

Position Statement of the American College of Pediatrics

Human Papilloma Virus Vaccination

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The American College of Pediatricians commends the researchers, prelicensure study participants, and vaccine manufacturers for bringing the Human Papilloma Virus (HPV) vaccine to fruition. Despite the monumental contribution of Dr. George N. Papanicolaou, who developed the “Pap” test in 1928 and published a description of its use in diagnosing uterine cancer in 1943, ***cervical cancer is still a major health problem for women. It is the 2nd most common cancer worldwide***, and the 11th most common cancer in American women. Despite a 70% reduction in deaths from cervical cancer with the routine use of Pap smears, in 2005 it still took the lives of 3710 women in the United States, and 290,000 worldwide. While the average age of death from malignancies in general is 72 years, the average age of women dying of cervical cancer is 57 years. The cost of cervical cancer screening and treatment has been calculated to be as high as 6 billion dollars per year in the United States alone.

Currently, an HPV vaccine is approved for children and adults ages 9-26. Despite encouraging results in prelicensure studies, ***research definitively establishing the duration of HPV vaccine protection, degree of protection and spectrum of side effects remain to be determined.***

As of 2006, HPV vaccines have been tested on 25,000 people in 33 countries. The Merck trials involved 20,541 women 16 to 26 years of age, and 1,121 girls between 9 and 15 years of age.^{1,2} [ref.] Vaccine recipients were given 3 doses over a 6 month period. About half of the 16 to 26 year olds in the Merck studies received that manufacturer’s HPV vaccine (Gardasil, which targets HPV types 6, 11, 16, and 18) and the other half was given placebo. Compared to those given placebo, study participants immunized with Gardasil had significantly fewer genital warts and Pap smear abnormalities. Vaccine recipients had 16.5% fewer definitive procedures for HPV cervical problems, including local electrosurgery, laser treatment, or “cold knife” local surgery, and 26.5% fewer excisions for external genital warts. The average length of follow up in the 4 studies conducted by Merck ranged from 2 to 4 years. Blood antibody levels against HPV in the vaccine group peaked at 7 months after immunization, declined through the 2nd year, and stabilized at 36 months, remaining at levels above pre-immunization. For the girls aged 9 to 15 years immunized with Gardasil, blood antibody levels showed a good response and “the efficacy of Gardasil in 9 to 15 year old girls is inferred.”³ The number of 9 year old girls vaccinated in all trials has been reported to be 250. Also, according to the Merck published report on Gardasil, the “duration of immunity following a complete schedule of immunization with Gardasil has not been established.”⁴ The Glaxo Smith Kline trials include some data on crossprotection against HPV types not included in the vaccine. Their Cervarix vaccine, which includes only HPV material targeted at HPV types 16 and 18, also provided protection against types 45 and 31.

To help resolve the questions left by these limited, short term data, **the American College of Pediatricians recommends that HPV vaccine manufacturers establish vaccine registries for HPV vaccine recipients.** The registries should be designed to assure patient privacy and collect long term data. **Because the average time between initial HPV infection and death from cervical cancer is 20 years, definitive conclusions about HPV vaccine efficacy will take years to establish.** Future research should also address the use of the vaccine in males.

Until further research is completed, HPV vaccine recipients should be fully informed as to the current limits of knowledge regarding the vaccine's potency and duration of protection. Waning protection is an issue with almost every vaccine in existence. In the 1980's it became clear that a single mumps-measles-rubella (MMR) vaccine was insufficient to offer complete protection against measles. When approved in 1995 a single dose of chickenpox vaccine was expected to offer long-lasting protection, now we know a booster is needed. **It may be years before we know with certainty the duration of protection afforded by HPV vaccines. Delaying the administration of the vaccine until the recipient is sexually active and therefore at risk of HPV exposure should be considered.** Parents and adolescents should also be reminded that 30% of cervical cancers are not caused by HPV strains included in the current HPV vaccines. They should also understand that this vaccine offers no protection against other forms of sexually transmitted diseases.

Cervical cancer causing HPV infection is spread only by penetrating vaginal sexual intercourse with direct penile-to-cervix contact. Although DNA from HPV was detected on the external genitalia of up to 20% of virginal women in one study, it was not found on the cervix in any of the same women in the absence of a history of vaginal sexual intercourse. Not all adolescents engage in penetrating vaginal sexual intercourse. ***Families with firmly enforced restrictions on sexual conduct, whose children do not participate in penetrating vaginal sexual intercourse outside of marriage, should have those values respected; it should be acknowledged that the child will not require HPV vaccination prior to marriage.*** There are other adolescents, who will engage in vaginal sexual intercourse, but do so with advanced planning without impulsivity. Because the duration of protection offered by HPV vaccination is uncertain, these adolescents should be offered the option of deferring immunization until the age of initiation of sexual intercourse. ***Whatever their views on sexual conduct, all families deserve equal respect and should be offered affordable HPV vaccination. They should be counseled, however, that HPV vaccination is not completely protective against cervical cancer.*** Special cellular characteristics of the developing adolescent cervix make it especially susceptible to infection with STDs. Condom use provides some but not complete protection against cervical HPV infection. Parents and adolescents must understand that receiving this vaccine does not make all sexual activity "safe." ***The most medically safe sexual conduct for adolescents is abstinence until marriage, and they should be counseled accordingly.***

The American College of Pediatricians is opposed to any legislation which would

require HPV vaccination for school attendance. Excluding children from school for refusal to be vaccinated for a disease spread only by penetrating vaginal intercourse is a serious, precedent-setting action that trespasses on the right of parents to make medical decisions for their children as well as on the rights of the children to attend school. In addition, this vaccine prevents a disease which is exclusively sexually transmitted; mandating it as early as 9 years of age places the medical provider in an ethical dilemma. First, the administration of the vaccine requires explanation to both the parent and the child. Parents may have chosen not to introduce the subject of sexual activity to their nine year olds due to their physical and emotional immaturity. Also, most 9-12 year old children are not sexually active; many have not entered puberty. Forcing a parent to forsake his/her better judgment and discuss this information with the child would be inappropriate and unnecessarily intrusive.

The American College of Pediatricians recommends that parents use the availability of this vaccine to usher in a discussion of human sexuality in a way consistent with their culture and values at a time when they determine their child is ready to receive the information. Parents should closely monitor their children's activities, reinforce their values, and consent to vaccination when appropriate. At that time, physicians should introduce the value of sexual abstinence as the only way to completely eliminate the risks associated with sexual activity.

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The American College of Pediatricians is a national medical association of licensed physicians and healthcare professionals who specialize in the care of infants, children, and adolescents. The mission of the College is "to enable all children to reach their optimal, physical and emotional health and well-being." We promote "a society where all children from the moment of their conception are valued unselfishly." The College further notes, "that children are the future of our nation and society. As such, they deserve to be reared in the best possible family environment and supported by physicians committed to ensuring their optimal health and well-being."

References

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