



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. 22

March 26, 2012

New Recommendations on the Use of Quadrivalent Human Papillomavirus Vaccine in Males

On October 25, 2011, the Advisory Committee on Immunization Practices (ACIP) of the U.S. Centers for Disease Control and Prevention (CDC) voted to recommend the routine use of the quadrivalent human papillomavirus vaccine (HPV4; Gardasil[®], Merck & Co. Inc.) in boys 11 or 12 years of age. Prior to this announcement, the vaccine was only recommended for females.

This advisory summarizes the new recommendations which became official on December 23, 2011 and are published in the December issue of CDC's [*Morbidity and Mortality Weekly Report*](#) (MMWR).

This advisory contains:

1. Background information
2. Summary of ACIP's recommendations for HPV vaccine
3. Texas Vaccines for Children program
4. ImmTrac
5. Texas school and child-care facilities requirements for HPV vaccine
6. Epidemiology and surveillance
7. Reporting vaccine adverse events
8. Resources

1) Background

The CDC reports that human papillomavirus (HPV) infection is the most common sexually transmitted disease in the United States. Most sexually active men and women will acquire the virus at some point in their lives.

At this time, 2 vaccines are available that protect against HPV. HPV4 (Gardasil[®], Merck) is directed against HPV 6, 11, 16, and 18, and was licensed by the Food and Drug Administration (FDA) for use in females age 9 through 26 years in June 2006. In 2009, HPV4 was licensed for use in males for prevention of genital warts; in December 2010, FDA added prevention of anal cancer in males and females as an indication for use.

The other bivalent vaccine (HPV2; Cervarix[®], GlaxoSmithKline) protects against HPV 16 and 18, and was licensed in October 2009. HPV2 is FDA-approved only for females age 9 through 25 years.

After the FDA approved the HPV4 vaccine for males in 2009, the ACIP voted for “permissive” — but not routine — use of it in boys and men 9 to 26 years of age for the prevention of genital warts.

On October 25, 2011, the ACIP extended their recommendation for the HPV4 vaccine to be routinely administered to 11 or 12-year-old boys.

2) Summary of ACIP Recommendations

These new recommendations apply only to Gardasil[®], as Cervarix[®] is not currently approved for males. Following are the recommendations published in *MMWR* for administering HPV4 to males:

- Routinely vaccinate males age 11 or 12 years with a 3-dose series of HPV4. The series can be started beginning at age 9 years.
- Vaccinate males age 13 through 21 years if they have not been vaccinated previously or have not completed the 3-dose series.
- Males 22 through 26 years of age may be vaccinated.
- Routinely vaccinate males through age 26 years if they are immunocompromised as a result of infection (including HIV), disease, or medical conditions and have not been vaccinated previously or have not completed the 3-dose series.
- Routinely vaccinate men who have sex with men (MSM) through age 26 years if they have not been vaccinated previously or have not completed the 3-dose series.

These recommendations replace the October 2009 ACIP guidance that HPV4 may be given to males 9 through 26 years of age.

3) Texas Vaccines for Children program

The Texas Vaccines for Children (TVFC) program offers Gardasil[®] to TVFC providers for males 9 through 18 years of age. Immunization of males with the quadrivalent HPV vaccine reduces the likelihood of acquiring genital warts, and should ideally be administered before potential exposure to HPV through sexual contact.

A 3-dose HPV vaccine series is recommended for females and males at age 11 or 12 years old with the following schedule: the quadrivalent HPV vaccine (for use in females and males) or the bivalent HPV vaccine (for use in females) is to be administered in a 3-dose schedule. The second dose should be

administered 1 to 2 months after the first dose and the third dose should be administered 6 months after the first dose.

The HPV vaccines series should be completed with the same HPV vaccine product whenever possible.

Catch-up vaccination

Vaccination is recommended for females and males 13 through 18 years of age who have not been previously vaccinated or who have not completed the full series.

Other vaccination

Eligible females and males as young as 9 years old may be vaccinated.

Interrupted vaccination schedule

If the vaccine schedule is interrupted for either the quadrivalent or bivalent HPV vaccine, the vaccine series does not need to be restarted. If the series is interrupted after the first dose, the second dose should be administered as soon as possible, and the second and third doses should be separated by an interval of at least 12 weeks with a minimum interval of 24 weeks between the first and third doses. If only the third dose is delayed, it should be administered as soon as possible.

Dosage Intervals

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.

For other questions or information, please contact your health service region, or TVFC consultant.

4) ImmTrac

ImmTrac users can report administration of quadrivalent human papillomavirus vaccine (HPV4, Gardasil[®]) using CPT code 90649 and brand name Gardasil[®]; and administration of bivalent (HPV2, Cervarix[®]) using CPT code 90650 and brand name Cervarix[®].

For more information about ImmTrac, please refer to: www.ImmTrac.com.

5) 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>.

6) 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. Approximately 22,000 HPV associated

cancers occur annually in the United States, including an estimated 7,000 HPV associated cancers in males.

7) Reporting vaccine adverse events

An adverse event is a health problem that is reported after someone gets a vaccine or medicine.

Adverse events from privately purchased vaccine should 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 copy of the form is also available in the TVFC Toolkit. For more information about VAERS, or for a pre-addressed postage-paid VAERS form, you can contact DSHS at (800)252-9152.

8) Resources

- ACIP Recommendations on HPV vaccine:
http://www.immunize.org/acip/acipvax_hpv.asp
- Package insert (Gardasil[®])
http://www.merck.com/product/usa/pi_circulars/g/gardasil/gardasil_pi.pdf
- Package insert (Cervarix[®])
http://us.gsk.com/products/assets/us_cervarix.pdf
- Gardasil[®] Vaccine Information Statement:
<http://www.immunize.org/vis/vis-hpv-gardasil.pdf>
- The DSHS Addendum to Gardasil[®] VIS is available at:
<http://www.dshs.state.tx.us/immunize/literature/litlist.shtm>; (Scroll down to number 7a.)

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

Texas Department of State Health Services, Immunization Branch (MC-1946)
P.O. Box 149347, Austin, Texas 78714-9347. (512)458-7284 or (800)252-9152
www.ImmunizeTexas.com

