

HPV Vaccine is Safe – (Gardasil)

09/09/2015 CS256663A

What are HPV Vaccines?

HPV vaccines protect against certain cancers caused by human papillomavirus (HPV) infection. HPV infection can cause cervical, vaginal, and vulvar cancers in women and penile cancer in men. HPV can also cause anal cancer, throat (oropharyngeal) cancer, and genital warts in both men and women. There are currently three HPV vaccines available for use in the United States. This fact sheet summarizes what we know about the safety of Gardasil, one of the available HPV vaccines.

How Do I Know HPV Vaccine is Safe?

As with all approved vaccines, CDC and the Food and Drug Administration (FDA) closely monitor the safety of HPV vaccine to identify **adverse events** and **side effects**. Pre-licensure clinical trials and data collected after the vaccine was made available show that it is very safe.

Adverse event: a health problem that happens after vaccination that may or may not be caused by a vaccine.

Side effect: a health problem that has been shown to be linked to a vaccine by scientific studies.

What Are the Side Effects?

HPV vaccine is very safe, and it is effective at protecting against some HPV types that cause cancer. Vaccines, like any medicine, can have side effects. Many people who get HPV vaccine have no side effects at all. Some people report having very mild side effects, like a sore arm from the shot. The most common side effects are usually mild.

Common Side Effects of HPV Vaccines

- Pain, redness, or swelling in the arm where the shot was given
- Headache or feeling tired
- Fever
- Nausea
- Muscle or joint pain

Understanding HPV Vaccine Safety Studies and Monitoring

It is important to understand the following when reading about HPV vaccine safety studies:

Anyone can report side effects and adverse events.

CDC and FDA maintain a vaccine safety monitoring system called the [Vaccine Adverse Event Reporting System \(VAERS\)](#). VAERS accepts reports from anyone, including doctors, patients, and parents. While VAERS provides useful information on vaccine safety, the data have limitations. It is generally not possible to use VAERS to determine whether a vaccine caused an adverse event.

HPV vaccine has many of the same, mild side effects as other vaccines.

Common, mild side effects reported during HPV vaccine safety studies include pain in the arm where the shot was given, fever, dizziness and nausea. These are similar to side effects seen with other vaccines.

Some preteens and teens might faint after getting the HPV vaccine or any shot. People should sit or lie down for about 15 minutes after getting a shot. This can help prevent fainting.

CDC has carefully studied the risks of HPV vaccination.

HPV vaccination is recommended because the benefits, such as prevention of cancer, far outweigh the risks of possible side effects.

Benefits

Cancer Prevention

- Cervical, vaginal, and vulvar
- Likely penile cancer in men
- Likely anal and oropharyngeal cancer in women and men

Potential Risks

- Chance of fainting
- Pain, redness, or swelling in the arm where the shot was given



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What Do the Studies Say?

Scientists at CDC and FDA continuously monitor the safety of HPV vaccine. While monitoring activities help identify possible side effects and adverse events, they do not prove the side effects were caused by Gardasil.

- [Monitoring](#) by CDC and FDA in 2009 revealed most side effects reported after receiving HPV vaccine were non-serious, including: fainting; dizziness; nausea; headache; and pain, swelling, or redness in the arm where the shot was given.

Formal studies have also looked at whether or not specific adverse events can be linked to Gardasil:

- A 2011 [study](#) found women and girls who received Gardasil were no more at risk of allergic reactions, anaphylaxis (severe allergic reaction), Guillain-Barré Syndrome (GBS), stroke, blood clots, appendicitis, or seizures than those who were unvaccinated or who received other vaccines.
- A 2012 [study](#) that looked at when adverse events occur found Gardasil may be associated with skin infections where the shot is given during the two weeks after vaccination and fainting on the day the shot is received.
- A 2013 [study](#) that included almost 1 million girls found Gardasil was not associated with blood clots or adverse events related to the autoimmune and brain systems.
- A 2014 [study](#) that included over 1 million women found Gardasil was not associated with venous thromboembolism, also called VTE or blood clots.

Several studies have shown that there is no relationship between Gardasil and [autoimmune disorders](#):

- A 2012 [study](#) and a 2014 [study](#) both found women and girls who received the Gardasil shot were not more likely to develop autoimmune disorders than those who were unvaccinated.
- A 2015 [study](#) found women and girls who received Gardasil were not more likely than those who were unvaccinated to develop multiple sclerosis (MS) or other similar diseases.

Gardasil is not recommended during pregnancy. However, some women may receive the Gardasil shot before realizing they are pregnant. There have been several studies that found pregnant women who received Gardasil did not experience any problems:

- A 2015 [study](#) found no safety concerns for pregnant woman who received Gardasil, or for their babies.
- The Gardasil Pregnancy Registry, maintained by the manufacturer, received many reports of pregnant women who were vaccinated, and found no evidence that the vaccine affects fertility, pregnancy, or the health of the baby.

Related Scientific Articles

Arnheim-Dahlström L, Pasternak B, Svanström H, Sparén P, Hviid A. [Autoimmune, neurological, and venous thromboembolic adverse events after immunisation of adolescent girls with quadrivalent human papillomavirus vaccine in Denmark and Sweden: Cohort study](#). *BMJ*. 2013 Oct;347:f5906.

Chao C, Klein NP, Velicer CM, Sy LS, Slezak JM, Takhar H, et al. [Surveillance of autoimmune conditions following routine use of quadrivalent human papillomavirus vaccine](#). *J Intern Med*. 2012 Feb; 271(2):193-203. Epub 2011 Nov.

Gee J, Naleway A, Shui I, Baggs J, Yin R, Li R, et al. [Monitoring the safety of quadrivalent human papillomavirus vaccine: Findings from the Vaccine Safety Datalink](#). *Vaccine*. 2011 Oct; 29(46):8279-84.

Grimaldi-Bensouda L, Guillemot D, Godeau B, Benichou J, Lebrun-Frenay C, Papeix C, et al. [Autoimmune disorders and quadrivalent human papillomavirus vaccination of young female subjects](#). *J Intern Med*. 2014 Apr; 275(4):398-408. Epub 2013 Nov 22.

Klein NP, Hansen J, Chao C, Velicer C, Emery M, Slezak J, et al. [Safety of quadrivalent human papillomavirus vaccine administered routinely to females](#). *Arch Pediatr Adolesc Med*. 2012 Dec; 166(12):1140-8.

Macartney KK, Chiu C, Georgousakis M, Brotherton JM. [Safety of human papillomavirus vaccines: A review](#). *Drug Saf*. 2013 Jun; 36(6):393-412.

Markowitz LE, Dunne EF, Saraiya M, Chesson HW, Curtis CR, Gee J, et al. [Human papillomavirus vaccination: Recommendations of the Advisory Committee on Immunization Practices \(ACIP\)](#). *MMWR* 63(RR05);1-30

Moro PL, Zheteyeva Y, Lewis P, Shi J, Yue X, Museru OI, et al. [Safety of quadrivalent human papillomavirus vaccine \(Gardasil®\) in pregnancy: Adverse events among non-manufacturer reports in the Vaccine Adverse Event Reporting System, 2006-2013](#). *Vaccine*. 2015 Jan; 33(4): 519-22.

Scheller NM, Pasternak B, Svanström H, Hviid A. [Quadrivalent human papillomavirus vaccine and the risk of venous thromboembolism](#). *JAMA*. 2014 Jul;312(2):187-8.

Scheller NM, Svanström H, Pasternak B, Arnheim-Dahlström L, Sundström K, Katharina Fink K, et al. [Quadrivalent HPV vaccination and risk of multiple sclerosis and other demyelinating diseases of the central nervous system](#). *JAMA*. 2015 Jan; 313(1):54-61.

Slade BA, Leidel L, Vellozzi C, Woo EJ, Hua W, Sutherland A, et al. [Postlicensure safety surveillance for quadrivalent human papillomavirus recombinant vaccine](#). *JAMA*. 2009; 302(7):750-7

The Centers for Disease Control and Prevention, American Academy of Family Physicians, and American Academy of Pediatrics strongly recommend children receive all vaccines according to the recommended schedule.