Centers for Disease Control and Prevention
CDC 24/7: Saving Lives. Protecting People.™

Vaccine Safety

Human Papillomavirus (HPV) Vaccine

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 (/cancer/hpv/statistics/cases.htm), 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] (/vaccines/vpd-vac/hpv/downloads/dis-HPV-color-office.pdf) 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] (/vaccines/vpd-vac/hpv/downloads/dis-HPV-color-office.pdf), Cervarix® (http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm186957.htm) (http://www.cdc.gov/Other/disclaimer.html), Gardasil® (http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm094042.htm) (http://www.cdc.gov/Other/disclaimer.html), Vaccine Information Statements (http://www.cdc.gov/vaccines/hcp/vis/index.html)

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:

- The Vaccine Adverse Event Reporting System (VAERS) – (/vaccinesafety/Activities/vaers.html) 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) – (/vaccinesafety/Activities/vsd.html) 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 - (/vaccinesafety/Activities/CISA.html) 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 (http://www.cdc.gov/vaccinesafety/Vaccines/HPV/hpv_gardasil_recall.html).

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 (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=600.80) (http://www.cdc.gov/Other/disclaimer.html)."

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 (http://www.ncbi.nlm.nih.gov/pubmed/19690307) (http://www.cdc.gov/Other/disclaimer.html).

VAERS data continue to be routinely monitored and analyzed by CDC and FDA, with a detailed review of every serious (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=600.80) (http://www.cdc.gov/Other/disclaimer.html) VAERS report.

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) (/flu/protect/vaccine/guillainbarre.htm), stroke, venous thromboembolism (VTE), appendicitis, seizures, syncope (/vaccinesafety/Concerns/syncope_faqs.html) (fainting), and allergic reactions. None of these adverse events were found to be any more common after HPV vaccination than among their comparison groups (http://www.sciencedirect.com/science/article/pii/S0264410X11013831) (http://www.cdc.gov/Other/disclaimer.html). 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.

Institute of Medicine

In 2011, the Institute of Medicine (IOM) produced a report, *Adverse Effects of Vaccines: Evidence and Causality* (http://www.iom.edu/Reports/2011/Adverse-Effects-of-Vaccines-Evidence-and-Causality.aspx) (http://www.cdc.gov/Other/disclaimer.html). 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) (http://www.cdc.gov/vaccinesafety/Concerns/syncope_faqs.html) 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 (http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6002a1.htm).

Resources

- Advisory Committee on Immunization Practices (ACIP) HPV Vaccine Recommendations (/vaccines/hcp/acip-recs/vacc-specific/hpv.html)
- JAMA Report Summary on HPV--Gardasil (/vaccinesafety/Vaccines/HPV/jama.html)
- Frequently Asked Questions about HPV Vaccine Safety (http://www.cdc.gov/vaccinesafety/Vaccines/HPV/hpv_faqs.html)
- Information from FDA and CDC on the Safety of Gardasil (http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/VaccineSafety/ucm179549.htm) (http://www.cdc.gov/Other/disclaimer.html)
- CDC Medscape Commentary: Safety Data on the HPV Vaccine—Reassure Your Patients (http://www.medscape.com/viewarticle/722555) (http://www.cdc.gov/Other/disclaimer.html)
- HPV Vaccine Information Statements (http://www.cdc.gov/vaccines/pubs/vis/default.htm#HPV)
- Institute of Medicine (IOM) report: *Adverse Effects of Vaccines: Evidence and Causality* (http://www.iom.edu/Reports/2011/Adverse-Effects-of-Vaccines-Evidence-and-Causality.aspx) (http://www.cdc.gov/Other/disclaimer.html)
- Package Insert for Gardasil [PDF - 262 KB] (http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM111263.pdf) (http://www.cdc.gov/Other/disclaimer.html)
- Package Insert for Cervarix [PDF - 289 KB] (http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM186981.pdf) (http://www.cdc.gov/Other/disclaimer.html)

Related Science

Klein NP, Hansen J, Chao C et al. Safety of quadrivalent human papillomavirus vaccine administered routinely to females (http://www.ncbi.nlm.nih.gov/pubmed/23027469) (http://www.cdc.gov/Other/disclaimer.html). 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 (http://www.ncbi.nlm.nih.gov/pubmed/21973261) (http://www.cdc.gov/Other/disclaimer.html). J Intern Med 2012;271:193-203.

Gee J, Naleway A, Shui I, Baggs J, Yinc R, Lic R, Kulldorff, 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 (http://www.sciencedirect.com/science/article/pii/S0264410X11013831) (http://www.cdc.gov/Other/disclaimer.html), *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. (http://www.ncbi.nlm.nih.gov/pubmed/19690307) (http://www.cdc.gov/Other/disclaimer.html) *JAMA* 2009 Aug 10;302(7):750-7.

Centers for Disease Control and Prevention (CDC) and ACIP. Quadrivalent human papillomavirus vaccine. [PDF - 444 KB] (http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5602a1.htm) *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 (http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5920a4.htm) .

MMWR - FDA Licensure of Quadrivalent Human Papillomavirus Vaccine (HPV4, Gardasil) for Use in Males and Guidance from ACIP (http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5920a5.htm) .

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)

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

USA.gov Government Made Easy