

Quadrivalent Human Papillomavirus Vaccine

In June 2006, the Food and Drug Administration announced the approval of the first vaccine against human papillomavirus (HPV), the primary cause of cervical cancer. Gardasil®, manufactured by Merck, protects against HPV types 16 and 18, which together are responsible for 70% of cervical cancers, and types 6, 11, which along with type 18 are responsible for 90% of genital warts.

In women who had not already been infected, the vaccine was nearly 100% effective in preventing precancerous cervical lesions, precancerous vaginal and vulvar lesions, and genital warts caused by infection with the HPV types targeted by the vaccine. While the study period was not long enough for cervical cancer to develop, the prevention of these precancerous lesions is believed highly likely to result in the prevention of cervical cancers. The vaccine appears to be both safe and well tolerated. During the studies no serious side effects were reported. The most commonly reported side effects were brief injection site soreness and low-grade fevers.

About HPV

HPV is the most common sexually transmitted infection in the U.S., with about 20 million people currently infected. The CDC estimates about 6.2 million Americans become infected with genital HPV each year. It is most common in young women and men who are in their late teens and early twenties. Over half of all sexually active men and women become infected at some time in their lives. Consistent condom use can decrease the risk of sexually transmitted infections, including HPV.

Approximately ten of the 30 identified genital HPV types can lead, in rare cases, to development of cervical cancer. There are approximately 9,700 new cases of cervical cancer and 3,700 deaths attributed to it in the U.S. each year. Worldwide, cervical cancer is the second most common cancer in women and is estimated to cause over 470,000 new cases and 233,000 deaths each year. The new quadrivalent HPV vaccine protects against the two types of HPV that cause 70% of cervical cancers.

The Advisory Committee on Immunization Practices (ACIP) voted to recommend that the quadrivalent HPV vaccine be routinely administered to girls when they are 11-12 years old.

Routine vaccination recommended

The Advisory Committee on Immunization Practices (ACIP) voted to recommend that the quadrivalent HPV vaccine be routinely administered to girls when they are 11-12 years of age. The ACIP recommendation also allows for vaccination of girls beginning at nine years of age as well as catch-up vaccination of girls and women 13-26 years of age. The vaccine should ideally be administered before onset of sexual activity when women are exposed to the viruses, but females who are already sexually active should still be vaccinated.

Gardasil® is a recombinant vaccine (made from non-infectious HPV-like particles [VLP]) that is given as three injections over a six-month period. The second dose is given two months after the first dose and the third dose is given six months after the first dose (at least 12 weeks after the second dose). The dose is 0.5 mL given intramuscularly. The vaccine may be administered at the same visit as other age appropriate vaccines are provided, such as tetanus-diphtheria-acellular pertussis vaccine (Tdap), meningococcal conjugate vaccine (MCV4), and catch-up doses of hepatitis B vaccine, measles-mumps-rubella vaccine (MMR) and the now recommended second dose of varicella vaccine if not previously received.

Quadrivalent HPV vaccine is contraindicated for persons with a history of immediate hypersensitivity to yeast or to any vaccine component. The vaccine is not recommended for use in pregnancy. Although the vaccine has not been causally associated with adverse outcomes of pregnancy or adverse events to the developing fetus, data on vaccination during pregnancy are limited. Breastfeeding women may be vaccinated. Immunocompromised persons also may be vaccinated; however, the immune response to the vaccine might be less than that of immunocompetent persons.

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As with other new vaccines the duration of immunity that the quadrivalent HPV vaccine will offer is not known. Current studies (with five-year follow-up) indicate that the vaccine is effective for at least five years. Since there has been no evidence of waning immunity during that time period, it is expected that the vaccine will offer long-term protection. It should be noted that data from clinical trials demonstrated a greater immune response in girl's ages ten to 15 compared to young women ages 16 to 25.

Efficacy exceptions

Although immunization with quadrivalent HPV vaccine is expected to prevent most cases of cervical cancer due to HPV types included in the vaccine (6, 11, 16, and 18), females are not protected if they have been infected with these HPV type(s) prior to vaccination, indicating the importance of immunization before potential exposure to the virus. In addition, the vaccine will not treat existing HPV infections or their complications. Also, the vaccine does not protect against less common HPV types not included in the vaccine, thus routine and regular pap screening remains critically important in detecting precancerous changes in the cervix, and allowing treatment before cervical cancer develops.

Challenges to providing vaccine

There may be challenges in reaching the target population for vaccination. Although 11-12 years of age is a recommended age for health assessments (including immunization needs) few children this age routinely see their health care providers, let alone see their provider three times as will be necessary to receive the full series of vaccine doses. Providers are encouraged to recall patients for immunization assessments and to use health care visits made for another reason as an opportunity to assess immunization needs, including HPV vaccine.

In addition to educating parents about the need to complete all three doses to be protected, providers will need to use reminder systems to remind parents when their child needs to return for the second and/or third doses.

Studies underway

The manufacturer is conducting several studies, including additional studies to further evaluate general safety and long-term effectiveness. The manufacturer will also monitor the pregnancy outcomes of women who receive Gardasil® while unknowingly pregnant. In addition, the manufacturer has an ongoing study to evaluate the safety and effectiveness of Gardasil in males.

The Vaccines for Children (VFC) Program will provide free vaccine to VFC providers for use in female children and adolescents less than 19 years of age who are CHDP-eligible, uninsured, American Indian, or Alaska Native. It is anticipated the vaccine will be available to VFC providers the end of this year or early in 2007.

In the private sector, the vaccine is now available through some health plans and clinics. California requires insurers to cover vaccination for those age groups recommended by the ACIP.

For additional information visit CDC's National Immunization Program's website at: <http://www.cdc.gov/nip/vaccine/hpv/default.htm>, or contact the County's Immunization Program at (213) 351-7800.

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