Centers for Disease Control and Prevention

Vaccine Safety

Vaccine Safety Home

Human Papillomavirus (HPV) Vaccine

Safety Information

About HPV

Human papillomavirus (HPV) is the most common sexually transmitted infection in the United States. The virus is spread through intimate skin-to-skin contact. HPV infections are so common that nearly all men and women will get at least one type of HPV at some time in their lives. Most infections are asymptomatic and become undetectable, but some can be persistent and can progress to cancer in both women and men later in life.

HPV infections that do not go away can cause:

- Cervical, vaginal, and vulvar cancers (in women)
- Penile cancer (in men)
- Anal cancer
- Cancer of the back of the throat (oropharynx)
- Genital warts

Learn more about HPV

There is a safe and effective HPV vaccine that can prevent the infections that most commonly cause cancer.

Available Vaccine

Vaccine Information Statements

Vaccine Information Statements (VISs) are information sheets produced by CDC that explain both the benefits and risks of a vaccine.

HPV

Human papillomavirus vaccine (Gardasil 9)

There is one licensed HPV vaccine available in the United States.

Gardasil 9 (human papillomavirus 9-valent vaccine, recombinant; 9vHPV) was approved by FDA for use in 2014. The safety of Gardasil 9 was studied in clinical trials with more than 15,000 participants before it was licensed and continues to be monitored. Gardasil 9 protects against 9 types of cancer-causing HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58.

For HPV vaccine to be most effective, the series should begin prior to exposure to HPV.

Who Should Get HPV Vaccine

CDC recommends HPV vaccination for all boys and girls at ages 11-12 to protect against HPV-related infections and cancers. Anyone starting the series before the age of 15 should receive two doses of HPV vaccine, with at least six months between the first and second doses. Adolescents who receive the two doses less than five months apart will require a third dose of HPV vaccine.

Talk with your healthcare provider about vaccines.

They can answer questions and offer advice based on your specific health needs.

CDC recommends HPV vaccination for everyone through age 26 years, if not vaccinated already. Teens and young adults who start the series at ages 15 through 26 years still need three doses of HPV vaccine. Three doses are also recommended for people with certain immunocompromising conditions ages 9 through 26 years.

Some adults age 27 through 45 years who are not already vaccinated may decide to get HPV vaccine after speaking with their doctor about their risk for new HPV infections and the possible benefits of vaccination. HPV vaccination in this age range provides less benefit, as more people have already been exposed to HPV.

For more information, see Who should get HPV Vaccine.

Child and Adult Immunization Schedules
Get CDC's official recommended immunization schedules for children, adolescents, and adults.

Manufacturer Package Insert

Gardasil 9 [PDF – 25 pages] : The Food and Drug Administration (FDA) approved this vaccine in 2014. It is approved for use in children at age 9.

Common Side Effects

HPV vaccine is safe and effective at preventing HPV-related infections and cancers. Vaccines, like any medicine, can have side effects. Many people who get the HPV vaccine have no side effects at all. The most common side effects are usually mild, like a sore arm from the shot.

Severe allergic reactions following vaccination are rare, but can be life threatening.
Symptoms of a severe allergic reaction can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness.

If such reactions occur, call 9-1-1 and get the person to the nearest hospital.

HPV Vaccine (Gardasil 9)

Common Side Effects

- Pain, redness, or swelling in the arm where the shot was given
- Fever

- Headache or feeling tired
- Nausea
- Muscle or joint pain

Who Should Not Get the HPV Vaccine

People should not get HPV vaccine if they:

- Have ever had life-threatening allergic reaction to any component of HPV vaccine, or to a previous dose of HPV vaccine
- Are pregnant

HPV vaccine is not recommended for pregnant women. However, receiving HPV vaccine when pregnant is not cause for alarm. If a woman is found to be pregnant after starting the HPV vaccine series, second and/or third doses should be delayed until she is no longer pregnant. Women who are breastfeeding may get the vaccine.

People should talk their healthcare provider before getting HPV vaccine if they:

- Have severe allergies, including an allergy to yeast

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting HPV vaccine.

In some cases, your healthcare provider may decide to postpone HPV vaccination to a future visit.

More information about contraindications and precautions.

More Information

Frequently Asked Questions about HPV Vaccine Safety

Learn more about the safety of HPV vaccine.

Who Should NOT Get These Vaccines?

Some people should not get certain vaccines or should wait before getting them. Read the CDC guidelines for each vaccine.

HPV Vaccine – ACIP Recommendations and Guidance

Official guidance on HPV vaccine from the Advisory Committee on Immunization Practices (ACIP).

HPV Resources for Clinicians

Information for healthcare professionals: how to recommend and answer questions about HPV vaccination.

Report Possible Adverse Events To VAERS

The Vaccine Adverse Event Reporting System (VAERS) is an early warning system, co-managed by CDC and FDA, that monitors for potential vaccine safety problems.

Healthcare providers and vaccine manufacturers are required by law to report certain adverse events following vaccination to VAERS; patients and caregivers can also submit reports.

For more information, see Report an Adverse Event to VAERS .

A Closer Look at the Safety Data

Findings from many vaccine safety monitoring systems and more than 160 studies have shown that HPV vaccines have a favorable safety profile—the body of scientific evidence overwhelmingly supports their safety.

- In November 2019, initial post-licensure safety monitoring of Gardasil 9 was published in *Pediatrics*. In two separate articles, analyses from the Vaccine Adverse Event Reporting System (VAERS) and the Vaccine Safety Datalink (VSD) were presented. Both included multiple years of data, and did not identify any unexpected safety problems with Gardasil 9. These findings support the favorable safety profile that was established in pre-licensure clinical trials.
    - **Analysis from VAERS:** Researchers reviewed 7,244 reports submitted to the Vaccine Adverse Event Reporting System following HPV vaccination from December 2014 through December 2017. Of those reports, around 97% were classified as non-serious; around 3% were considered serious. The analysis did not detect any new or unexpected safety concerns. **Source:** Safety of the 9-Valent Human Papillomavirus Vaccine. [Pediatrics. 2019]
    - **Analysis from VSD:** The Vaccine Safety Datalink conducted near-real time surveillance from October 2015 through October 2017, looking at 11 pre-specified adverse events. During this two-year time period, nearly 840,000 doses were administered to people aged 9-26 years at six VSD sites. No new safety concerns were identified. **Source:** Near Real-Time Surveillance to Assess the Safety of the 9-Valen Human Papillomavirus Vaccine. [Pediatrics 2019]

- In 2014, before Gardasil 9 was licensed by the FDA, its safety was evaluated across seven studies. The safety findings from these pre-licensure studies show that Gardasil 9 has a similar safety profile to Gardasil, an earlier version of the vaccine. The main findings from these studies:
    - The most common side effect reported was pain, swelling, and redness in the arm where the shot was given.
    - These mild side effects may occur more often after Gardasil 9 vaccination than after Gardasil. Women and girls who received Gardasil 9 reported higher rates of swelling and redness where the shot was given than those who received Gardasil. Reports of swelling and redness also increased with each following dose for those receiving Gardasil 9.

- In 2014, CDC published a report analyzing health events reported to VAERS following Gardasil vaccination from June 2006 through March 2014. About 92% of the Gardasil reports were classified as non-serious. The most common adverse events reported were:
    - Syncope (fainting)
    - Dizziness
    - Nausea
    - Headache
    - Fever
    - Injection site reactions (pain, swelling, and redness)

  Although rare, fainting was found to happen after HPV vaccination. In response, FDA changed Gardasil's guidance for doctors to include information about preventing falls and injuries from fainting. CDC and the Advisory Committee on Immunization Practices included this guidance in the recommendations for HPV vaccination. Based on these recommendations, healthcare professionals should administer HPV vaccinations while the patient is seated or lying down.

  The patient should then remain seated and be observed for 15 minutes. CDC continues to remind doctors and nurses to observe this guidance and to share this information with all their patients.
  Source: Human Papillomavirus Vaccination: Recommendations of the Advisory Committee on Immunization Practices (ACIP). [MMWR. 2014]

- In 2011, the Institute of Medicine (IOM) reviewed published and unpublished studies of the safety of eight vaccines, including HPV. The published report, Adverse Effects of Vaccines: Evidence and Causality, concluded:

- Syncope (fainting) may be caused by injected vaccines, including HPV vaccines.
- Very rarely, any vaccine, including HPV vaccine, can cause anaphylaxis. Some people are allergic to certain ingredients in vaccines. As recommended by ACIP, people who experienced a severe allergic reaction (e.g., anaphylaxis) to a previous vaccine dose or to a vaccine component, including yeast, should not receive the HPV vaccine.
  Source: Adverse Effects of Vaccines: Evidence and Causality. [Institute of Medicine. 2011]

Which adverse events are considered "serious?"

By the Code of Federal Regulations (CFR) Title 21, an adverse event is defined as serious if it involves any of the following outcomes:

- Death
- A life-threatening adverse event
- A persistent or significant disability or incapacity
- A congenital anomaly or birth defect
- Hospitalization, or prolongation of existing hospitalization

Learn more about adverse events.

How CDC Monitors Vaccine Safety

CDC and FDA monitor the safety of vaccines after they are approved or authorized. If a problem is found with a vaccine, CDC and FDA will inform health officials, health care providers, and the public.

CDC uses 3 systems to monitor vaccine safety:

- The Vaccine Adverse Event Reporting System (VAERS): an early warning system, co-managed by CDC and FDA, to monitor for potential vaccine safety problems. Anyone can report possible vaccine side effects to VAERS.
- The Vaccine Safety Datalink (VSD): a collaboration between CDC and 13 healthcare organizations that conducts vaccine safety monitoring and research.
- The Clinical Immunization Safety Assessment (CISA) Project: a partnership between CDC and several medical research centers that provides expert consultation and conducts clinical research on vaccine-associated health risks.

Related Scientific Articles

2019

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