

INFORMATION PAPER

Military Vaccine Agency

27 November 2006

SUBJECT: Human Papillomavirus (HPV) and HPV Vaccine

1. Purpose: To describe human papillomavirus and the vaccine to prevent it.

2. Facts.

a. Microbiology. Human papillomavirus is the name of a group of viruses that includes more than 100 different strains or types. More than 30 of these viruses are sexually transmitted and can infect the genital area of men and women including the skin of the penis, vulva (area outside the vagina), or anus, and the linings of the vagina, cervix, or rectum.

b. Epidemiology. Genital HPV infection is a sexually transmitted disease (STD) that is caused by human papillomavirus (HPV). The types of HPV that infect the genital area are spread primarily through genital contact. Most HPV infections have no signs or symptoms; therefore, most infected people are unaware they are infected, yet they can transmit the virus to a sexual partner. Rarely, a pregnant woman can pass HPV to her baby during vaginal delivery. A baby that is exposed to HPV very rarely develops warts in the throat or vocal chords. Most people who become infected with HPV will not have any symptoms and will clear the infection on their own. Based on epidemiological and experimental studies, a causal link between HPV and the development of cervical cancer in women has been shown.

c. Vaccine. In preclinical animal models, both prophylactic and therapeutic vaccines have effectively induced HPV-specific cell mediated immune responses protecting animals from viral challenge or eliminating established tumors. Merck & Co. and GlaxoSmithKline (GSK) have developed and commercialized HPV vaccines. Merck's vaccine, Gardasil, is a quadravalent vaccine that is protective against strains 6, 11, 16 and 18 HPV virus, which can lead to genital warts and cervical cancer. Gardasil was approved by the Food and Drug Administration (FDA) in June of 2006. GSK also developed a vaccine, Cervarix, which is intended to protect against the cancer-causing strains 16 and 18. Early results have indicated that both HPV vaccines are extremely effective. GSK has not yet received FDA licensure for Cervarix .

d. Immunization. GARDASIL® is given intramuscularly in three 0.5-mL doses. Gardasil is indicated for girls and women 9 through 26 years of age. The second dose should be given two months after the first dose and the third dose should be given six months after the first dose.

e. Cautions. The following people should not receive GARDASIL: people with a history of a severe allergic reaction to a previous dose or any vaccine component.

GARDASIL is not recommended for use in pregnant women. The decision to administer or delay vaccination because of a current or recent febrile illness depends largely on the severity of the symptoms. Low-grade fever itself and mild upper respiratory infection are not generally contraindications to vaccination.

f. Adverse Events. GARDASIL has been shown to be generally well tolerated in women and girls as young as 9 years of age. The most commonly reported side effects included: pain, swelling, itching, and redness at the injection site and fever. Difficulty breathing (bronchospasm) has been reported very rarely.

g. DoD Policy. Administer Gardasil consistent with the FDA-approved product label and ACIP recommendations.

h. Special Considerations. Gardasil will not protect against infections not caused by HPV types 6, 11, 16 or 18. Women already infected with one strain of the HPV virus may still benefit from the HPV vaccine. The vaccine is not intended for treatment of active genital warts or cervical cancer. Women who receive GARDASIL should continue cervical cancer screening.

3. References:

- a. Advisory Committee on Immunization Practices.
- b. CDC disease information. www.cdc.gov/std/HPV/STDFact-HPV.htm
- c. Multiple resources (e.g., package insert, Vaccine Information Statements, etc.) assembled by Military Vaccine Agency: <http://www.vaccines.mil/hpv>

CPT Allison Christ/703 681-5101
Approved by LTC Ford