



DEPARTMENT OF THE NAVY
BUREAU OF MEDICINE AND SURGERY
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IN REPLY REFER TO

6010
Ser M3/5/AT-35197
21 Apr 09

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

Subj: POLICY GUIDANCE ON THE SAFETY OF THE HUMAN PAPILLOMAVIRUS
VACCINE

- Ref: (a) Centers for Disease Control (CDC), "Reports of Health Concerns Following HPV
Vaccination," February 26, 2009
(b) CDC, "Questions and Answers about HPV Vaccine Safety," October 21, 2008
(c) U.S. Food and Drug Administration, "Addressing Questions About Gardasil,"
September 29, 2008

1. There has been recent consumer concern over the safety of Gardasil, the Human Papillomavirus (HPV) vaccine administered to girls and women aged 9 to 26 years of age for the prevention of cervical, vaginal and vulvar cancer, and genital warts caused by HPV types 6, 11, 16, and 18. Recent media attention has suggested an association between Gardasil and serious medical conditions, including death. The Centers for Disease Control and Prevention (CDC) and U.S. Food and Drug Administration (FDA) have objectively examined these reports using the Vaccine Adverse Events Reporting System (VAERS), Vaccine Safety Datalink (VSD) Project, and Clinical Immunization Safety Assessment (CISA) Network looking for trends that would suggest a link with Gardasil. As of December 31, 2008, 11,916 adverse events were reported to VAERS in association with the HPV vaccine. Of these reports, 6% were deemed to be serious, including Guillain-Barré syndrome, thrombophilia, seizures, and 32 reports of death. After analysis, the CDC/FDA found no common pattern to link Gardasil to any of the adverse events beyond the spontaneous rate expected in the population for this age range and gender. The CDC and FDA continually review all of the safety information available to them about Gardasil. Currently, their recommendation is that Gardasil is safe to use and effective in preventing 4 types of HPV. The FDA has changed Gardasil's prescribing information to include information to providers about preventing falls from fainting, which can occur after injections and vaccinations among adolescents.

2. The following recommendations are provided, per references (a) through (c), to all healthcare personnel who may counsel patients on the risks and/or benefits of Gardasil:

a. Current CDC and FDA recommendations are that Gardasil is safe to use and effective in preventing 4 types of HPV.

b. It is recommended for girls and women aged 9 to 26 years, and is approved for the prevention of cervical, vaginal and vulvar cancer, and genital warts caused by HPV types 6, 11, 16, and 18.

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c. The FDA has changed Gardasil's prescribing information to include information to providers about preventing falls from fainting, which can occur after injections and vaccinations among adolescents. Medical personnel should ensure recipients of the vaccine remain seated in clinic spaces for at least 15 minutes.

d. Healthcare personnel are encouraged to monitor the CDC and FDA websites (below) for updates regarding Gardasil, because no vaccine or medication is completely without risk:
<http://www.cdc.gov/vaccinesafety/vaers/gardasil.htm>
<http://www.fda.gov/cber/products/gardasil.htm>

e. Regardless of whether vaccination is chosen, Pap screening throughout life should continue to be emphasized and remain an essential element of preventive women's health care.



A. M. ROBINSON, JR.