

FDA-approved HPV vaccine raises questions – DCL offers answers

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On June 8, 2006, the U.S. Food and Drug Administration (FDA) approved Merck's GARDASIL®, as the first, and currently only, FDA-approved HPV vaccine. While this medical breakthrough is revolutionary, and to be celebrated, it raises several questions regarding the future of cervical cancer screening. DCL Medical Laboratories would like to help answer some of your questions.

About the Vaccine

GARDASIL® is a non-infectious, recombinant, quadrivalent vaccine prepared from highly purified virus-like particles. The FDA has approved it for the prevention of cervical cancer, cervical pre-cancers and vaginal pre-cancers caused by HPV types 16 and 18. It has also been approved for the prevention of genital warts and low-grade cervical lesions caused by HPV types 6, 11, 16 and 18.

GARDASIL® performed well in clinical trials by preventing 100 percent of HPV 16- and 18- related cervical pre-cancers and non-invasive cervical cancers. The vaccine prevented 95 percent of low-grade cervical dysplasia and pre-cancers caused by HPV 6, 11, 16 or 18. It prevented 99 percent of cases of genital warts caused by HPV 6 or 11.

Merck's vaccine is currently approved for women aged 9 to 26 in the form of three doses, the second given two months after the initial dose and the third given six months after the initial dose. The catalog price is \$120 per dose.

How the Vaccine will Affect Cervical Cancer Screening

While the approval of an HPV vaccine is a major breakthrough in the prevention of cervical cancer, Merck & Co., Inc., the National Cancer Institute and the Centers for Disease Control (CDC), as well as DCL Medical Laboratories, still recommend regular PAP and HPV testing.

References

Centers for Disease Control. (2006, June). HPV vaccine Q&A. Retrieved June 23, 2006 from www.cdc.gov/std/healthcomm/fact_sheets.htm

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National Cancer Institute. (2006, June 8). Statement from the National Cancer Institute on FDA Approval of the HPV Vaccine. Retrieved June 28, 2006, from www.cancer.gov/newscenter/pressreleases/HPVStatement

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Some of the reasons why:

- GARDASIL® only includes HPV types 6, 11, 16 and 18. Types 6 and 11 cause benign genital warts. While types 16 and 18 cause 67% of cervical cancers, 70% of anogenital cancers and 52% of CIN 2 and 3 lesions, there are more than 100 types of HPV. Cervical cancer screening is necessary to protect women from the many other types of HPV.
- GARDASIL® is a prophylactic vaccine rather than therapeutic; it will work to prevent HPV infections, but it will not treat established infections or lesions. Women with HPV infections prior to the availability of the vaccine will still require screening.
- The vaccine is currently only recommended for women ages 9 to 26. Persistent HPV infections, those most likely to result in cervical cancer, occur most frequently in women over age 30. Women currently over the age of 26 will not receive the vaccine and not all women between the ages of 9 and 26 will be immediately vaccinated.

The HPV vaccine in combination with PAP and HPV testing will lead to a reduced risk of cervical cancer.

DCL's Role in Clinical Trials for the Vaccine

In 1999, DCL entered into a relationship with Merck through Covance Central Laboratory Services to serve as a consultant to establish protocols for the global study to test the vaccine.

Additionally, DCL was the laboratory of record for all Pap Smears, biopsies and HPV testing, as well as gonorrhea and Chlamydia testing in relation to the clinical trial.

DCL Medical Laboratories researches, markets and performs testing for medical diagnostic applications with a primary focus on women's health. DCL strives to be the preferred laboratory partner providing innovative and consultative solutions to help clients improve patients' lives.