

[Skip directly to search](#) [Skip directly to A to Z list](#) [Skip directly to navigation](#) [Skip directly to site content](#) [Skip directly to page options](#)  
[CDC Home](#)



[CDC 24/7: Saving Lives. Protecting](#)

[People.™](#)

Search The CDC



# Vaccine Safety

## Vaccine Safety

- [Vaccines Safety Basics](#)
  - [Diphtheria, Tetanus, and Pertussis Vaccines: DTaP, Td, and Tdap](#)
  - [Haemophilus Influenzae Type B \(Hib\)](#)
    - [Hib Summary](#)
  - [Human Papillomavirus \(HPV\)](#)
    - [FAQs about HPV Vaccine Safety](#)
    - [FAQ: Gardasil Vaccine recall](#)
    - [JAMA Report Summary](#)
    - [Information from FDA and CDC on Gardasil and its Safety \(Archived\)](#)
  - [Measles, Mumps, Rubella \(MMR\)](#)
    - [MMR Vaccine Safety Studies](#)
  - [Measles, Mumps, Rubella, Varicella \(MMRV\)](#)
    - [Information on the VSD MMRV Vaccine Safety Study](#)
    - [MMRV Vaccine Safety Studies](#)
    - [MMRV and Febrile Seizures](#)
  - [Rotavirus](#)
  - [Varicella](#)
- [Addressing Common Concerns](#)
  - [Adjuvants](#)
  - [Autism](#)
    - [Vaccine not associated with autism](#)
    - [CDC Statement: 2004 Pediatrics Paper](#)
  - [CDC Statement on Pandemrix](#)
  - [Fainting \(Syncope\)](#)
    - [FAQs about Fainting \(Syncope\) After Vaccination](#)
  - [Childhood Vaccines and Febrile Seizures](#)
    - [Influenza Season 2012-2013](#)
    - [Influenza Season 2010-2011](#)
  - [GBS](#)
    - [GBS and Menactra Meningococcal Vaccine](#)
    - [FAQs about GBS and Menactra Meningococcal Vaccine](#)
  - [IOM Assessment of Studies on Childhood Immunization Schedule](#)
  - [IOM Report on Adverse Effects of Vaccines](#)
  - [Pregnancy and Influenza Vaccine Safety](#)
  - [Sudden Infant Death Syndrome \(SIDS\)](#)
  - [Thimerosal](#)

[CDC Study on Thimerosal and Risk of Autism](#)

- [Infant & Environmental Exposures to Thimerosal](#)
- [FAQs about Thimerosal](#)
- [Timeline: Thimerosal in Vaccines \(1999-2010\)](#)
- [Publications](#)
- [FAQs about Hep B and Multiple Sclerosis \(MS\)](#)
- [FAQs about Multiple Vaccines and the Immune System](#)
- [FAQs about Vaccine Recalls](#)
- [FAQs about Vaccine Safety](#)
- [Vaccine Monitoring](#)
  - [History of Vaccine Safety](#)
- [Activities](#)
  - [About Immunization Safety Office \(ISO\)](#)
    - [Scientific Agenda](#)
    - [Scientific Agenda Archive](#)
  - [Clinical Immunization Safety Assessment \(CISA\) Project](#)
    - [CISA Clinician Resources](#)
    - [CISA Evaluation](#)
    - [Current Studies](#)
    - [Historical Background 2001-2012](#)
    - [Publications & Technical Reports](#)
      - [Technical Reports](#)
  - [Emergency Preparedness](#)
    - [Smallpox](#)
    - [Swine Flu](#)
  - [Vaccine Adverse Event Reporting System \(VAERS\)](#)
    - [Summary of Adverse Events in Pregnant Women](#)
    - [VAERS Print and Web Material](#)
    - [Publications](#)
  - [Vaccine Safety Datalink \(VSD\)](#)
    - [Accessing Data from VSD](#)
    - [Guidelines for VSD Data Sharing](#)
    - [Publications](#)
    - [Rapid Cycle Analysis](#)
  - [Archived Activity Documents](#)
    - [Archived History of Vaccine Safety](#)
- [Specific Groups of People](#)
  - [Vaccine Safety Information for Parents](#)
- [Resource Library](#)
  - [2013-2014](#)
  - [2011-2012](#)
  - [2010](#)
  - [2009](#)
  - [2008](#)
  - [2007](#)
  - [2006](#)
  - [2005](#)
  - [2004](#)
  - [2003](#)
  - [2002](#)
  - [2001](#)
  - [2000](#)

## HPV Related Quick Links

- [HPV Vaccine Information Statement \(VIS\)](#)

- [Who Should Not Get Vaccinated](#)
- [HPV and HPV Disease Information](#)
- [FDA HPV Vaccine Information](#)
- [To Report an Adverse Event in VAERS](#)
- [Related Information on Guillain-Barré Syndrome](#)
- [Vaccine Safety](#)
- [Vaccines Safety Basics](#)

[Share/Compartir](#)

# Human Papillomavirus (HPV) Vaccine

## On this Page

- [How CDC Monitors HPV Vaccine Safety](#)
- [Gardasil Vaccine Lot Recalled](#)
- [A Closer Look at the Safety Data](#)
- [Resources](#)
- [Related Science](#)

Approximately 79 million Americans are infected with human papillomavirus (HPV), and approximately 14 million people will become newly infected each year. Some HPV types can cause cervical, vaginal, and vulvar cancer among women, penile cancer among men, and anal and some oropharyngeal cancers among both men and women. Other HPV types can cause genital warts among both sexes. Each year in the United States an estimated 27,000 [new cancers attributable to HPV occur](#), 17,600 among females (of which 10,400 are cervical cancer) and 9,300 among males (of which 7,200 are oropharyngeal cancers).

There are, however, two HPV vaccines available (Gardasil® and Cervarix®) which protect against the types of HPV infection that cause most cervical cancers (HPV types 16 and 18). Both vaccines should be given as a three-shot series. Clinical trials and post-licensure monitoring data show that both vaccines are safe.

[CDC recommends HPV vaccination](#) [\[PDF - 225 KB\]](#) for the prevention of HPV infections responsible for most types of cervical cancer. As with all approved vaccines, CDC and the Food and Drug Administration (FDA) closely monitor the safety of HPV vaccines following licensure. Any problems detected with these vaccines will be reported to health officials, health care providers, and the public. Needed action will be taken to ensure the public's health and safety.

Read more: [HPV vaccination recommendations](#) [\[PDF - 225 KB\]](#) , [Cervarix®](#) , [Gardasil®](#) , [Vaccine Information Statements](#)

## How CDC Monitors HPV Vaccine Safety

Vaccines continue to be monitored for safety after they are licensed. Additionally, vaccine safety monitoring is of growing importance due to the development and use of new vaccines, expanded vaccine recommendations, and new global immunization initiatives. Following licensure, CDC and FDA primarily use three systems to monitor and evaluate the safety of vaccines, including HPV. These systems can detect rare adverse events that were not identified during pre-licensure clinical trials. The three systems are:

Young woman smiling



- The [Vaccine Adverse Event Reporting System \(VAERS\)](#) –an early warning public health system where people can report adverse health events following vaccination, that helps CDC and FDA detect possible new, unexpected, or increased trends in reported adverse events
- The [Vaccine Safety Datalink \(VSD\)](#) –a collaboration between CDC and several healthcare organizations which uses de-identified health records to monitor and evaluate adverse events following vaccination
- The [Clinical Immunization Safety Assessment \(CISA\) Project](#) -a collaboration between CDC and several medical research centers in the United States to conduct research to understand how adverse events might be caused by vaccines

Vaccine safety surveillance and other vaccine safety activities help ensure that U.S. vaccines are held to very high standards of safety.

## Gardasil Vaccine Lot Recalled

One lot of Gardasil® vaccine was recently recalled by the manufacturer, although no concerning adverse events have been seen among people vaccinated with this lot. For more information, click [here](#).

[Top of Page](#)

## A Closer Look at the HPV Vaccine Safety Data

### Vaccine Adverse Event Reporting System (VAERS)


In the United States, post-licensure vaccine safety monitoring and evaluation are conducted independently by federal agencies and vaccine manufacturers. From June 2006-March 2014, approximately 67 million doses of HPV vaccines were distributed and VAERS received approximately 25,000 adverse event reports occurring in girls and women who received HPV vaccines; 92% were classified as “non-[serious](#)



.”

The most commonly reported symptoms were:

- injection-site reactions
- dizziness
- syncope (fainting)
- nausea
- headache


To date, adverse events reported to VAERS are consistent with those identified during the vaccine’s pre-licensure clinical trials, and reporting patterns have remained unchanged, with no new concerns, since [a summary of VAERS reports was published in 2009](#) 

VAERS data continue to be routinely monitored and analyzed by CDC and FDA, with a detailed review of

every [serious](#)  VAERS report.


[Top of Page](#)

## Vaccine Safety Datalink (VSD)

In 2011, the CDC studied the occurrence of specific adverse events following more than 600,000 doses of Gardasil. Adverse events in the HPV vaccinated population were compared to another appropriate population (such as adolescents vaccinated with vaccines other than HPV) and included [Guillain–Barré syndrome \(GBS\)](#), stroke, venous thromboembolism (VTE), appendicitis, seizures, [syncope](#) (fainting), and allergic reactions. [None of these adverse events were found to be any more common after HPV vaccination than among their comparison groups](#) . Anaphylaxis, a very severe allergic reaction, was also included in this study. One confirmed case of anaphylaxis was identified out of 600,558 doses studied, a rate similar to what has been previously published for anaphylaxis following all childhood vaccines.

[Top of Page](#)

## Institute of Medicine








In 2011, the Institute of Medicine (IOM) produced a report, [Adverse Effects of Vaccines: Evidence and Causality](#) . In this report, they concluded that some people who receive injected vaccines, including HPV vaccine, experience syncope. This report also affirmed that anaphylaxis can occur in susceptible people after they receive of a variety of vaccines, including HPV vaccines. People with severe allergic reactions to any component of a vaccine should not receive that vaccine.

### Post-licensure safety monitoring from June 2006 through March 2014 continues to show:

- No new or unusual patterns of adverse events to suggest a HPV vaccine safety concern.
- [Syncope \(fainting\)](#) can occur among adolescents who receive vaccines, including HPV vaccine. To decrease the risk of falls and other injuries that might follow syncope, CDC's Advisory Committee on Immunization Practices (ACIP) recommends that clinicians consider [observing patients for 15 minutes after vaccination](#).


[Top of Page](#)


## Resources


- [Advisory Committee on Immunization Practices \(ACIP\) HPV Vaccine Recommendations](#)
- [JAMA Report Summary on HPV--Gardasil](#)
- [Frequently Asked Questions about HPV Vaccine Safety](#)
- [Information from FDA and CDC on the Safety of Gardasil](#) 
- [CDC Medscape Commentary: Safety Data on the HPV Vaccine—Reassure Your Patients](#) 
- [HPV Vaccine Information Statements](#)
- [Institute of Medicine \(IOM\) report: Adverse Effects of Vaccines: Evidence and Causality](#) 
- [Package Insert for Gardasil](#)  [PDF - 262 KB] 
- [Package Insert for Cervarix](#)  [PDF - 289 KB] 


[Top of Page](#)

## Related Science

Klein NP, Hansen J, Chao C et al. [Safety of quadrivalent human papillomavirus vaccine administered routinely to females](#)  . Arch Pediatr Adolesc Med 2012;166:1140-1148.

Chao C, Klein NP, Velicer CM et al. [Surveillance of autoimmune conditions following routine use of quadrivalent human papillomavirus vaccine](#)  . J Intern Med 2012;271:193-203.

Gee J, Naleway A, Shui I, Baggs J, Yinc R, Lic R, Kuldorff, M, Lewis E, Fireman B, Daley, MF, Klein NP, Weintraub ES. [Monitoring the safety of quadrivalent human papillomavirus vaccine: Findings from the Vaccine Safety Datalink](#)  , *Vaccine* 2011 Oct 26;Vol 29, Issue 46: 8279-8284.

Slade BA, Leidel L, Vellozzi C, Woo EJ, Hua J, Sutherland A, Izurieta HS, Ball R, Miller N, Braun MM, Markowitz LE, Iskander J. [Postlicensure safety surveillance for quadrivalent human papillomavirus recombinant vaccine.](#)  *JAMA* 2009 Aug 10;302(7):750-7.

Centers for Disease Control and Prevention (CDC) and ACIP. [Quadrivalent human papillomavirus vaccine. \[PDF - 444 KB\]](#) *MMWR* 2007 Mar 23; 56(RR-2).

[MMWR - FDA Licensure of Bivalent Human Papillomavirus Vaccine \(HPV2, Cervarix\) for Use in Females and Updated HPV Vaccination Recommendations from ACIP.](#)

[MMWR - FDA Licensure of Quadrivalent Human Papillomavirus Vaccine \(HPV4, Gardasil\) for Use in Males and Guidance from ACIP.](#)

[Top of Page](#)

- [Print page](#)

### Get email updates

To receive email updates about this page, enter your email address:

Submit Button Enter Email Address








[What's this?](#)

### Contact Us:

- Centers for Disease Control and Prevention  
1600 Clifton Rd  
Atlanta, GA 30333
- 800-CDC-INFO  
(800-232-4636)  
TTY: (888) 232-6348
- [Contact CDC-INFO](#)

### File Formats Help:

- 

- 
- 
- 
- 
- 
- 
- 

[How do I view different file formats \(PDF, DOC, PPT, MPEG\) on this site?](#)



- [Print](#)
- [Updates](#)
- Page last reviewed: August 18, 2014
- Page last updated: September 25, 2014
- Content source: [Centers for Disease Control and Prevention National Center for Emerging and Zoonotic Infectious Diseases \(NCEZID\) Division of Healthcare Quality Promotion \(DHQP\)](#)
- [Home](#)
- [A-Z Index](#)
- [Policies](#)
- [Using this Site](#)
- [Link to Us](#)
- [Contact CDC](#)



Centers for Disease Control and Prevention 1600 Clifton Road Atlanta, GA 30329-4027, USA  
800-CDC-INFO (800-232-4636) TTY: (888) 232-6348 - [Contact CDC-INFO](#)

[A-Z Index](#)

1. [A](#)
2. [B](#)
3. [C](#)
4. [D](#)
5. [E](#)
6. [E](#)
7. [G](#)
8. [H](#)
9. [I](#)
10. [J](#)
11. [K](#)
12. [L](#)
13. [M](#)
14. [N](#)
15. [O](#)
16. [P](#)
17. [Q](#)
18. [R](#)
19. [S](#)
20. [T](#)
21. [U](#)

- 22. [V](#)
- 23. [W](#)
- 24. [X](#)
- 25. [Y](#)
- 26. [Z](#)
- 27. <#>