

Human Papillomavirus (HPV) Vaccination

Maryland Department of Health

The Importance of Vaccines

Eliminating Vaccine-Preventable Disease for All Maryland Residents

The health of the community is everyone's responsibility. The mission of Maryland's Department of Health (MDH) is to work with Maryland's health care delivery system to promote and improve the health and safety of all Marylanders through disease prevention, access to care, quality management, and community engagement.¹ As part of the goal to prevent-disease for everyone, MDH strives for the reduction or elimination of vaccine-preventable diseases.

Vaccine Use Saves Lives

Diseases that were once common in this country and around the world, including polio, measles, diphtheria, pertussis (whooping cough), rubella (German measles), mumps, and tetanus can now be prevented by vaccination.²

Comparison of 20th Century Annual and 2013 Disease Morbidity (Incidence Count) in US³

Disease	20 th Century Annual Morbidity	2013 Reported Cases	% Decrease
Smallpox	29,005	0	100%
Diphtheria	21,053	0	100%
Pertussis	200,752	28,639	86%
Tetanus	580	26	96%
Polio	16,316	1	>99%
Measles	530,217	187	>99%
Mumps	162,344	584	>99%
Rubella	47,745	9	99%

Since coming into widespread use, vaccines have saved billions of lives. They have enhanced the quality of life, eliminated a huge burden of suffering and disability, and contributed to the length of life.⁴ While our grandparents and great grandparents may remember diseases such as Smallpox and Polio, the success of vaccination has spared younger generations from the devastating effects of these and other diseases.

Building Immunity from Disease

Immunity is the body's way of preventing disease. The immune system recognizes viruses and bacteria that enter the body as "foreign invaders" (called *antigens*) and produces proteins called *antibodies* to fight them. The first time a child is infected with a specific antigen, such as measles virus, the immune system produces antibodies designed to fight it. This takes time and usually the immune system can't work fast enough to prevent the antigen from causing disease, so the child still gets sick. However, the immune system "remembers" that antigen. If it ever enters the body again, even after many years, the immune

system is able to produce antibodies fast enough to keep it from causing disease a second time. This protection is called immunity.⁵

Vaccines contain the same antigens (or parts of antigens) that cause diseases but the antigens in vaccines are either killed, or weakened to the point that they don't cause disease. However, they *are* strong enough to make the immune system produce antibodies that lead to immunity. In other words, a vaccine is a *safer* substitute for a child's first exposure to a disease. The child gets protection without having to get sick. Through vaccination, children can develop immunity without suffering from the actual diseases that vaccines prevent.⁶

Community Immunity

Community immunity, sometimes called herd immunity, is a form of indirect protection from contagious diseases that occurs when a large percentage of a population becomes immune to an infection. In a population where a large number of people are immune, the spread of infection is likely to be disrupted which stops or slows the spread of the disease. As more individuals become immune, the smaller the probability that those who are not immune will come in contact with an infectious individual. Through vaccination efforts, community immunity exists for many contagious diseases. However, if the number of vaccinated individuals goes down, community immunity can be compromised.⁷

Creating and maintaining community immunity is especially important because there are members of the community who cannot be immunized. For example, newborn infants may be too young to receive certain vaccines. Also, some members of our community may be allergic to components of certain vaccines and cannot receive the vaccine. Lastly, people with a weak or compromised immune system, including those who have had an organ transplant, are HIV positive, have a current diagnosis of lymphoma or leukemia, or are undergoing chemotherapy are at increased risk of serious complications if they became infected. As a result, these members of the community rely on the protection from others who can be vaccinated to keep them safe.⁸

Preventing HPV Related Cancers

About HPV

HPV is a very common and widespread virus, consisting of more than 150 related viruses. Nearly everyone will be infected in their lifetime. In most cases, HPV infections go away on their own and do not cause any health problems. But when some HPV infections do not go away, they can cause cancer. More than 40 HPV types can be spread through intimate skin-to-skin contact.⁹

About 14 million new genital HPV infections occur each year. In fact, the Centers for Disease Control and Prevention (CDC) estimates that more than 90% of sexually active men and 80% of sexually active women will be infected with at least one type of HPV at some point in their lives. Around one-half of these infections are with a high-risk HPV type.¹⁰

- High-risk HPVs can cause cancer. About a dozen high-risk HPV types have been identified. Two of these, HPV types 16 and 18, are responsible for most HPV-caused cancers.
- Low-risk HPVs do not cause cancer but can cause skin warts on or around the genitals, anus, mouth, or throat. For example, HPV types 6 and 11 cause 90% of all genital warts. HPV types 6 and 11 also

cause recurrent benign tumors to grow in the air passages leading from the nose and mouth into the lungs.¹¹

Most high-risk HPV infections occur without any symptoms, go away within 1 to 2 years, and do not cause cancer. Some HPV infections, however, can persist for many years. Persistent infections with high-risk HPV types can lead to cell changes that, if untreated, may progress to cancer.¹²

HPV Related Cancers

Every year, over 27,000 women and men in the United States are affected by a cancer caused by HPV—that’s a new case every 20 minutes. Persistent HPV infection can cause various cancers including:

- **Cervical cancer:** The most common HPV cancer. Almost all cervical cancer is caused by HPV.
- **Vulvar cancer:** About 69% are linked to HPV.
- **Vaginal cancer:** About 75% are linked to HPV.
- **Penile cancer:** About 63% are linked to HPV.
- **Anal cancer:** About 91% are linked to HPV.
- **Cancer of the head and throat:** About 72% are linked to HPV. (Note: Many of these cancers may be related to tobacco and alcohol use)¹³

HPV Vaccines

HPV vaccination can prevent infection with the HPV types that most commonly cause these cancers. There are three licensed HPV vaccines currently available in the United States.

Available HPV Vaccines ¹⁴

Vaccine Name	Year Approved by FDA	Protection against HPV Types
Gardasil 9	2014	HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58
Gardasil	2006	HPV types 6, 11, 16, and 18
Cervarix	2009	HPV types 16 and 18

HPV Vaccination Recommendations

The CDC recommends the HPV vaccine be given to 11- to 12-year-old boys and girls so they are protected *before ever being exposed* to the virus. Research has shown that preteens have a better immune response to the vaccine than those in their late teens and early 20s. Also, the preteen years are a time when other vaccinations are given and when children are likely to still be getting regular medical check-ups.¹⁵

As of October 19, 2016, the CDC recommends that 11- to 14-year-olds receive two doses of HPV vaccine at least six months apart rather than the previously recommended three doses. Teens and young adults who start the series later, at ages 15 through 26 years, will continue to need three doses of HPV vaccine to protect against cancer-causing HPV infection.¹⁶ Teenage boys and girls who did not start or finish the HPV

vaccine series when they were younger should get it now. Young women can get the HPV vaccine through age 26, and young men can get vaccinated through age 21. The vaccine is also recommended for any man who has sex with men through age 26, and for men with compromised immune systems (including HIV) through age 26, if they did not get the HPV vaccine when they were younger.¹⁷

HPV Vaccine Effectiveness and Safety

The HPV vaccines, like all vaccines, goes through a rigorous process to ensure they are effective and safe. Prior to a vaccine being made available, clinical trials are carried out by the vaccine manufacturer and the Food and Drug Administration (FDA) study the results to make decisions as to whether a vaccine is safe, effective, and ready to be licensed for use. Although most common side effects of a vaccine are identified in studies before the vaccine is licensed, rare adverse events may not be detected in these studies. Therefore, the U.S. vaccine safety system continuously monitors for possible side effects after a vaccine is licensed. When millions of people receive a vaccine, less common side effects that were not identified earlier may be identified.¹⁸

HPV Vaccine Effectiveness

HPV vaccines have been shown to be highly effective in preventing infection with the types of HPV they target when given before initial exposure to the virus. In the trials that led to approval of Gardasil and Cervarix, these vaccines were found to provide nearly 100% protection against HPV types 16 and 18 and the cell changes that these persistent infections can cause. Gardasil 9 is as effective as Gardasil for the prevention of diseases caused by the four shared HPV types (6, 11, 16, and 18). The trials that led to approval of Gardasil 9 found it to be 97% effective in preventing cervical, vulvar, and vaginal disease caused by the five additional HPV types (31, 33, 45, 52, and 58) that it targets.¹⁹

Current studies have followed vaccinated individuals for ten years and show that there is no evidence of weakened protection over time.²⁰ Ongoing monitoring of effectiveness will continue and each vaccine currently on the market has been proven to maintain effectiveness since being introduced. Long-term studies of vaccine efficacy that are still in progress will help scientists better understand the total duration of protection.²¹

HPV Vaccine Side Effects

Vaccines, like any medicine, can have side effects. All of the HPV vaccines were tested in thousands of people around the world before they were approved. To date, all studies show no serious side effects caused by the vaccines, and no deaths have been the result of any HPV vaccine.²² Many people who get the HPV vaccine have no side effects at all. Some people report having very mild side effects, like a sore arm from the shot, fainting, nausea, or fever. The most common side effects are usually mild. Brief fainting spells and related symptoms (such as jerking movements) can happen after any medical procedure, including vaccination. Although fainting may have a variety of possible causes, it is often triggered by pain or anxiety. To keep people from getting hurt from fainting, a 15-minute waiting period for people of all ages is recommended after any vaccination. On very rare occasions, severe (anaphylactic) allergic reactions may occur after a vaccination. People with severe allergies to any component of a vaccine should not receive that vaccine.²³

Monitoring the Safety of HPV Vaccines

The CDC and FDA monitor the safety of vaccines after they are licensed. Three systems are used to monitor vaccine safety:

- The [Vaccine Adverse Event Reporting System \(VAERS\)](#) – A system that helps CDC and FDA monitor problems following vaccination. Adverse events reported to VAERS are not necessarily side effects caused by the vaccine. An adverse event is a health problem that happens after vaccination that may or may not be caused by a vaccine. It is also important to note that anyone can report suspected vaccine reactions and issues to VAERS. Given this, a report to VAERS does not necessarily mean a vaccine is the cause of the reported problem that occurred following vaccination.²⁴
- The [Vaccine Safety Datalink \(VSD\)](#) – A collaboration between CDC and several health care organizations that allows ongoing monitoring and proactive searches of vaccine-related data.
- The [Clinical Immunization Safety Assessment \(CISA\) Project](#) – A partnership between CDC and several medical centers that conduct clinical research on vaccine-associated health risks in certain groups of people.²⁵

In 2014, before it was licensed by the FDA, the safety of Gardasil 9 was evaluated across seven studies. The safety findings from these pre-licensure studies show it has a similar safety profile to Gardasil. The main findings from these studies are:

- 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.

The CDC also 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. Among the 8% of reports classified as serious, headache, nausea, vomiting, and fever were the most frequent reported symptoms. Ongoing HPV vaccine safety monitoring efforts include:

- Review of reports to VAERS to search for unusual adverse events or changing patterns of adverse events.
- Continued monitoring and research in VSD, including the new Gardasil 9 vaccine.
- Regular consultation with CISA experts, as needed, on clinically complex adverse events.²⁶

Importance of the HPV Vaccine

HPV vaccination is important because it protects against cancers caused by HPV infection. Extensive studies have shown that HPV vaccines are a very safe and effective way to protect against the HPV types that have been shown to cause cancer in both boys and girls.

Benefits and Potential Risks of the HPV Vaccine

Benefits	Potential Risks
<p><u>HPV Related Cancer Protection:</u></p> <ul style="list-style-type: none"> • Cervical, vaginal, and vulvar cancer in women • Anal cancer in men and women • Penile cancer in men • Oropharyngeal (throat) cancer in women and men 	<p><u>Common Side Effects:</u></p> <ul style="list-style-type: none"> • Pain, redness, or swelling in the arm where the shot was given • Chance of fainting • Nausea • Fever

HPV Vaccination Impact on Community Immunity

A recent study published by Cincinnati Children’s Hospital Center shows HPV vaccination not only protects vaccinated women from high risk HPV types that cause cancer, but it also shows evidence of population immunity for those who are not vaccinated. The study followed 3 groups of women from 2006 to 2014 and showed that the prevalence of the HPV types included in the vaccine decreased more than 90% in vaccinated women and more than 30% in unvaccinated women. This decrease in unvaccinated women suggests increases in HPV vaccination will provide greater population level protection.²⁷

Vaccine Financing

The HPV vaccine costs approximately \$130 per injection. Based on updated dose recommendations by the CDC, 11- to 14-year-olds would receive two doses at a total cost of approximately \$260. Teens and young adults who start the series later, at ages 15 through 26, would continue to need three doses at a total cost of approximately \$390.

- **Private Insurance**
 - The majority of people in the target age group for the HPV vaccine have private insurance. The Federal Affordable Care Act (ACA) requires all new private insurance plans to cover some recommended preventive services without consumer cost-sharing. The HPV vaccines for the recommended age groups of males and females are covered under this policy. In the case of Gardasil 9, it is estimated most plans will begin covering the new vaccine in January 2017.
 - Individuals who obtain insurance through the new health exchanges are also covered for the HPV vaccine without cost-sharing.
- **Public Financing**
 - **Vaccines for Children (VFC) Program** – This program covers vaccine costs for children and teens who don’t have insurance and for some children and teens who are underinsured. The VFC program provides free vaccines to children and teens younger than 19 years of age, who are either Medicaid-eligible, American Indian or Alaska Native, or uninsured.
 - **Medicaid** – The VFC pays for vaccinations for all children through age 18 with Medicaid. Women and men ages 19 and 20 with Medicaid are eligible for Medicaid coverage of all vaccines recommended by the Advisory Committee on Immunization Practices, including HPV vaccination, as an Early and Periodic Screening Diagnosis and Treatment program service.²⁸

HPV Vaccination Educational Resources

Parents should talk to their child's doctor to learn more about the HPV vaccine and other vaccinations.

When looking for information online, it is important to use reputable sources, such as:

- CDC (<https://www.cdc.gov/hpv/>)
- National Cancer Institute (<https://www.cancer.gov/about-cancer/causes-prevention/risk/infectious-agents/hpv-vaccine-fact-sheet>)
- American Cancer Society
(<http://www.cancer.org/cancer/cancercauses/othercarcinogens/infectiousagents/hpv/hpv-landing>)

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10. Source: <https://www.cancer.gov/about-cancer/causes-prevention/risk/infectious-agents/hpv-vaccine-fact-sheet>
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