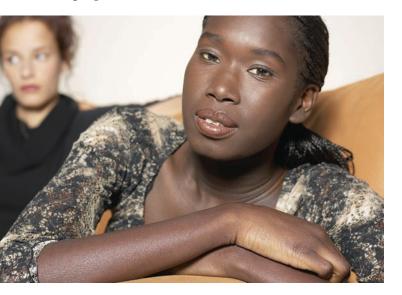


Vaccinating boys and men could directly provide benefit as it should protect against infection with HPV types 6 and 11 which are responsible for causing over 90 percent of genital warts. It should also indirectly benefit women as men are carriers for HPV types 16 and 18, as well as types 6 and 11.



- Q: What do medical experts recommend regarding vaccination and state-mandated vaccination as a condition for school attendance?
- A: The Centers for Disease Control and Prevention's expert body on immunization, the Advisory Committee on Immunization Practices (ACIP), has recommended routine vaccination of 11- and 12-year-old girls. This recommendation is based upon the medical fact that vaccination must precede infection with HPV strains 6, 11, 16, and 18, in order to confer immunity, and upon national statistics that a large number of American youth become sexually active by age 15. Engaging in sexual activity places adolescents at high risk for acquiring HPV infection.

A large part of the medical community has either directly opposed or urged caution towards mandatory vaccination for a number of reasons. Current clinical trial data only exists for five years of results, meaning that longerterm immunity from the vaccine has not been demonstrated yet. The vaccine doesn't fulfill general criteria for compulsory vaccination as a condition for school attendance, in that the virus is *not* spread through casual contact that places children in the school setting at higher risk for "catching" the virus. Finally, the high cost of the vaccine may make it unaffordable for families who do not qualify for coverage through public or private insurance programs.



- 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, there is insufficient public health justification to require vaccination for school attendance. A mandate may also lead parents to believe that the vaccine is the only available way to reduce the risk of cervical cancer and HPV infection, 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 the right of parents to be the pivotal decision maker regarding their children's health.
- Q: Where can I go to obtain further medical information and advice about vaccination with Gardasil or HPV vaccines?
- A: The following organizations are recommended for resources concerning HPV and HPV vaccines:
  - Family Research Council, www.frc.org
  - American College of Pediatricians, www.acpeds.org
  - Focus on the Family, www.family.org
  - Medical Institute for Sexual Health, www.medinstitute.org.

#### FOOTNOTES

- 1 National Cancer Instutute, Dictionary of Cancer Terms. U.S. National Institutes of Health. ww.cancer.gov (February 6, 2007).
- 3 Human Papillomavirus: HPV Information for Clinicians, Centers for Disease Control and Prevention (November 2006): p. 7, 9.
- 4 Ibid, p. 1, 2.
- 5 Ibid, p. 3.
- 6 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.
- 7 Human Papillomavirus: HPV Information for Clinicians, Centers for Disease Control and Prevention (November 2006): p. 9.
- 8 Fact Sheets: Women's Health Policy Facts. HPV Vaccine: Implementation and Financing Policy. The Henry J. Kaiser Family Foundation (January 2007).
- 9 Human Papillomavirus: HPV Information for Clinicians, Centers for Disease Control and Prevention (November 2006): p. 9.
- 10 Ibid, p. 10.
- 11 VRBPAC Background Document, Gardasil HPV Quadrivalent Vaccine (May 18, 2006). VRBPAC Meeting. Merck and Co.
- 12 Genital Warts and HPV Information at www. gardasil.com. Know the Link: Genital Warts and HPV. Important Information about Gardasil (February 2, 2007).
- 13 Ibid.
- 14 Human Papillomavirus: HPV Information for Clinicians, Centers for Disease Control and Prevention (November 2006): p. 10.

## ADDITIONAL RESOURCES FROM

## FAMILY RESEARCH COUNCIL



#### Politicized Science: The Manipulated Approval of RU-486 and Its Dangers to Women's Health BC07A01

RU-486's ability to bring an end to a human life developing in the womb is known to all, but the drug's considerable harmful effects on women's health have been minimized or ignored completely. Several organizations, including the Family Research Council, have unearthed a vast amount of information regarding safety concerns about the drug, as well as evidence documenting

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# Homosexuality in Your Child's School **BC06D02**

This pamphlet describes how pro-homosexual activists work their way up from seemingly innocent-sounding "safe schools" programs (which treat traditional values as being equivalent to racism), to one-sided "training" of teachers and students, to injecting homosexuality into every subject in the curriculum. Their final step is the active punishment of those who dare to express disapproval of homosexual behavior.

This pamphlet will equip you to oppose this promotion of homosexuality in your child's school.



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