



From the Texas Department of State Health Services Immunization Branch

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.

To view past issues, go to: www.dshs.state.tx.us/immunize/vacadvise/

Advisory No. 14

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Updated Recommendations for the Use of Human Papillomavirus (HPV) Vaccine, Including Use in Males

On October 21, 2009, the Advisory Committee on Immunization Practices (ACIP) voted on updated recommendations for use of human papillomavirus (HPV) vaccine, including recommendations for the new bivalent HPV (types 16 and 18) vaccine (Cervarix®) for females and the quadrivalent HPV (types 6, 11, 16 and 18) vaccine (Gardasil®) for females and males.

This advisory summarizes the indications for Cervarix® use and provides updated recommendations for use of human papillomavirus (HPV) vaccine from the ACIP.

This advisory contains:

1. Summary of provisional recommendations from the ACIP for use of HPV vaccine
2. Texas Vaccines for Children program
3. ImmTrac
4. Texas school and child-care facilities requirements for HPV vaccine
5. Epidemiology and surveillance
6. Reporting vaccine adverse events
7. Resources

1) Summary of Provisional Recommendations from the ACIP

Highlights of the ACIP provisional recommendations include the following:

For Females

- Routine HPV vaccination of females age 11 or 12 years with 3 doses of HPV vaccine. The vaccination series can be started beginning at age 9 years.
- Routine HPV vaccination for females 13 through 26 years of age who have not been previously vaccinated or who have not completed the full vaccination series. Ideally, vaccine should be administered before potential exposure to HPV through sexual contact.
- Routine vaccination with either the bivalent HPV vaccine or the quadrivalent vaccine for the prevention of cervical cancers and precancers.
- ACIP recommends vaccination with the quadrivalent HPV vaccine for prevention of cervical cancer and precancers, and genital warts.*

Whenever possible the same HPV vaccine product should be used for all doses in the series.

For Males

The 3-dose series of quadrivalent HPV vaccine may be given to males 9 through 26 years of age to reduce their likelihood of acquiring genital warts. Ideally, vaccine should be administered before potential exposure to HPV through sexual contact.

The minimum interval between the first and second doses of vaccine is 4 weeks and the minimum recommended interval between the second and third dose of vaccine is 12 weeks. The minimum interval between the first and third dose is 24 weeks. Inadequate doses of HPV vaccine or vaccine doses received after a shorter-than-recommended dosing interval should be re-administered.

Precautions and Contraindications

- HPV vaccines are not recommended for use in pregnant women. However, pregnancy testing is not needed before vaccination. Any exposure to vaccine during pregnancy should be reported to the appropriate vaccine pregnancy registry:
 - 1-800-968-8999 (Merck and Co., Inc. for quadrivalent HPV vaccine)
 - 1-888-452-9622 (GlaxoSmithKline for bivalent HPV vaccine)
- HPV vaccines are contraindicated for persons with a history of immediate hypersensitivity to any vaccine component. Quadrivalent HPV vaccine is contraindicated for persons with a history of immediate hypersensitivity to yeast. Bivalent HPV vaccine in prefilled syringes is contraindicated for persons with anaphylactic latex allergy.
- Syncope can occur after vaccination, most commonly among adolescents and young adults. To avoid serious injury related to a syncopal episode, vaccine providers should consider observing patients for 15 minutes after they are vaccinated.

The complete provisional recommendations for HPV vaccination can be found at:

<http://www.cdc.gov/vaccines/recs/provisional/downloads/hpv-vac-dec2009-508.pdf>

*The quadrivalent vaccine has also been demonstrated to protect against vulvar and vaginal cancers and precancers.

2) Texas Vaccines for Children program

The Texas Vaccines for Children (TVFC) program is now offering Gardasil® to TVFC providers for use in males 9 through 18 years of age.

The bivalent HPV (types 16 and 18) vaccine, Cervarix®, is not available through the TVFC program at this time.

For complete information on the HPV vaccine please refer to the package insert. For questions related to the TVFC program, please contact your local health department or health service region representative.

3) ImmTrac

ImmTrac users can record the administration of HPV vaccine using the following ImmTrac codes:

- Cervarix®: HPV2 (bivalent) or CPT code 90650
- Gardasil®: HPV4 (quadrivalent) or CPT code 90649

Although ImmTrac can record HPV vaccine doses administered, and doses will be reflected on the client immunization history, the ImmTrac immunization scheduler will not generate recommendations at this time. Providers should review the child's immunization history and consult ACIP recommendations to determine if administration of HPV vaccine is appropriate.

For more information about ImmTrac, please visit www.ImmTrac.com.

4) Texas school and child-care facilities requirement for HPV vaccine

Immunization against human papillomavirus is not required for a person's admission to any elementary or secondary school. DSHS provides educational material about the human papillomavirus vaccine. This material is currently found at <http://www.dshs.state.tx.us/immunize/hpv.shtm>.

5) Epidemiology and surveillance

Human Papillomavirus (HPV) is the most common sexually transmitted infection in the United States. Most HPV infections are asymptomatic and result in no clinical disease. Clinical manifestations of HPV infection include anogenital warts, laryngeal papillomas, cervical cancer precursors, and cancers, including cervical, anal, vaginal, vulvar, penile, and some head and neck cancer. HPV is transmitted by direct contact, usually sexual, with an infected person. Transmission occurs most frequently with sexual intercourse but can be transmitted by nonsexual routes such as transmission from a woman to a newborn infant at the time of birth.

An estimated 20 million people are currently infected with HPV in the United States. HPV is so common that at least 50% of sexually active men and women get it at some point in their lives. An estimated 6.2 million new HPV infections occur annually. Prevalence of HPV among adolescent girls is as high as 64%.

6) Reporting adverse events after vaccination

An adverse event is a health problem that is reported after someone gets a vaccine or medicine. Note that persons may experience adverse events shortly after vaccination which may or may not be caused by the vaccine. Adverse events following vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS). While VAERS is an important system for helping to find potential signs, VAERS is primarily used to detect signals that may require

further investigation, but is not able to determine if an adverse event was caused by vaccination.

Adverse events from privately purchased vaccine may be reported directly to VAERS at <http://vaers.hhs.gov/>. Secure web-based reporting is available on the VAERS website. You may also contact VAERS at (800) 822-7967 for forms and information.

In Texas, reports of adverse events following vaccination at public health clinics or with vaccine provided through public funding such as the Texas Vaccines for Children (TVFC) program should be reported through the Texas Department of State Health Services, Immunization Branch via fax or mail.

- Fax a completed VAERS Form to: 1-866-624-0180 (toll-free)
- Mail a completed VAERS form to DSHS, Immunization Branch, MC-1946, P.O. Box 149347, Austin, TX 78714-9347

A pre-addressed and postage-paid VAERS form can be obtained by calling the Immunization Branch. A copy of the form is also available in the TVFC Toolkit. For more information about VAERS, you can contact DSHS at 800- 252-9152.

7) Resources

- Cervarix® package insert:
<http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm186957.htm>
- Gardasil® package insert:
<http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM094042>
- (HPV) Information from CDC:
<http://www.cdc.gov/hpv/>
- Updated (interim) VISs for HPV vaccine (one for Gardasil® and one for Cervarix®):
<http://www.cdc.gov/vaccines/pubs/vis/default.htm#hpv>

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

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