DEPARTMENT OF THE NAVY
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IN REPLY REFER TO

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MEMORANDUM FOR COMMANDER, NAVY MEDICINE EAST
COMMANDER, NAVY MEDICINE WEST
COMMANDER, NAVY MEDICINE NATIONAL CAPITAL AREA
COMMANDER, NAVY MEDICINE SUPPORT COMMAND

SUBJECT: Recommendations for the Use of Quadrivalent Human Papilloma Virus (HPV) Vaccine in Navy and Marine Corps Beneficiaries

Ref: (a) Centers for Disease Control and Prevention. Quadrivalent Human Papilloma Virus Vaccine: Recommendations of the Advisory Committee on Immunization Practices (ACIP) 12 March 2007 http://www.cdc.gov/mmwr/pdf/rr/rr5602.pdf

Encl: (1) Recommendations for the Use of Quadrivalent Human Papilloma Virus Vaccine

This memorandum establishes Navy Medicine policy regarding the use of the new quadrivalent human papilloma virus (HPV) vaccine in Navy and Marine Corps beneficiaries. The Advisory Committee on Immunization Practice (ACIP) recently released recommendations, outlined in reference (a), stating that all females age 9-26 are eligible to receive the new HPV vaccine (Gardasil™). This vaccine is highly efficacious in preventing persistent HPV infection, cervical cancer precursor lesions, vaginal and vulvar cancer precursor lesions, and genital warts. Per the reference, 90-100 percent vaccine efficacy has been reported in females not previously exposed to HPV.

As this vaccine is new, it is important to counsel Military Health System eligible female beneficiaries regarding its potential benefits, limitations, and risks as outlined in enclosure (1). Among Active Duty females, recruits will benefit the most from HPV vaccination, and emphasis must be placed on appropriate counseling and offering of the immunization to them.

Maximum vaccine benefit is likely to be achieved through immunizing 11-12 year old females with an overall minimal risk of HPV contact. Females as young as 9 years old can receive it as well. A catch-up vaccination schedule has been recommended by the ACIP for those women age 13-26 that have not started the series. A woman's risk of HPV infection increases the longer she has been sexually active and the greater the number of sexual partners. Preliminary data suggests Gardasil™ is only marginally effective in this latter risk group of women. These issues are important to discuss when counseling beneficiaries about the HPV vaccine, as there is currently no reliable serological test to determine prior infection.

Although the use of the HPV vaccine will more than likely reduce the incidence of cervical cancer long term, it does not eliminate the need to get routine cervical cancer screening per MANMED 15-112. It is estimated several thousand cases of cervical

cancer will still occur nationwide even if all eligible females received the vaccination and have regular Pap screening. Gardasil™ does not protect against all HPV types that can cause cervical cancer. Consequently, appropriate counseling prior to vaccination must emphasize continued routine Pap screening, tobacco cessation, and other cervical cancer risk factor mitigation strategies.

The point of contact for this matter is Lieutenant Commander Marlene Sanchez, Office of Women's Health, who can be contacted at (202) 762-3739 or marlene.sanchez@med.navy.mil.

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Recommendations for the Use of the Quadrivalent HPV Vaccine in Female Navy and Marine Corps Beneficiaries.

Candidates for Routine Vaccination.

1. HPV vaccine should be offered as a non-mandatory vaccination to all female Navy or Marine Corps beneficiaries ages 11-26 years, at convenient clinical opportunities, e.g., well-child visits, periodic well woman examinations, etc.

2. Routine vaccination with three of doses of HPV vaccine is recommended for females ages 11-12 years. The vaccination series can be started in females as young as 9 years of age.

Candidates for Catch-up Vaccination

1. HPV vaccination is also recommended for females ages 13–26 years who have not been previously vaccinated or who have not completed the full series.

2. Per the Advisory Committee on Immunization Practice (ACIP), it is not possible for clinicians to assess the extent to which sexually active persons would benefit from vaccination. However, preferentially, the vaccine should be administered before potential exposure to HPV through sexual contact.

3. Within the Navy and Marine Corps, the HPV vaccine counseling and administration should be incorporated into the recruit (also OCS, OIS, ROTC, etc.) well-woman intake screening examination to facilitate early vaccination of interested females. This population of service members would most likely receive the greatest benefit from the vaccine.

Vaccine Counseling

1. The patient's decision to receive the HPV vaccination should be made only after receiving counseling given from a knowledgeable health care provider.

2. This counseling will allow each patient to make an informed decision regarding whether or not receiving the HPV vaccine will benefit her based on personal sexual history and knowledge of vaccine benefits, limitations, and risk.

3. Issues for discussion during counseling should include but not limited to:

a. The requirement to continue with regular Pap screening even after HPV vaccination, as 30% of cervical cancers are caused by viral types not contained in the vaccine.

b. The marked reduction of vaccine efficacy in populations of females with an increased likelihood of previous or current HPV infections, e.g., multiple lifetime sexual partners.

c. Quadrivalent HPV vaccine can be given to females with an equivocal or abnormal Pap screening, genital warts or a positive Hybrid Capture II high-risk test. Results of clinical trials to date do not indicate the vaccine will have any therapeutic effect on established HPV infection or cervical lesions.

d. Potential side effects and adverse event profile. Mild to moderate pain, swelling, or erythema at the injection site were the most common reported side effects, similar to other vaccines. Adverse events were generally 1% above placebo including fever, nausea, vomiting, diarrhea, etc. Only a very small number of women in the clinical trials were unable to complete the full series of immunizations due to severe side effects or adverse events.

4. A CDC Vaccine Information Sheet (VIS) should also be provided to the patient prior to the administration of the vaccine.

Dosage and Administration

1. Quadrivalent HPV vaccine is administered in a three dose schedule. The second and third dose should be administered 2 and 6 months after the first dose.

2. The minimum dosage interval between the first and second doses is 4 weeks. The minimum recommended interval between the second and third dose is 12 weeks.

3. Quadrivalent HPV vaccine can be administered at the same visit as other age appropriate vaccines such as Td, Tdap, and quadrivalent meningococcal conjugate vaccine (MCV4), etc.

4. An interruption in the dosage schedule does not require that the vaccination series be restarted. The series should be continued from the last dose observing the minimum recommended intervals between doses. Vaccine efficacy is significantly decreased if less than three doses are administered.

Use during Pregnancy and Breastfeeding

1. Quadrivalent HPV vaccine is not currently recommended for use during pregnancy as data on vaccination during pregnancy is limited. Any exposure to the vaccine during pregnancy should be reported to the Vaccine Pregnancy Registry (1-800-986-8999).

2. Breastfeeding women can receive quadrivalent HPV vaccine.

Precautions and Contraindications

1. Quadrivalent HPV vaccine is a yeast-cell derived product and is contraindicated in individuals with a history of immediate hypersensitivity to yeast or any other vaccine component.

2. Quadrivalent HPV vaccine can be administered to females with minor acute illnesses (e.g., diarrhea or mild upper respiratory tract infections with or without fever). Vaccination of females with moderate or severe illness should be deferred until the individual recovers.

3. Post-vaccination syncope is the second most frequently reported adverse reaction, most commonly among adolescents and young adults. Adherence to a 20 minute post-vaccination observation period should be enforced.

4. Any adverse events following immunization should be reported to the Vaccine Adverse Event Reporting System (www.vaers.hhs.gov). All clinical significant events should be reported regardless of whether or not a causal relationship can be established.

Recordkeeping

1. All immunizations given to military personnel or other beneficiaries should be entered into an electronic immunization tracking database (e.g., AHLTA, MRRS, etc). If electronic data entry is not available, all immunizations will be recorded in individual health records.

These recommendations reflect the current scientific understanding and opinion regarding the quadrivalent HPV vaccine at the time of release of this policy letter. Changes to these recommendations may result as new information from ongoing clinical trials and post-marketing surveillance becomes available.