Gardasil®: Introducing the New Human Papillomavirus Vaccine

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In 2006, the U.S. Food and Drug Administration (FDA) approved the first vaccine for prevention of cervical cancer based on the molecular biology of the disease. Gardasil® (quadrivalent human papillomavirus [HPV] [types 6, 11, 16, and 18] recombinant vaccine, Merck & Co., Inc., Whitehouse Station, NJ) combats the common types of HPV responsible for cervical cancer precursor lesions. This article provides a simple overview of the (a) epidemiology of HPV, (b) HPV vaccine, (c) dosing and administration, and (d) nursing implications about this possibly life-saving vaccine.

Epidemiology

According to the American Cancer Society ([ACS], 2006), approximately 9,710 women are diagnosed with cervical cancer annually. HPV is a DNA virus that exists in more than 100 strains or types; about 30 types are sexually transmitted (Centers for Disease Control and Prevention [CDC], 2004). Approximately 20 million people are affected by HPV, and more than 6.2 million Americans are newly diagnosed with HPV infections every year (CDC). By age 50, 80% of women will have a genital HPV infection (CDC).

Gardasil vaccinates against HPV types 6, 11, 16, and 18, which makes it a quadrivalent (FDA, 2006). HPV types 6 and 11 are categorized as low risk and are associated with 90% of common genital warts and low-grade squamous intraepithelial lesions. HPV types 16 and 18 are categorized as high risk and are associated with the development of cervical cancer, particularly high-grade squamous intraepithelial lesions and cervical intraepithelial neoplasia 1–3 (FDA). See Figure 1 for a histology of cervical cancer.

Despite the high incidence of HPV infection in the general population, cervical cancer is relatively rare (relegated to few HPV types), and rates of cervical cancer have been declining since the introduction of the Pap test as the primary screening tool (ACS, 2006; Papanicolaou, 1949).

Gardasil Vaccine

The Garadsil HPV vaccine, unlike previous vaccines for the disease, is composed of highly purified, virus-like particles. The particles are specific to the major capsids (protein coat or shell of a virus particle) of the L1 protein of HPV types 6, 11, 16, and 18. When fully constituted, Gardasil is a white, cloudy liquid. Merck & Co., Inc., offers the vaccine in two forms.

- Single-dose vials (0.5 ml)
- Single-dose, prefilled, Luer Lock syringes (0.5 ml)

The vaccine should be refrigerated at 36–46°F and should not be frozen. The vaccine is prophylactic and not meant to treat individuals already exposed to HPV. It does not protect against strains of HPV other than types 6, 11, 16, and 18.

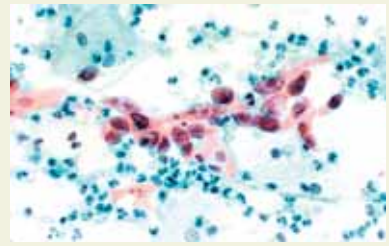

Figure 1. Cervical Cancer Histology

Note. Image courtesy of the National Cancer Institute.

Dosing and Administration

Gardasil is a noninfectious vaccine; it is a sterile preparation for intramuscular injection. The vaccine is similar to the hepatitis B vaccine because it is administered in three stages: dose 1, then two months after dose 1, and finally six months after dose 1.

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Digital Object Identifier: 10.1188/06.CJON.559-560