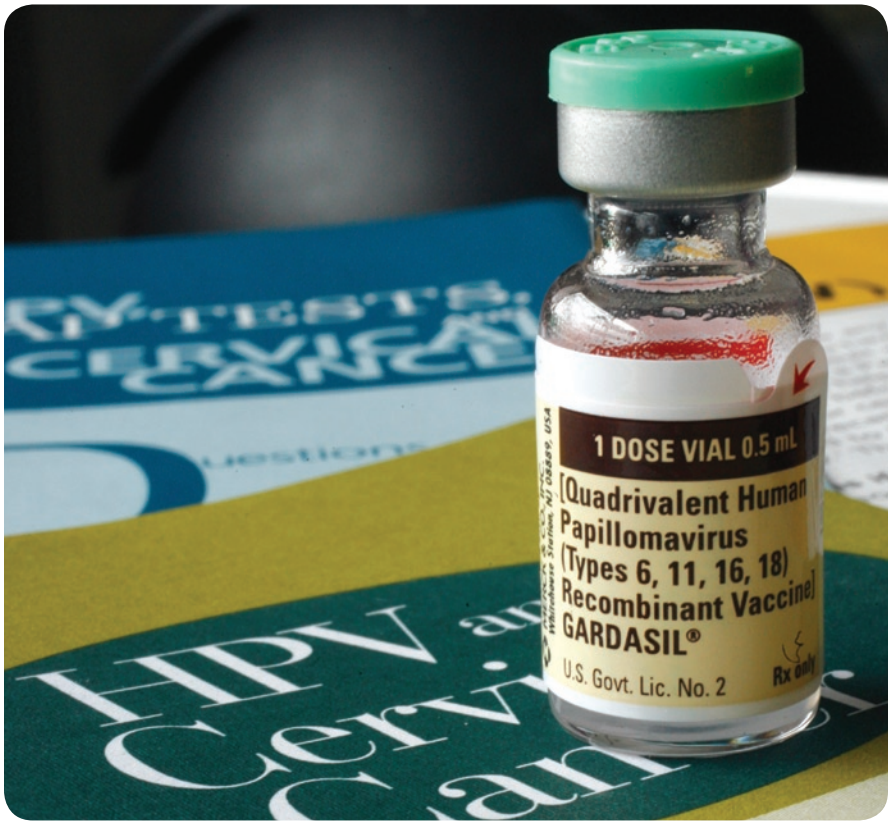
Addressing Questions About Gardasil

Recently, questions have been raised about the safety of Gardasil, a vaccine that prevents infection with types of human papillomavirus (HPV) that cause most cases of cervical cancer and genital warts, and some vulvar and vaginal cancers.



Associated Press

What is Gardasil?

Gardasil is a vaccine for use in girls and women 9 through 26 years of age. It is approved for preventing cancer of the cervix, vulva and vagina, and for preventing genital warts caused by the types of HPV contained in the vaccine.

These four HPV types (6, 11, 16, and 18) cause about 70% of cervical cancers and about 90% of genital warts. They are also known to cause some vulvar and vaginal cancers. (Percentages related to these conditions are not well defined.)

Why is Gardasil needed?

Gardasil may benefit the health of millions of people. Each year, more than 12,000 American women are diagnosed with cervical cancer, and almost 4,000 women die from this disease. In addition, about 6.2 million Americans become infected with genital HPV each year. Worldwide, cervical cancer is the second most common cancer in women, with 233,000 deaths per year.

Is Gardasil safe?

Based on ongoing assessments of vaccine safety information, the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) continue to find that Gardasil is a safe and effective vaccine.

Studies involving approximately 21,000 girls and women in the United States and worldwide were conducted to evaluate the safety and effectiveness of Gardasil before the vaccine was approved by FDA. Approximately half of the study participants received Gardasil, and the other half received a control.

Why have questions been raised about the vaccine's safety?

There have been reports of serious adverse events in girls and women that have received the vaccine. These include death and Guillain-Barre Syndrome (GBS), a rare neurological disorder that causes muscle weakness.

Should these reports worry me?

Based on the review and assessment of vaccine safety information avail-

FDA and CDC take all concerns about vaccine safety seriously, and, as they do with all licensed vaccines, will continue to closely monitor Gardasil's safety.

able, FDA and CDC continue to find that the benefits of Gardasil outweigh the risks.

Twenty deaths had been reported to the FDA- and CDC-administered Vaccine Adverse Event Reporting System (VAERS) as of June 30, 2008, in women that received Gardasil.

However, no common pattern to these deaths has been detected that would suggest they were caused by the vaccine. In cases where autopsy, death certificate, and medical records were available, the cause of death was explained by factors other than the vaccine.

Given the large number of vaccine doses distributed, it is expected that, by chance alone, serious adverse events and some deaths will be reported in a large population during the time period following vaccinations.

The manufacturer, Merck and Co., has distributed more than 16 million doses of Gardasil nationwide. As of June 30, there were 9,749 VAERS reports of adverse events following Gardasil vaccination. Of these, 94% were classified as reports of non-serious events.

Also, FDA routinely reviews manufacturing information, and has not identified any issues affecting the safety, purity, and potency of Gardasil.

What non-serious problems have been reported?

- Syncope (Fainting)
- Pain at the injection site
- Headache
- Nausea
- Fever

Fainting, which may sometimes cause serious injuries from falling, is common after injections and vaccinations, especially in adolescents. FDA and CDC have reminded health care professionals that women receiving Gardasil should be watched carefully for 15 minutes after vaccination to avoid potential injury from a fall. The vaccine's prescribing information includes this as well.

What are FDA and CDC doing about the concerns?

FDA and CDC take all concerns about vaccine safety seriously, and, as they do with all licensed vaccines, will continue to closely monitor Gardasil's safety.

Because available information indicates that Gardasil continues to be safe and effective, and that its benefits continue to outweigh its risks:

- CDC has not changed its recommendations for use of Gardasil.
- FDA has not made any changes to the Warnings or Precautions sections in the vaccine's prescribing information related to safety.

How is Gardasil's safety being monitored?

- FDA and CDC closely monitor the safety of all vaccines through VAERS, which receives unconfirmed reports of possible side effects following the use of vaccines licensed in the United States.
- Each batch (known as a "lot") of Gardasil is manufactured and tested for quality control according to the requirements of its FDA license. FDA verifies this, as it does with other vaccines, by performing a lot-by-lot batch review process.
- FDA's review assures the appropriateness of manufacturing processes and confirmation of testing results. It also includes regular unannounced on-site inspections.
- No batch may be released for distribution until it has successfully completed all testing and review requirements.
- FDA analyzes possible side effects associated with individual lots to look for any unusual patterns.

CDC also has other systems in place to monitor the safety of all licensed vaccines. FDA

This article appears on FDA's Consumer Health Information Web page (*www.fda.gov/consumer*), which features the latest updates on FDA-regulated products. Sign up for free e-mail subscriptions at *www.fda.gov/consumer/consumerenews.html.*

For More Information

CDC and FDA Information on Gardasil's Safety
www.fda.gov/cber/safety/gardasil071408.htm

Vaccine Adverse Event Reporting System (VAERS) Web site
www.vaers.hhs.gov

FDA Press Release (Sept. 12, 2008): Approval of Expanded Uses for Gardasil to Include Preventing Certain Vulvar and Vaginal Cancers
www.fda.gov/bbs/topics/NEWS/2008/NEW01885.html