

Provider Talking Points for HPV Vaccine

Provider Response Statement

Sometimes people are diagnosed with health problems after vaccination, but this does not mean the vaccine caused the health problem – there are usually other causes. In fact, tens of millions of doses of HPV vaccine have been given safely, and most people who get the vaccine have mild side effects (like a sore arm from the shot) or no side effects at all. Not getting HPV vaccine for your child leaves them vulnerable to HPV cancers later in life. I've vaccinated my children (or grandchildren, etc.) and I recommend that your child begin the HPV vaccine series today.

Key Messages

- It's natural to worry about your child's health. As a parent, you might even have concerns about the safety of medical products and procedures recommended for your child. Vaccines – including human papillomavirus (HPV) vaccines – are some of the safest medical products available for use in the United States because they are held to the highest standard of safety.
- Years of testing are required by law before vaccines can be licensed. Vaccines are carefully monitored even after they are licensed to ensure that they are very safe. ***The benefits of vaccination far outweigh any potential risk of side effects.*** For HPV vaccines, those benefits include cancer prevention, and the potential side effects are mild, like a sore arm where the shot was given.
- Sometimes a person does get sick after getting a vaccine. While this is unfortunate, it does not mean that the vaccine caused the health problem. Health problems actually caused by vaccines are very rare and are usually related to preexisting conditions or contraindications. These include:
 - Anyone who has had a severe, life-threatening allergic reaction to a dose of HPV vaccine should not get another dose.
 - Anyone who has a severe (life threatening) allergy to any component of HPV vaccine should not get the vaccine. *Tell your doctor if you have any severe allergies that you know of, including a severe allergy to yeast.*
 - HPV vaccine is not recommended for pregnant women. If you learn that you were pregnant when you were vaccinated, there is no reason to expect any problems for you or the baby. Any woman who learns she was pregnant when she got this HPV vaccine is encouraged to contact the manufacturer's registry for HPV vaccination during pregnancy at 1-800-986-8999. Women who are breastfeeding may be vaccinated.
 - If you have a mild illness you can probably get the vaccine today. If you are moderately or severely ill, you should probably wait until you recover. Your doctor can advise you.
- To protect your child's health, it's important to have the facts. The facts are:
 - HPV vaccines are safe. Most side effects related to HPV vaccination are mild, like soreness in the arm where the shot was given.
 - HPV vaccines are cancer prevention. HPV vaccination protects your child from HPV infections that cause cancer.

HPV vaccines are cancer prevention

- HPV is short for human papillomavirus. There are more than 40 HPV types that infect human mucosal surfaces, mostly the genitals and mouth/throat. Although most infections will go away naturally, some infections that don't go away can cause cancers in men and women.
- HPV vaccines are life-saving vaccines that protect against HPV infections that cause most cases of cervical cancer and many cases of less common cancers including cancers of the anus, penis, vulva, vagina, and oropharynx (back of the throat, including the base of the tongue and tonsils).
- About 79 million people in the U.S., most in their teens and early 20s, are infected with HPV. About 14 million people become infected every year. With such high rates of infection, preteens and teens need the HPV vaccine now to prevent HPV cancers later in life.

HPV vaccines are safe

- All vaccines used in the United States are required to go through years of extensive safety testing before they are licensed by the U.S. Food and Drug Administration (FDA). Each HPV vaccine recommended for your child was tested during clinical trials before being licensed and was found to be safe and effective. Before licensing:
 - Gardasil 9 (9-valent HPV vaccine) was studied in more than 15,000 males and females.
 - Gardasil (quadrivalent HPV vaccine) was studied in more than 29,000 males and females.
 - Cervarix (bivalent HPV vaccine) was studied in more than 30,000 females.
- After a vaccine is approved, FDA and CDC continue to monitor its safety for any possible side effects (adverse events), especially for rare events that might not have been identified in the pre-licensure clinical trials. It is important to always keep in mind “adverse events” include a number of scenarios and do not always mean a vaccine caused a health problem.

Adverse Event

An “adverse event” is any health problem that happens after a shot or other vaccine. An adverse event might be truly caused by a vaccine, or it might be pure coincidence. Adverse events include:

True reactions to the vaccine

These reactions include both common, known **side effects** and more serious reactions, like allergic reactions.

Unrelated events.

These are experiences that would have occurred even if the person had not been vaccinated. They happen after vaccination but are not caused by the vaccine.

Reactions related to mistakes in vaccine preparation, handling, or administration

These can happen because of an oversight on the manufacturer's behalf or if a doctor makes a mistake when storing or giving a vaccine.

Events that cannot be related directly to the vaccine

The cause of these events is unknown, and there is not enough evidence to say they are caused by a vaccine.

Side Effect

A side effect is any health problem shown by studies to be caused by a vaccine. Like any medication, vaccines can cause side effects. Usually vaccine side effects are minor (for example, a sore arm where a shot was given or a low-grade fever after a vaccine) and go away on their own within a few days

- Approximately 67 million doses of Gardasil were distributed in the U.S. from June 2006 (when the vaccine was first licensed by FDA) through March 2014.

- CDC and FDA have no concerns about the safety of Gardasil after years of vaccine safety studies and monitoring activities since Gardasil was licensed in 2006.
- Adverse events reported after HPV vaccination are similar to those reported after other vaccines recommended for adolescents, including meningococcal conjugate and Tdap vaccination.
- Ongoing vaccine safety monitoring and research have confirmed Gardasil's safety profile. CDC and FDA have monitored Vaccine Adverse Event Reporting System (VAERS) reports related to Gardasil, and studies have searched for associations between vaccination and many specific health problems.
 - [Monitoring](#) by CDC and FDA in 2009 revealed most side effects reported after receiving Gardasil were non-serious, including: fainting; dizziness; nausea; headache; and pain, swelling, or redness in the arm where the shot was given.
 - A 2011 [study](#) found women and girls who received Gardasil were no more at risk of allergic reactions, severe allergic reactions (anaphylaxis), Guillain–Barré Syndrome (GBS), stroke, blood clots, appendicitis, seizures, or fainting (syncope) than those who were unvaccinated or who received other vaccines.
 - 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 2013 [study](#) that included almost 1 million girls found Gardasil was not associated with blood clots or adverse events related to the immune and nervous systems.
 - A 2014 [study](#) that included over 1 million women found Gardasil was not associated with venous thromboembolism, also called VTE or blood clots.
 - 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 neurodegenerative diseases.

HPV vaccines are not associated with cerebral vasculitis

- In 2012, [CDC convened a Clinical Immunization Safety Assessment \(CISA\) working group](#) to review previous findings that 2 deaths related to cerebral vasculitis – also called central nervous system (CNS) vasculitis – occurred in association with HPV vaccination.
- On review, the panel, which included medical doctors and research scientists, identified scientific concerns with the authors' suggestions. The panel found:
 - The authors did not clearly discuss their methods and the methods that were discussed were not adequate for accurately identifying CNS vasculitis in brain tissue.
 - There was a lack of evidence to support the authors' claims that the two patients had CNS vasculitis or that the deaths were caused by the HPV vaccine

References

1. Arnheim-Dahlström L, Pasternak B, Svanström H, Sparén P, Hviid A. [Autoimmune, neurological, and venous thromboembolic adverse events after immunization of adolescent girls with quadrivalent human papillomavirus vaccine in Denmark and Sweden: Cohort study.](#) *BMJ*. 2013 Oct; 347:f5906.
2. 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.
3. 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.
4. 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.
5. 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.
6. 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.
7. 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-