INFORMATION PAPER

Military Vaccine Agency
20 January 2012

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), anus, linings of the vagina, cervix, or rectum.

b. Disease. Genital human papillomavirus (HPV) is the most common sexually transmitted infection in the United States. It is estimated that 6.2 million persons are newly infected every year. Human papillomavirus (HPV) types 16 and 18 are associated with the development of 70% of cervical cancer cases. Other HPV associated cancers in females include a subset of vulvar, vaginal, anus, and oropharyngeal and oral cavity cancers caused primarily by HPV 16. HPV types 6 and 11 are associated with 90% of genital warts and most cases of recurrent respiratory papillomatosis.

c. 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 skin to skin contact. Most HPV infections have no signs or symptoms; therefore, most people are unaware they are infected, but they can continue to transmit the virus to a sexual partner. Rarely, a pregnant woman can pass HPV to her baby during vaginal delivery. 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 cancers, such as, cervical, anal, vulvar, vaginal, penile, as well as oropharyngeal has been shown.

d. Vaccine.

1) Merck & Company's vaccine, Gardasil, is a quadravalent vaccine that is directed against two oncogenic types (HPV 16 and 18) and two non-oncogenic types (HPV 6 and 11). Gardasil was approved by the Food and Drug Administration (FDA) in June of 2006.

2) GlaxoSmithKline's vaccine, Cervarix, is a bivalent non-infectious recombinant, AS04-adjuvanted vaccine that is directed against two oncogenic types (HPV 16 and 18) Cervarix was approved by the Food and Drug Administration (FDA) in October of 2009.

e. Cautions.

1) Gardasil should not be administered to people with a history of a hypersensitivity including severe allergic reaction to yeast (a vaccine component), a previous dose of the vaccine, or any vaccine component. Gardasil is not recommended for use in pregnant women.

2) Prefilled syringes of Cervarix should not be administered to people with a history of hypersensitivity to latex. Cervarix should not be administered to people with a history of a hypersensitivity to a previous dose of the vaccine or any vaccine component. Cervarix is not recommended for use in pregnant women.

f. Immunization.

1) GARDASIL® is a three dose series administered at 0, 2, and 6 month intervals. Each dose is 0.5-mL administered as an intramuscularly injection in the deltoid. Gardasil is licensed for males and females 9 through 26 years of age. The Advisory Committee on Immunization Practices (ACIP) recommends routine vaccination of males and females aged 11-12 years. Vaccination is recommended for females 13-26 or males aged 13 - 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. Each dose must be mixed well before administering. Due to the possibility of injury from syncope (fainting), observation for 15 minutes after administration is highly recommended. Women or men 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.

2) Cervarix ® is a three dose series administered at 0, 1, and 6 month intervals. Each dose is 0.5-mL administered as an intramuscularly injection in the deltoid. Cervarix is indicated for females 10 through 25 years of age. Due to the possibility of injury from syncope (fainting), observation for 15 minutes after administration is highly recommended. 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 cervical cancer. Women who receive Cervarix should continue cervical cancer screening.

g. Adverse Events.

1) GARDASIL has been shown to be generally well tolerated in males and females as young as 9 years of age. The most commonly reported side effect was headaches other reported side effects included: pain, swelling, itching, and redness at the injection site, nausea, dizinesss, and fever. Fainting (syncope) and difficulty breathing (bronchospasm) has been reported very rarely.

2) Cervarix has been shown to be generally well tolerated in women and girls as young as 9 years of age. The most commonly reported side effect was headaches other reported side effects included: pain, swelling, itching, and redness at the injection site, fatigue, myalgia, gastrointestinal symptoms, and arthralgia. Fainting (syncope) has been reported very rarely.

h. DoD Policy. Administer HPV vaccines consistent with the FDA-approved product label and ACIP recommendations. HPV vaccines are not mandatory for DoD active duty or reserve members.

i. Special Consideration. None.

3. References:

a. Centers for Disease Control and Prevention. Quadrivalent Human Papillomavirus Vaccine. Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2007;56 (RR-2): 1-32.

b. Multiple resources (e.g., Package inserts and Vaccine Information Statements) assembled by Military Vaccine Agency: http://www.vaccines.mil/hpv

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