



## HPV Vaccine Factsheet

Human papillomavirus (HPV) is a common virus that spreads easily through sexual contact. It is estimated that nearly half of all men and more than three out of four women have HPV at some point in their lives. Most, but not all, HPV infections go away within 8 to 13 months. HPV can remain in the body for years without being detected because it generally has no symptoms, making it difficult to determine how long a person has been infected or who passed the infection to them. Therefore, most people do not know they are carrying the virus and can unknowingly spread it.<sup>1</sup> There are about 40 different strains of genital HPV, which can cause genital warts and a variety of cancers in both sexes, including cervical cancer in women and anal or penile cancer in men.<sup>2</sup>

### *HPV Vaccine Facts at a Glance*

- There are two HPV vaccines currently available in the United States:
  - **Gardasil®:**
    - In 2006, the Food and Drug Administration (FDA) approved Merck's HPV vaccine, Gardasil, for use by girls and women ages 9–26.
    - In 2009, the FDA approved Gardasil for use by boys and men ages 9–26.
  - **Cervarix®:**
    - In 2009, the FDA approved GlaxoSmithKline's HPV vaccine, Cervarix, for use by girls and women ages 10–25.<sup>3</sup>
- Centers for Disease Control and Prevention (CDC) reports 37.2% of girls age 13-17 have started the three-shot HPV vaccination series.<sup>4</sup>
- At least 19 states have enacted legislation to require, fund, or educate the public about HPV vaccines.<sup>5</sup>
- The U.S. Citizenship and Immigration Services removed HPV vaccines from the list of mandatory vaccinations for immigrants in December 2009.<sup>6</sup>

### *Question and Answer on HPV Vaccines*

#### **Why do we need HPV vaccines?**

- HPV vaccines can prevent the most common types of HPV that cause a variety of cancers and genital warts in women and men. Both Gardasil and Cervarix target the most common cancer-causing HPV strains, 16 and 18. Gardasil also protects against strains 6 and 11, linked to genital warts.<sup>7</sup> A study in the *Lancet* found that Cervarix also protects against the next three most cancer-causing strains: 31, 33, and 45.<sup>8</sup> Gardasil and Cervarix do not protect against all HPV cancer-causing strains and routine Pap screenings are still necessary to protect against cervical cancer.
- The American Cancer Society estimates 12,200 new cases of cervical cancer in women and 5,260 new cases of anal cancer in women and men for 2011 in the U.S.<sup>9</sup> Cervical cancer occurs most often in Hispanic women, at a rate that is more than double the rate for non-

Hispanic white women. African-American women develop cervical cancer about 50% more often than non-Hispanic white women.<sup>10</sup> Further, about 1% of sexually active adults in the U.S. have genital warts at any given time.<sup>11</sup>

### **What are the key facts about HPV vaccines?**

- **Effectiveness:**
  - Gardasil has shown 100% effectiveness after the third vaccination in females, and proven immunization for up to 5 years.<sup>12</sup> Cervarix has shown 100% effectiveness and proven immunization for up to 4.5 years.<sup>13</sup> Although there is strong evidence that the vaccines will provide long-lasting protection, studies are being conducted to determine if a booster shot will be necessary. As of now, the FDA does not recommend a booster shot. In addition, because Cervarix and Gardasil are “prophylactic” (or preventative) vaccines they protect against contraction of HPV, but do not eliminate an existing infection (like cancer or warts).<sup>14</sup>
- **Safety:**
  - Both Gardasil and Cervarix have low-risk profiles. They consist of papillomavirus-like particles—empty shells of viral structural proteins from brewer’s yeast that cannot transmit the virus. The FDA and CDC remind immunization providers to watch individuals for up to 15 minutes after vaccination to avoid potential injury from fall.
- **Cost and Coverage:**
  - Gardasil and Cervarix must be administered in three separate visits within a period of six months (0, 1 or 2, and 6 months). Each dose costs about \$125, so the three-shot series costs about \$375, not including the price of a doctor’s visit.<sup>15</sup>
  - Most, but not all, health insurance plans cover Cervarix and Gardasil. Check with your insurance provider for more information.
  - Parents without health insurance can get their children vaccinated through the Vaccines for Children (VFC) program. VFC provides free vaccinations to doctors who serve eligible children. Eligible children include: Medicaid-eligible children under 19 years, American Indian, Alaska Native children, or child lacking health insurance. Children who have health insurance that does not cover these vaccines can receive VFC vaccines through Federally Qualified Health Centers or Rural Health Centers. Learn more about VFC here: [www.cdc.gov/vaccines/programs/vfc](http://www.cdc.gov/vaccines/programs/vfc).<sup>16</sup>
  - The World Health Organization has approved both Gardasil and Cervarix for use in its Prequalification Programme, which allows various United Nations agencies and partners, like the United Nations Children’s Fund (UNICEF) and the Joint United Nations Programme on HIV/AIDS (UNAID), to purchase and distribute large amounts of quality medicines and vaccines cheaply to needy populations.<sup>17</sup>
- **Acceptability:**
  - There is high acceptance among parents and providers for routine adolescent vaccination, and even higher acceptance for older adolescents. Acceptance rates increase with education about the vaccines’ safety, efficacy, and appropriateness.<sup>18</sup>

### **Who should and should not get HPV vaccines?**

- According to the CDC, females ages 9–26 should use either Gardasil or Cervarix, while boys and young men are recommended to use Gardasil. Women and men who have begun

sexual activity before getting all three doses can still benefit from the vaccine if they have not already been infected with the HPV types included in the vaccination they received.<sup>19</sup>

- The CDC does not recommend Gardasil for women and women older than 26 as studies have not shown that it would be equally safe and effective for these ages. However, there is evidence that vaccination helps prevent HPV in women ages 25–45.<sup>20</sup>
- Pregnant women are advised *not* to get vaccinated until post-pregnancy.

#### When should one get vaccinated for HPV?

- HPV vaccines are most effective if all three shots are administered before exposure to the virus via sexual activity. For this reason, doctors recommend both girls and boys get vaccinated during health check-ups in their preteen years.
- Either Gardasil or Cervarix can be given to girls ages 11 or older, while only Gardasil can be given to preteen boys. To ensure complete inoculation, it is important to follow the first dose with two more doses.<sup>21</sup>

#### What are the side effects associated with HPV vaccines?

- HPV vaccines are safe and effective. They cause no serious side effects. Common, mild side effects may include: pain, redness, and swelling at the injection site; abdominal, muscle, or joint pain; fever; headache; fatigue; fainting; nausea; vomiting; and diarrhea.<sup>22, 23</sup>

#### How are Gardasil and Cervarix similar and different?

Similarities <sup>24, 25</sup>	Differences
<ul style="list-style-type: none"> <li>• Safe</li> </ul>	<ul style="list-style-type: none"> <li>• Only Gardasil protects against HPV 6 and 11, which cause most genital warts and can lead to recurrent respiratory papillomatosis (RRP)—a rare condition that causes throat warts</li> </ul>
<ul style="list-style-type: none"> <li>• Administered as shots and require three doses (no studies show whether fewer doses are equally effective)</li> </ul>	<ul style="list-style-type: none"> <li>• Studies show that only Gardasil prevents vaginal and vulvar cancers caused by HPV 16 and 18; there are no such studies on Cervarix</li> </ul>
<ul style="list-style-type: none"> <li>• Prevent cervical cancer and precancer in women as they are very effective against HPV 16 and 18, which together cause about 70% of cervical cancers</li> </ul>	<ul style="list-style-type: none"> <li>• Composed of different adjuvants, i.e., substances added to vaccines to increase the body’s immune response</li> </ul>

<sup>1</sup> “Human Papillomavirus.” Planned Parenthood. Retrieved on March 25, 2011 from <http://www.plannedparenthood.org/health-topics/stds-hiv-safer-sex/hpv-4272.htm>.

<sup>2</sup> “Vaccines and Preventable Diseases: HPV Vaccination,” Centers for Disease Control and Prevention. Retrieved February 14, 2011 from <http://www.cdc.gov/vaccines/vpd-vac/hpv/#recs>.

<sup>3</sup> “Should Your Child Get the HPV Vaccine?” WebMD. Retrieved March 8, 2011 from <http://children.webmd.com/vaccines/features/should-your-child-get-hpv-vaccine>.

<sup>4</sup> Centers for Disease Control and Prevention (CDC), National, state, and local area vaccination coverage among adolescents aged 13–17 years—U.S., 2008, *MMWR Morb Mortal Wkly Rep* **58** (36) (2009), pp. 997–1001.

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- <sup>5</sup> “HPV Vaccine,” National Conference of State Legislatures. Retrieved March 9, 2011 from <http://www.ncsl.org/IssuesResearch/Health/HPVVaccineStateLegislation/tabid/14381/Default.aspx>.
- <sup>6</sup> “CIS Issues Update on Immigrant Vaccination Requirements,” Willmoth Immigration Law, LLC. Retrieved March 8, 2011 from <http://www.willmothlaw.com/blog/31-vaccination-requirements.html>.
- <sup>7</sup> According to research conducted by Gynecologic Cancer Prevention Research Group at Dartmouth Medical School, Cervarix has shown protection against strains 35 and 41 as well which together make up 10% of the cause of cervical cancer (GSK Release, April 6, 2006).
- <sup>8</sup> “Efficacy of human papillomavirus (HPV)-16/18 AS04-adjuvanted vaccine against cervical infection and precancer caused by oncogenic HPA types (PATRICIA): final analysis of double-blind, randomized study in young women.” The Lancet Website. Retrieved July 14, 2009. from [http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(09\)61248-4/fulltext#article\\_upsell](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(09)61248-4/fulltext#article_upsell).
- <sup>9</sup> “Estimated New Cancer Cases and Death by Sex for All Sites.” American Cancer Society. Retrieved March 10, 2011 from <http://www.cancer.org/acs/groups/content/@epidemiologysurveillance/documents/document/acspc-026210.pdf>
- <sup>10</sup> “What are key statistics about cervical cancer.” American Cancer Society. Retrieved March 25, 2011 from <http://www.cancer.org/cancer/cervicalcancer/detailedguide/cervical-cancer-key-statistics>
- <sup>11</sup> Sexually Transmitted Diseases. “Genital HPV Infection.” Retrieved March 10, 2011 at <http://www.cdc.gov/std/hpv/stdfact-hpv.htm>.
- <sup>12</sup> “Efficacy of human papillomavirus (HPV).”
- <sup>13</sup> GlaxoSmithKline Release. April 6, 2006.
- <sup>14</sup> “Vaccines and Preventable Diseases: HPV Vaccine – Questions & Answers,” Centers for Disease Control and Prevention. Retrieved February 14, 2011 from <http://www.cdc.gov/vaccines/vpd-vac/hpv/vac-faqs.htm>.
- <sup>15</sup> “HPV Vaccine,” Planned Parenthood. Retrieved March 9, 2011 from <http://www.plannedparenthood.org/health-topics/stds-hiv-safer-sex/hpv-vaccine-19345.htm>.
- <sup>16</sup> “Vaccines and Preventable Diseases: HPV Vaccine – Questions & Answers.”
- <sup>17</sup> “Prequalification Programme.” The World Health Organization Website. Retrieved July 14, 2009 from <http://apps.who.int/prequal>.
- <sup>18</sup> Liddon, Nicole, CDC. “The Future of Cervical Health for Underserved Populations.” Congressional Black Caucus, Washington, DC. March 16, 2006.
- <sup>19</sup> “Vaccines and Preventable Diseases: HPV Vaccine – Questions & Answers.”
- <sup>20</sup> “Preliminary HPV Results for Women Older Than 25.” The Lancet Website. Retrieved July 23, 2009 from [http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(09\)61045-X/fulltext](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(09)61045-X/fulltext).
- <sup>21</sup> “Vaccines and Preventable Diseases: HPV Vaccine – Questions & Answers.”
- <sup>22</sup> “HPV (Human Papillomavirus) Vaccine Gardasil®: What You Need to Know,” Centers for Disease Control and Prevention. Retrieved February 14, 2011 from <http://www.cdc.gov/vaccines/pubs/vis/downloads/vis-hpv-gardasil.pdf>.
- <sup>23</sup> “HPV (Human Papillomavirus) Vaccine Cervarix®: What You Need to Know,” Centers for Disease Control and Prevention. Retrieved February 14, 2011 from <http://www.cdc.gov/vaccines/pubs/vis/downloads/vis-hpv-cervarix.pdf>.
- <sup>24</sup> “Vaccines and Preventable Diseases: HPV Vaccine – Questions & Answers.”
- <sup>25</sup> “Human Papillomaviruses and Cancer,” National Cancer Institute. Retrieved March 8, 2011 from <http://www.cancer.gov/cancertopics/factsheet/Risk/HPV>.