

# FACT SHEET ON HUMAN PAPILOMAVIRUS - HPV

**What is HPV?** Human Papillomavirus is a virus affecting both men and women. Over 100 “strains” (types) of HPV have been identified. More than 30 strains are sexually-transmitted infections (STIs) which together make HPV the most prevalent STI in the United States. The Centers for Disease Control and Prevention (CDC) reports that 20 million Americans currently are infected with sexually transmitted HPV, and 6.2 million new infections occur annually. The *Journal of the American Medical Assn.* (2/27/07) reports current HPV infections in *women 14-59 years of age* are almost 25 million. The CDC estimates that 50% of sexually active men and women acquire a sexually transmitted HPV infection in their lifetimes. As used herein, “HPV” refers only to strains that are transmitted sexually.

Most HPV infections present no symptoms and are transient (i.e., eliminated by one’s immune system). About 70% of women are clear of the infection within one year; 91% are clear within two years. Only about 10% of women with HPV develop persistent infections.

**What is the link between HPV and cervical cancer?** Fourteen strains of HPV are classified as “high risk” for being associated with invasive cancers of the cervix and other sites. HPV 16 and HPV 18 are found in about 70% of cervical cancers. The remaining 12 high risk strains together are associated with 30% of cervical cancers. In addition, 11 common strains of HPV may cause benign or “low-grade” cervical cell changes, although rarely invasive cancers. Two of these strains, most commonly found in genital warts, are HPV 6 and HPV 11. The *JAMA* study (above) reports that only 2.3% of women aged 14-59 are infected with one of the two cancer-related HPV strains targeted by Gardasil, and only 1.4% of women are infected with one of the two genital warts-related HPV strains protected by Gardasil. Cervical cancer develops very slowly, with a typical incubation period of 10 to 15 years during which time routine exams – the traditional “Pap” test, the newer, more precise liquid-based Pap test, and the HPV DNA test – can identify pre-cancerous cell changes and lesions. These tests and subsequent treatments are credited with a 74% drop in U.S. deaths from cervical cancer since 1955. The National Institutes of Health (NIH) estimates that half the diagnoses of cervical cancer are among women who have never been screened and an additional 10% are among women who have not been screened in the previous five years. Lack of screening is the single most important risk factor associated with cervical cancer. Other risk factors are: suppressed immune system, cigarette smoking, long-term use of oral contraceptives, and co-infections such as Chlamydia.

**What is Gardasil?** Merck’s Gardasil vaccine has been shown to prevent four HPV strains: 16 and 18, associated with 70% of cervical cancers, and 6

and 11, associated with 90% of cases of genital warts. The vaccine is given in three doses at 0, 2 and 6 months, at a base cost of \$120 per dose. Additional fees for office visits and staff time could increase the total patient cost to \$540 or more.

**What are some limitations of Gardasil?** Because Gardasil affords no known protection against other strains of HPV which are associated with 30% of cervical cancers, routine screening (Pap and HPV DNA tests) will still be necessary. Research has shown that condoms afford only limited protection against HPV.

### **Some concerns that have been raised related to mandatory immunization.**

Dr. Jon Abramson, chairman of the CDC advisory committee on immunization practices (ACIP) that recommended Gardasil, told reporters he opposes mandatory Gardasil vaccination of preteen girls because a child in school is not at an increased risk for HPV like she is measles. He was also concerned that state funds may be inadequate to cover mandatory vaccination. ACIP's executive secretary, Dr. Larry K. Pickering, also opposes mandates because more data on its safety, efficacy and cost are needed. Even with an opt-out policy in state laws mandating Gardasil vaccination of all girls entering 6<sup>th</sup> grade, for example, many have argued that parental rights to make medical decisions for their children would be infringed, as parents may feel pressured by the law or by their family doctor to consent. And with many questions left unanswered by Merck's limited clinical trials, it is difficult for parents to make an informed decision about inoculating their daughters with Gardasil. Some of these questions follow.

- Clinical trials followed subjects' health for a *maximum of four years*, but typically for only 1-3 years. Because the vaccine has not been studied more than 5 years, it is not yet known if booster shots will be needed every 5 or 10 years to maintain effectiveness. (If a girl is vaccinated at age 12, she will need a booster around the age of 16 and again in her early 20s.)
- Many have questioned the value of inoculating girls with Gardasil while not inoculating boys who can also carry and transmit the same HPV strains associated with cervical cancer in women.
- Limited research was done with Gardasil in the population of girls (ages 9-15) targeted for mandatory vaccination. The vaccine was given to fewer than 600 girls in this age group, and they were studied for only 18 months. Merck was able to measure only

an immune response to HPV, but not whether the vaccine did or could prevent lesions, genital warts, or cervical cancer.

- It is not known if Gardasil can cause fetal harm when given to a pregnant woman or if it affects reproductive capacity. In pregnancies that began within 30 days of a Gardasil vaccination, however, 5 cases of congenital anomaly were seen in the group that received Gardasil, while none were seen in the placebo group.

- The full extent of adverse side effects is unknown, but the incidence of arthritis (including juvenile arthritis and lupus) was three times greater among those vaccinated with Gardasil than among those receiving a placebo, according to Gardasil's package insert. In addition, the Vaccine Adverse Event Reporting Systems (VAERS) is a passive surveillance system which relies on voluntary reporting. It has been estimated that fewer than 10%, and possibly as low as 1-4%, of adverse events which occur during use of prescription drugs or vaccines are reported to the adverse events surveillance systems.

- There were several VAERS reports of HPV infection, genital warts and cervical lesions AFTER Gardasil vaccination. It is not reported if the girls were infected before their Gardasil injections or if Gardasil failed to protect them. One case, however, occurred in a 22-year-old woman who participated in a Merck trial in 2003, then showing "strong conversion to all 4 vaccine types." But according to a VAERS report, she tested positive for high risk HPV in 2006.

- FDA staff stated that clinical trial data from Merck indicated there may be "the potential for GARDASIL to enhance cervical disease in subjects who had evidence of persistent infection with vaccine-relevant HPV types prior to vaccination." Yet testing for HPV infection is not being done prior to vaccinating girls and women with Gardasil. All girls and women will continue to need cervical cancer screening, including those who've been vaccinated with Gardasil, once they become sexually active. Because improved screening *alone* can virtually eliminate cervical cancer, some believe the additional protection afforded by Gardasil is negligible. In addition, it has been argued that treatments to eliminate pre-cancerous cells produced by HPV strains 16 and 18 (in the 2% of women who may develop them) entails far less cost

than Merck's solution of inoculating potentially 100% of girls in the United States, at a base cost of \$360 each. Finally, the limited protective effect of Gardasil may not last to the age where young women are likely to be exposed to HPV strains 16 and 18, making costly periodic booster vaccinations necessary.

### **What is the National Catholic Bioethics Center position on the HVP vaccine?**

To answer this question is to restate the Catholic Church's position that all sexual activity is a right and good reserved exclusively to married spouses. It is known that the rate of sexually transmitted disease increases the more sexual partners one has. Given that acquiring HPV is typically the result of sexual activity outside of the covenant of marriage (though not always as will be noted) it would appear that the best solution to the problem would be the recognition that sexual activity should be reserved for marriage, and that prior to marriage, abstinence is the only course that gives an absolute guarantee of no transmission, not only for the human papillomavirus but for every other sexually transmitted disease as well.

That being stated, it must be recognized that one who is chaste and enters into marriage may still contract HPV as a result of a spouse's prior sexual activity. Also, and tragically, there are women and girls who are sexually assaulted. These individuals do have the right to be protected.

Therefore, the National Catholic Bioethics Center (NCBC) notes that the Advisory Committee for Immunization Practices has recommended that young women be vaccinated against the human papilloma virus (HPV) as a protection against cervical cancer, which is caused by certain strains of this virus. HPV is spread through, but is not limited to, sexual contact. Consequently, the most effective way to avoid contracting it is to abstain from sexual relations before marriage and to remain faithful within marriage.

The NCBC considers the HPV vaccination to be a morally acceptable method of protecting against this disease, but asks that civil authorities leave this decision to parents and not make such immunization mandatory. It also states that if the problem of sexual promiscuity is approached by getting a series of shots and taking various pills, then we are not exercising self-control, but are using medicine to palliate our vices. The HPV vaccine does not address the cause of the problem, but masks it, actually undermining our efforts to find an effective solution.

This document is based on information from:

Journal of the American Medical Association – 2/28/07 297: 813-819

National Cancer Institute – [www.cancer.gov/cancertopics/factsheet/risk/HPV](http://www.cancer.gov/cancertopics/factsheet/risk/HPV)

National Catholic Bioethics Center – [www.ncbcenter.org](http://www.ncbcenter.org) (search under HPV)