



From the Texas Department of State Health Services Immunization Branch

*The goal of the Vaccine Advisory is to disseminate 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.*

To view past issues, go to: [www.dshs.state.tx.us/immunize/vacadvise/](http://www.dshs.state.tx.us/immunize/vacadvise/)

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## Updated Recommendations for Use of Human Papillomavirus (HPV) 9-Valent Vaccine, Recombinant

In February 2015, the Advisory Committee on Immunization Practices (ACIP) voted to recommend 9-valent human papillomavirus vaccine as one of the three HPV vaccines that can be used for routine vaccination. The ACIP recommends initiation of routine HPV vaccination at age 11 or 12 years, as well as for previously unvaccinated females, and some unvaccinated males, through age 26 years.

This advisory summarizes the new recommendations which became official on March 27, 2015. Full recommendations are in the CDC's Morbidity and Mortality Weekly Report (MMWR) at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6411a3.htm>.

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Texas Department of State Health Services, Immunization Branch (MC-1946) P.O. Box 149347  
Austin, Texas 78714-9347 (800) 252-9152 [www.ImmunizeTexas.com](http://www.ImmunizeTexas.com)



## 1) Background and Surveillance

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<sup>®</sup> (HPV2), Gardasil<sup>®</sup> (HPV4), and Gardasil<sup>®</sup>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<sup>®</sup>) is not approved for use in males.

## 2) Summary of New ACIP Recommendations

ACIP recommends initiation of routine HPV vaccination begin at age 11 or 12 years; however, the vaccination series can be started as early as nine (9) years of age. Full HPV vaccination recommendations include:

- Use of HPV9, HPV4, or HPV2 for females aged 11 – 26 years who are unvaccinated or not completely vaccinated.
- Use of HPV9 or HPV4 for males aged 11 – 21 years who are unvaccinated or not completely vaccinated.
- Use of HPV9 or HPV4 for men who have sex with men and immunocompromised men through age 26 years if not previously vaccinated. Other males aged 22 – 26 years may be vaccinated.

The recommended schedule for HPV vaccine administration is 0, 1 – 2, and 6 months. However, providers should not miss an opportunity to vaccinate their patients. The minimum interval from the first dose to second dose is four weeks. Dose number three should not be given any earlier than 24 weeks after the first dose, but at least 12 weeks after the second dose. HPV vaccination should not be delayed in order to obtain a specific type of vaccine. If clinicians do not know, or do not have available the previously administered HPV vaccine product, any available HPV vaccine product may be used to continue or complete the series for females, and HPV9 or HPV4 may be used to continue or complete the series for males. For providers who choose to implement HPV9, but still have HPV4 stock in their office, doses of HPV4 can be used to complete the series for patients who have already received two doses of HPV4.

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

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 Immunization Branch encourages providers to complete the administration of any remaining HPV4 vaccine doses before transitioning, should they choose, to HPV9. Please note, at this time, the administration fee associated with HPV9 is not reimbursable by Medicaid until October 1, 2015.

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.state.tx.us/immunize/tvfc/tvfc\\_about](http://www.dshs.state.tx.us/immunize/tvfc/tvfc_about) or <http://www.dshs.state.tx.us/asn/>. For additional information on the VFC-ACIP resolution, please visit <http://www.cdc.gov/vaccines/programs/vfc/downloads/resolutions/2015-02-2-hpv.pdf>.

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

HPV vaccines are contraindicated for persons with a history of immediate hypersensitivity to any vaccine component. HPV4 and HPV9 are contraindicated for persons with a history of immediate hypersensitivity to yeast. HPV2 should not be administered to males or anyone with an anaphylactic allergy to latex.

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, no intervention is needed.

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

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 eight years of post-licensure vaccine safety monitoring and evaluation conducted independently by federal agencies and vaccine manufacturers, 67 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**

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?

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

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.

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

- HPV2 (Cervarix<sup>®</sup>): 90650
- HPV4 (Gardasil<sup>®</sup>): 90649
- HPV9 (Gardasil<sup>®</sup>9): 90651

### 9) Resources

- 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.*