

# STATE OF CONNECTICUT

## DEPARTMENT OF PUBLIC HEALTH


Raul Pino, M.D., M.P.H.  
Commissioner



Dannel P. Malloy  
Governor  
Nancy Wyman  
Lt. Governor

### Immunization Program

**TO:** Health Care Providers

**FROM:** Mick Bolduc   
Vaccine Coordinator-Connecticut Vaccine Program (CVP)

**DATE:** October 20, 2016

**SUBJECT:** HPV two dose Recommendation Guidance from the Advisory Committee on Immunization Practices (ACIP)

The primary purpose of this communication is to share the ACIP's guidance and rationale for the newly recommended two dose human papillomavirus (HPV) vaccine schedule for adolescents who complete the series before age 15.

Additional guidance is expected from CDC once the ACIP publishes in full the new recommendation, and the Immunization Program will share this additional information once it is available. Please see the following pages for the information we have currently from the ACIP.



Phone: (860) 509-7929 • Fax: (860) 509-7945  
410 Capitol Avenue, P.O. Box 340308  
Hartford, Connecticut 06134-0308  
[www.ct.gov/dph](http://www.ct.gov/dph)

*Affirmative Action/Equal Opportunity Employer*

**ACIP Meeting: HPV vaccine 2-dose recommendation  
October 19, 2016**

**CDC now recommends two doses of HPV vaccine for 11 or 12 year olds to prevent HPV cancers.**

- Younger adolescents (aged 9-14 years) who get vaccinated before their 15<sup>th</sup> birthday will only need two doses of HPV vaccine given 6 to 12 months apart to prevent HPV cancers.
- HPV vaccine is cancer prevention; two doses of HPV vaccine will provide safe, effective and long-lasting protection when given at the recommended ages of 11 and 12 years.
- This recommendation makes it easier for parents to protect their children by reducing the number of shots and trips to the doctor.

### Supporting Points

**CDC routinely recommends two doses of HPV vaccine for 11 and 12 year olds to prevent HPV cancers.**

- This reduces the number of doses younger adolescents need to complete an HPV vaccination series from three doses to two doses.
- The first dose is routinely recommended at 11-12 years old. Vaccination can be started at age 9. The second dose of the vaccine should be administered 6 to 12 months after the first dose.
- Teens and young adults who start the series at ages 15 through 26 years will continue to need three doses of HPV vaccine to protect against cancer-causing HPV infections.
- Adolescents aged 9 through 14 years who have already received two doses of HPV vaccine less than 5 months apart, will require a third dose.
- Three doses are recommended for people with weakened immune systems aged 9-26 years.

**The best way to protect children from HPV cancers is HPV vaccination at ages 11-12.**

- Like other vaccines, HPV vaccination is recommended for the age group in which vaccination will make the greatest impact on disease.
- Adolescents are also getting vaccines to protect against whooping cough and meningitis at ages 11-12.
- This recommendation provides an opportunity achieve protection against HPV cancers with two office visits instead of three.
- This recommendation also gives parents an extra incentive to protect their children from HPV cancer early, especially since their child will need three doses if they wait until after their 15<sup>th</sup> birthday.

**HPV vaccination provides safe, effective, and long-lasting protection against cancers caused by HPV.**

- After 10 years of HPV vaccination in the United States, evidence suggests that HPV vaccination is making a significant impact on HPV infection and HPV associated cancers and disease.
- Since the introduction of HPV vaccine, prevalence of HPV infection, genital warts, and cervical precancers has decreased in the United States.
  - HPV Infections: A [study](#) published earlier this year found a 64 percent drop in infections with the four HPV types targeted by the quadrivalent vaccine among teen girls (ages 14-19).
  - Genital Warts: A [2012 study](#) found a 38 percent drop in genital warts among teen girls (ages 15-19).
  - Cervical Precancer: A study published last week found a significant drop in high-grade cervical lesions detected through cervical cancer screening and cervical precancers diagnosed from biopsy specimens among teen girls (aged 15-19), decreasing by 8.3% and 14.4% per year, respectively.

### Additional Background

**Food and Drug Administration (FDA)**

- On October 7, 2016, The U.S. Food and Drug Administration (FDA) updated their approval for 9-valent HPV vaccine to add a 2-dose series for adolescents aged 9 through 14 years.

*Key points for internal CDC SMEs, external SMEs, and partner organizations*

- Information (including the approval letter and the revised product label for Gardasil 9) from the FDA is available online at:  
<http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm426445.htm>

**CDC and the Advisory Committee on Immunization Practices (ACIP) made this recommendation after a thorough review of studies on 2-dose schedules.**

- ACIP has been reviewing data on 2-dose HPV vaccination schedules since February 2016, which included a thorough review of all the available HPV vaccine data and studies of immune response, vaccine effectiveness, and duration of protection. Specifically:
  - Data from clinical trials showed two doses of HPV vaccine given in younger adolescents (aged 9-14 years) produced an immune response that was similar or higher than the response in young adults (aged 16-26 years) who received three doses.
  - Data available to date show that a 3-dose schedule in older adolescents and young adults provides long-lasting protection.
  - Study data suggest that a 2-dose schedule given to younger adolescents will also provide long-lasting protection
- Today's vote is an important reminder that the ACIP, CDC, FDA, and others monitor vaccines in use in the U.S. year-round. ACIP and CDC evaluate vaccination policy, and if necessary make changes to vaccine recommendations.
- The change in the HPV vaccination recommendation is an example of how the ACIP uses new study data and GRADE (Grading of Recommendations, Assessment, Development, and Evaluation) to make an evidenced based decision to ensure optimal use of vaccines.
- CDC will be communicating to parents, healthcare professionals, and insurers to provide guidance and education on the change in recommendation. Final recommendations will be outlined in CDC's [Morbidity and Mortality Weekly Report](#) in the coming weeks.

**ACIP**

- ACIP is a panel of experts that advises the CDC on vaccine recommendations in the United States.
- ACIP reviews data year-round to ensure that vaccine recommendations are based on the latest available evidence to provide optimal protection against serious diseases. The information that ACIP reviews for each vaccine always includes the following:
  - **The safety and effectiveness of the vaccine when given at specific ages.** Only vaccines licensed by the FDA are recommended, and vaccine manufacturers must conduct rigorous studies to show that a vaccine is safe and effective at specific ages.
  - **The severity of the disease.** Vaccines recommended for children prevent diseases that can be serious for them, potentially causing long-term health problems or death.
  - **The number of children who get the disease if there is no vaccine.** Vaccines that do not provide benefit to many children may not be recommended for all children. ACIP recommendations become official CDC recommendations when they are approved by the CDC Director and published in CDC's Morbidity and Mortality Weekly Report (MMWR).
  - **How well a vaccine works for children of different ages.** The immune response from a vaccine can vary depending on the age when the vaccine is given.

**HPV Vaccination Coverage**

- The latest HPV vaccination coverage estimates show that – while occurring at a slow pace – HPV vaccination is becoming more routine.
- Six out of 10 teen girls (63 percent) and five out of 10 teen boys (50 percent) in the United States have started the HPV vaccination series (i.e., received at least one dose of HPV vaccine), according to data from the [2015 National Immunization Survey-Teen \(NIS-Teen\)](#).

*Key points for internal CDC SMEs, external SMEs, and partner organizations*

- Although the majority of teens have started the HPV vaccine series, only four out of ten teen girls (42 percent) and three out of 10 teen boys (28 percent) boys have completed the 3-dose HPV vaccination series.