

INFORMATION PAPER

DHA-IHB
3 May 2016

SUBJECT: Human Papillomavirus (HPV) and HPV Vaccines

1. Purpose: To describe Human Papillomavirus and the vaccine to prevent it.
2. Facts.

a. Microbiology. Genital human papillomavirus (HPV) is the most common sexually transmitted infection in the United States; reports estimate that 14 million persons are newly infected every year with the virus. Most infections cause no symptoms and are self-limited. Very rarely (<2%), a persistent HPV infection can cause cervical cancer in women and other even rarer cancers such as: anogenital (anal) cancers, and oropharyngeal (tongue, soft palate, tonsils, and the throat) cancer in both men and women.

b. Disease. There are over 150 types of Human Papilloma viruses, 9 of which are associated with cancers, and 8 of which are most often associated with genital warts. The HPV infection is spread by direct skin-to-skin contact, including sexual intercourse, oral sex, or any other contact involving the genital area (such as hand to genital contact). There is a greater risk of becoming infected with HPV if one has multiple sexual partners at any time or if a partner has had multiple sexual partners. HPV is very resistant to heat and dryness; nonsexual transmission through fomites can occur, such as prolonged exposure to shared contaminated clothing. However, it is not possible to become infected with HPV by simply touching an object such as a toilet seat. Pregnant women can pass HPV onto their babies during birth, but this is not common. HPV types 16 and 18 are associated with the development of 70% of cervical cancers. HPV types 6 and 11 are associated with 90% of genital warts and most cases of recurrent respiratory papillomatosis.

c. Vaccine. There are three approved HPV vaccines to help prevent complications from HPV infection. HPV vaccines are recommended for both males and females and it is routinely given at 11 or 12 years of age.

(1) Gardasil-9 valent HPV (9vHPV) is a vaccine indicated in both males and females 9 through 26 years of age.

(a) Gardasil-9 is FDA approved at the following schedule: 0, 2 and 6 months. Three doses of Gardasil-9 are recommended with the second dose 2 months after the first dose and the third dose 6 months after the first dose, respectively.

(2) Gardasil 4-valent HPV (4vHPV) is a vaccine indicated in girls and women 9 through 26 years of age and is indicated in boys and men 9 through 26 years of age.

(b) Gardasil 4vHPV is FDA approved at the following schedule: 0, 2 and 6 months. 2 valent HPV and 4 valent HPV are each administered in a three dose schedule. The second dose is administered 2 months after the first dose and the third dose 6 months after the first dose, respectively.

(3) Cervarix 2 valent HPV (2vHPV) is a vaccine indicated in females 9 through 25 years of age. It is not approved for use in males.

(a) Cervarix is FDA approved at the following schedule: 0, 1, and 6 months. Three doses of Cervarix are recommended with the second dose 1 month after the first dose and the third dose 6 months after the first dose, respectively.

(4) Prevention

(a) Gardasil-9 (9vHPV) prevents genital warts in both males and females. It also prevents cancers caused by human papillomavirus (HPV) infections, to include: cervical, vaginal and vulvar cancers in females, as well as anal cancer in both female and males.

(b) 9vHPV vaccine also targets five additional cancer causing types (HPV 31, 33, 45, 52, 58) which account for about 15% of cervical cancers.

(c) 2vHPV and 4vHPV protects against HPV 16 and 18 types that cause approximately 66% of cervical cancers. 4vHPV also protects against HPV6 and 11 types that cause genital warts.

(d) Quadrivalent and 9vHPV vaccines each target HPV 16 and 18, types that cause about 66% of cervical cancers and the majority of other HPV-associated cancers in both women and men in the United States.

(e) Quadrivalent and 9vHPV vaccines also protect against HPV 6 and 11, types that cause anogenital warts.

(f) Quadrivalent and 9vHPV vaccines are licensed for use in females and males; bivalent HPV vaccine is licensed for use only in females.

(g) Cervarix is a vaccine indicated for the prevention of the following diseases caused by oncogenic human papillomavirus (HPV) types 16 and 18.

(h) Cervarix has not been demonstrated to provide protection against disease from vaccine and non-vaccine HPV types to which a woman has previously been exposed through sexual activity.

3. Limitations of Use and Effectiveness

a. Immunization. A 9v HPV vaccine was licensed for use in females and males. The 9vHPV vaccine is the third HPV vaccine licensed by the Food and Drug Administration; the other vaccines are bivalent HPV vaccine, licensed for use in females, and quadrivalent HPV vaccine, licensed for use in females and males.

ACIP recommends that routine HPV vaccination be initiated at age 11 or 12 years. The vaccination series can be started beginning at age 9 years. Vaccination is also recommended for females aged 13 through 26 years and for males aged 13 through 21 years who have not been vaccinated previously or who have not completed the 3-dose series. Males aged 22 through 26 years may be vaccinated. Vaccination of females is recommended with 2vHPV, 4vHPV (as long as this formulation is available), or 9-vHPV. Vaccination of males is recommended with 4vHPV (as long as this formulation is available) or 9vHPV. Vaccination is additionally recommended through age 26 for men who have sex with men and for immunocompromised persons, including those with HIV infection, if not vaccinated previously.

b. Cautions. HPV vaccine is not recommended for the following:

(1) Women who are pregnant

(2) Individuals who have had a life-threatening allergic reaction to a dose of HPV vaccine should not get another dose.

(3) Anyone who has a severe (life-threatening) allergic reaction to any component of HPV vaccine should not get the vaccine.

(4) Individuals, who are moderately or severely ill, should wait until they recover before getting the vaccines, or they can consult with their doctor.

d. Adverse Events. Mild or moderate problems can occur after vaccination for example, redness, pain, and swelling at the injection site, and headache. Also, individuals may experience high fever and fainting after vaccination. It is recommended that after receiving the vaccine, sitting or lying down for approximately 15 minutes can prevent injuries caused by a fall. Other symptoms can include difficulty breathing, hives, swelling of the face and throat, increase heart rate, dizziness, and weakness. These symptoms typically occur a few minutes to a few hours after the vaccination.

e. DoD Policy. HPV vaccination is not mandatory for Active Duty or Selected Reserve members; however facilities are encouraged to offer the vaccine to Service members who meet ACIP criteria.

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4. References.

a. Use of 9-Valent Human Papillomavirus (HPV) Vaccine: Updated HPV Vaccination Recommendations of the Advisory Committee on Immunization Practices MMWR March 27, 2015; 64:300-304

b. Markowitz LE, Dunne EF, Saraiya M, et al. Human papillomavirus vaccination: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR Recomm Rep 2014; 63:1–30.

c. Petrosky E, Bocchini J, Hariri S, et al. Use of 9-Valent Human Papillomavirus (HPV) Vaccine: Updated HPV Vaccination Recommendations of the Advisory Committee on Immunization Practices. MMWR 2015;64;300-4.

d. Multiple resources (e.g., Package inserts and Vaccine Information Statements): <http://www.health.mil/HPV>

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