



From the Texas Department of State Health Services Immunization Unit

*The goal of the Vaccine Advisory is to disseminate, in a timely manner, practical information related to vaccines, vaccine-preventable diseases, and the vaccine programs managed by the Immunization Branch. The Immunization Branch welcomes readers' input to improve the contents of this document.*

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## CDC Recommends Two HPV Shots for Younger Adolescents

The Centers for Disease Control and Prevention's (CDC's) Advisory Committee on Immunization Practices (ACIP) has updated its recommendation regarding the three injection series of HPV vaccination in adolescents, beginning at age 11–12 years. CDC now routinely recommends two doses of HPV vaccine for 11 or 12 year olds to prevent HPV cancers.

This advisory summarizes the new recommendations which became official on October 19, 2016 and are published in [Morbidity and Mortality Weekly Report \(MMWR\) / December 16, 2016 / 65\(49\);1405–1408](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6514a1.htm).

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## 1) Background and Surveillance

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Human papillomavirus (HPV) is the most common sexually transmitted infection in the United States. Almost every sexually active person will acquire HPV at some point in their lives. According to the CDC, there are about 79 million Americans currently infected with HPV and about 14 million new infections each year. An estimated 26,000 new HPV related cancers are diagnosed annually.

There are more than 150 types of human papillomaviruses. Some types of HPV can cause warts while others lead to cancer. HPV most commonly causes cancer of the cervix, however, it can also cause cancers of the vulva, vagina, penis, anus, back of the throat, base of the tongue, and the tonsils. HPV is most commonly transmitted through intimate skin-to-skin contact, including vaginal, anal, or oral sex. However, HPV can be transmitted by nonsexual routes as well, and can be passed even when an infected person has no signs or symptoms.

There are three different vaccines licensed by the Food and Drug Administration (FDA) to protect against HPV infection. The three vaccines are Cervarix® (HPV2), Gardasil® (HPV4), and Gardasil®9 (HPV9). The ACIP has not stated a preference for any of the HPV vaccines currently licensed in the United States. All HPV vaccines protect against HPV types 16 and 18 which cause approximately 66% of cervical cancers and the majority of other HPV-attributable cancers in the United States. HPV4 and HPV9 also protect against HPV types 6 and 11 which cause anogenital warts. HPV9 targets five additional cancer causing types, 31, 33, 45, 52, and 58, which account for about 15% of cervical cancers. HPV2 (Cervarix®) is not approved for use in males.

## 2) Summary of New ACIP Recommendations

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CDC and ACIP revised the recommendation after a thorough review of studies over several meetings. CDC and ACIP reviewed data from clinical trials showing two doses of HPV vaccine in younger adolescents (aged 9–14 years) produced an immune response similar or higher than the response in young adults (aged 16–26 years) who received three doses. On October 7, 2016, the U.S. Food and Drug Administration (FDA) approved adding a 2-dose schedule for 9-valent HPV vaccine (Gardasil® 9) for adolescents ages 9–14 years. CDC encourages clinicians to begin implementing the 2-dose schedule in their practice to protect their preteen patients from HPV cancers.

### Two Dose Recommendation

CDC recommends that adolescents 11–12 years of age should now receive two doses of HPV vaccine rather than the previously recommended three doses to protect against cancers caused by human papillomavirus (HPV) infections. This recommendation makes it easier for parents to protect their children by reducing the number of shots and trips to the doctor. Vaccination may begin as young as 9 years of age, and all persons who begin HPV vaccination before their 15<sup>th</sup> birthday should use the two dose schedule.

The second dose of HPV vaccine in the two dose series should be administered 6–12 months after the first dose for optimal protection. There is no maximum interval between HPV vaccine doses. The series does not need to be restarted if interrupted.

### Three Dose Recommendation

Teens and young adults who start the series at ages 15–26 years will continue to need three doses of HPV vaccine to protect against HPV infection. Adolescents 9–14 years of age who have already received two doses of HPV vaccine less than 5 months apart, will also require a third dose no

sooner than 12 weeks after the second dose and 5 months after the first dose. Additionally, three doses of HPV vaccine continue to be recommended for people with weakened immune systems aged 9–26 years.

### **3) Texas Vaccines for Children (TVFC) and Adult Safety Net (ASN) Availability**

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The TVFC and ASN Programs supply publicly purchased vaccine at no cost to enrolled providers. The Programs aim to increase access and reduce barriers to vaccination services in Texas. As of May 13, 2015, providers enrolled in the TVFC Program have the opportunity to order HPV9. However, the Immunizations Unit encourages providers to complete the administration of any remaining HPV4 vaccine doses before transitioning, should they choose, to HPV9.

Once the HPV9 vaccine is available through the ASN Program, updated information will be provided, and a memo will be distributed to enrolled providers. For more information on the TVFC and ASN programs, please visit <http://www.dshs.texas.gov/immunize/tvfc/> or <http://www.dshs.texas.gov/immunize/ASN/>.

For additional information on the VFC-ACIP resolution, please see [Advisory Committee on Immunization Practices, Vaccines for Children Program, Resolution No. 10/16-2: Vaccines to Prevent Human Papillomavirus \(PDF\)](#).

### **4) Precautions and Contraindications**

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HPV vaccines are contraindicated for persons with a history of immediate hypersensitivity to any HPV vaccine component, or to a previous dose of HPV vaccine. HPV2 is contraindicated for anyone with a history of being allergic to latex. HPV4 and HPV9 are contraindicated for persons with a history of immediate hypersensitivity to yeast (a vaccine component). HPV2 should not be administered to males or anyone with an anaphylactic allergy to latex. A moderate or severe acute illness is a precaution to vaccination, and vaccination should be deferred until symptoms of the acute illness improve.

HPV vaccines are not recommended for use in pregnant women, however, pregnancy testing is not needed before vaccination. If a dose of HPV has been administered during pregnancy, the remainder of the series should be delayed until after completion of the pregnancy. However, no intervention is needed. Women vaccinated during pregnancy may be reported to the respective manufacturer.

For immunocompromised persons, ACIP recommends continuing with the previously indicated 3-dose series of HPV vaccine. This includes persons with primary or secondary immunocompromising conditions that might reduce cell-mediated or humoral immunity, such as B lymphocyte antibody deficiencies, T-lymphocyte complete or partial defects, HIV infection, malignant neoplasm, transplantation, autoimmune disease or immunosuppressive therapy.

### **5) Human Papillomavirus (HPV) Vaccine Safety**

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Since licensure, both the CDC and the FDA have been closely monitoring the safety of HPV vaccines through three monitoring systems. These systems monitor adverse events already known to be caused by vaccines, as well as detect rare adverse events that were not identified during pre-licensure clinical trials. HPV vaccines have been studied in thousands of individuals worldwide, including the United States. These studies showed no serious safety concerns and found that all HPV vaccines are safe. Common, mild adverse events reported include pain at the injection site, fever, headache, dizziness, nausea, and syncope (fainting).

In the ten years of post-licensure vaccine safety monitoring and evaluation conducted independently by federal agencies and vaccine manufacturers, nearly 90 million doses of HPV vaccine have been distributed. No serious safety concerns have been linked to HPV vaccination as of July 2014.

## 6) Increasing HPV Immunization Rates

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Healthcare providers play a key role in HPV vaccination. A strong recommendation from clinicians is the best predictor of vaccination. Clinicians can utilize the following methods to help deliver a strong, concise, and clear HPV vaccination recommendation:

- Ensure wide availability of HPV vaccines.
- Recommend and promote the HPV vaccine in the same way, and at the same visit, as other adolescent vaccines.
- Use the “HPV is cancer prevention” message, because parents identify cancer prevention as important in their decision to vaccinate their children.
- Emphasize their belief in the importance of the HPV vaccine.
- Remind parents that the HPV vaccine is safe and effective.

## 7) Why Vaccinate 11–12 Year Olds?

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HPV vaccines offer the best protection to girls and boys who receive all three vaccine doses and have time to develop an immune response **before** they begin sexual activity. The immune response to this vaccine is better in preteens, and this could mean better protection. Remember, the HPV vaccines prevent cancer.

## 8) ImmTrac

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ImmTrac, the Texas Immunization Registry, is a no-cost service offered by the Texas Department of State Health Services (DSHS). It is a secure and confidential registry available to all Texans. ImmTrac safely consolidates and stores immunization information from multiple sources electronically in one centralized system. The registry is a major component of the DSHS initiative to increase vaccine coverage across Texas. 2vHPV (Cervarix®).

ImmTrac users can report administration of HPV vaccinations using the below CPT and CVX codes. For more information about ImmTrac, please refer to [www.ImmTrac.com](http://www.ImmTrac.com).

- HPV2 (Cervarix®): CPT 90650 or CVX 118
- HPV4 (Gardasil®): CPT 90649 or CVX 62
- HPV9 (Gardasil®9): CPT 90651 or CVX 165

## 9) Resources

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- Use of 9-valent Human Papillomavirus (HPV) Vaccine: Updated HPV Vaccination Recommendations of the ACIP  
<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6411a3.htm>
- Safe and effective vaccine that prevents cancer continues to be underutilized  
<http://www.cdc.gov/media/releases/2014/p0724-NIS-teen.html>

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*We hope you generously forward this advisory to others who may benefit from this information.*