

Centers for Disease Control and Prevention (CDC) Atlanta GA 30329

November 10, 2016

### Dear Awardee:

The Advisory Committee on Immunization Practices (ACIP) and the Centers for Disease Control and Prevention (CDC) now recommends only **two doses of HPV vaccine** for adolescents who begin the vaccination series before age 15. The updated dosing recommendations, summarized in the table below, are effective as of October 20, 2016.

HPV vaccine recommendations for target age groups remain the same as before. Routine HPV vaccination is recommended at age 11 or 12 years. The vaccination series can be started at age 9 years. Vaccination is recommended through age 26 for females and through age 21 for males not vaccinated previously. Males aged 22 through 26 years may be vaccinated; vaccination is recommended through age 26 years for males in some special populations and those with immunocompromising conditions.

### Recommended number of doses and dosing schedule for HPV vaccine

Recommended number of doses	Recommended dosing schedule	Population
2	0, 6–12 months	Persons initiating vaccination at ages 9 through 14 years, except immunocompromised persons
3	0, 1–2, 6 months	Persons initiating vaccination at ages 15 through 26 years, and immunocompromised persons initiating vaccination at ages 9 through 26 years

CDC encourages clinicians to begin implementing these new recommendations as soon as their practice is able.

## **Specifically, providers should:**

- Schedule patients starting the vaccination series before age 15 to receive their second dose of HPV vaccine 6-12 months after receiving the first dose.
- Continue to provide teens and young adults who start the series at ages 15 through 26 years three doses of HPV vaccine.

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While it will take time to incorporate a new dosing recommendation, a two-dose series means it will be easier to protect preteens from HPV related disease and cancers. However, because the HPV vaccine is widely available and covered by insurance plans, providers should be encouraged to review patient's vaccination history to adjust to the new recommendation. If a patient has already received the first dose of HPV vaccine before age 15 and received a second dose of vaccine at least 5 months later, the patient is considered adequately vaccinated and does not need a third dose under the new recommendations

CDC and ACIP made this recommendation after a thorough review of studies over several ACIP 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 to or higher than the response in young adults (aged 16-26 years) who received three doses.

We recognize that state health departments are working with clinical practices and other vaccine providers to address logistical and technological issues to fully implement the new HPV vaccine recommendations. Updating clinical decision support tools and electronic medical record systems is ongoing, and will take time. We appreciate all that you and providers are doing to implement the updated HPV vaccine recommendation. By reducing the number of vaccinations, we hope it will become more convenient to protect individuals from HPV cancers.

Attached is a list of Frequently Asked Questions we have received from Awardees and providers. We also encourage you to review the CDC Current Issues Netconference on the new HPV vaccine recommendations at (http://www.cdc.gov/vaccines/ed/ciinc/2016-10-26.html). If you have additional questions please email us at nipinfo@cdc.gov or contact your project officer.

Sincerely,

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Director, Immunization Services Division National Center for Immunization and Respiratory Diseases

Enclosure

# CDC Immunization Services Division FAQs about the new HPV Vaccine Recommendations by Awardees and Providers

## What has changed in the new HPV vaccine recommendations?

In October 2016, CDC updated HPV vaccination recommendations regarding dosing schedules. CDC now recommends 2 doses of HPV vaccine for people starting the vaccination series before the 15<sup>th</sup> birthday. Three doses of HPV vaccine are recommended for people starting the vaccination series on or after the 15<sup>th</sup> birthday and for people with certain immunocompromising conditions.

CDC continues to recommend routine vaccination for girls and boys at age 11 or 12 years. The vaccination series can be started at age 9 years. CDC also recommends vaccination through age 26 for females and through age 21 for males. Males age 22-26 may be vaccinated.

#### What is the recommended 2-dose HPV vaccination schedule?

For girls and boys starting the vaccination series before the 15th birthday, the recommended schedule is 2 doses of HPV vaccine. The second dose should be given 6–12 months after the first dose (0, 6–12 month schedule).

#### Who should still receive a 3-dose schedule?

CDC continues to recommend a 3-dose schedule for persons starting the HPV vaccination series on or after the 15th birthday, and for persons with certain immunocompromising conditions. The second dose should be given 1–2 months after the first dose, and the third dose should be given 6 months after the first dose (0, 1–2, 6 month schedule).

#### What is the recommendation for persons with immunocompromising conditions?

CDC recommends 3 doses of HPV vaccine (0, 1–2, 6 months) for immunocompromised people aged 9 through 26 years. People whose immune responses might be lower, for example due to HIV infection, cancer, autoimmune disease, or taking immunosuppressant medications, should receive 3 doses to make sure they get the most benefit. However, children with asthma, diabetes, and other conditions that would not suppress immune response to HPV vaccination can receive a 2-dose schedule.

#### Why is the 2-dose schedule change recommended only for girls and boys aged 9-14 years?

ACIP makes recommendations based on the best available scientific evidence. Immunogenicity studies have shown that 2 doses of HPV vaccine given to 9–14 year-olds at least 6 months apart were as good as or better than 3 doses given to older adolescents and young adults. Studies have not been done to show this in adolescents age 15 years or older.

If a HPV vaccine series was started with quadrivalent HPV vaccine or bivalent HPV vaccine and will be completed with 9-valent HPV vaccine, what are the intervals for the remaining doses in a 3-dose or 2-dose series?

If the first dose of any vaccine was given before the 15th birthday, vaccination should be completed according to a 2-dose schedule. In a 2-dose series, the second dose is recommended 6–12 months after the first dose (0, 6–12 month schedule).

If the first dose of any vaccine was given on or after the 15th birthday, vaccination should be completed according to a 3-dose schedule. In a 3-dose series, the second dose is recommended 1–2 months after the first dose, and the third dose is recommended 6 months after the first dose (0, 1–2, 6 month schedule.

If a vaccination schedule is interrupted, vaccine doses do not need to be repeated.

# Does the recently recommended 2-dose HPV series provide the same protection as the 3-dose HPV series?

For 9 through 14 year olds, the 2-dose series provides the same protection than the three-dose series in older adolescents. Antibody levels were significantly higher for all nine 9-valent vaccine types in 9 through 14 year olds who received a 2-dose series (0, 6 month or 0, 12 month schedule) compared to 16 through 26 year olds who received a 3-dose series (0, 2, 6 month schedule).

# Does ACIP have a preference for the 2-dose schedule or 3-dose schedule for children 9 through 14 years of age?

ACIP recommends the 2-dose series for children 9 through 14 years of age, except for persons with certain immunocompromising conditions. The second dose should be administered 6–12 months after the first dose. (0, 6–12 month schedule)

#### Can the 4-day grace period be applied to the minimum age of 9 years?

Yes, the 4-day grace period can be applied to any minimum interval or minimum age that appears on Table 1 of the General Recommendations on Immunization. So a dose administered within 4 days before the 9<sup>th</sup> birthday can be counted as a valid first dose and does not need to be repeated. Also, if you have someone in your office 4 or fewer days before their 9<sup>th</sup> birthday, and you are concerned that the patient may not return for a follow-up visit to get the HPV vaccine, you can administer a first dose of HPV vaccine at that time.

#### What is the minimum interval between dose 1 and dose 2 of the 2-dose HPV series?

The minimum interval between dose 1 and dose 2 of the 2-dose HPV series is five months. This corresponds to five calendar months. If the second dose is administered at a shorter interval, an additional dose is recommended 6-12 months after the 1<sup>st</sup> dose, and at least 12 weeks after the 2<sup>nd</sup> dose.

# Can the 4-day grace period be applied to the minimum interval between dose 1 and dose 2 of the 2-dose HPV schedule?

Yes. Even though every alternate schedule does not appear on Table 1 of the General Recommendations on Immunization, if an acceptable schedule exists, we do allow the four day grace period to be applied. So if the 2 dose schedule is acceptable, and the 2<sup>nd</sup> dose is administered within 4 days before the completion of the 5 calendar-month interval, this dose should be counted. Also, if you have someone in your office 4 days or less before this 5 calendar month interval is complete, and you are concerned that the patient may not return for a follow-up visit to get the HPV vaccine, you can administer a first dose of HPV vaccine at that time.

Does the 2-dose schedule need to be complete with the same vaccine, all doses 9vHPV, for example? Or can it be "mixed" like with 1 dose of 4vHPV and the other 9vHPV?

9vHPV may be used to continue or complete a vaccination series started with 4vHPV or 2vHPV. So a 2-dose series can consist of 1 dose of 4vHPV and 1 dose of 9vHPV.

A 16 year old, with a history of 1 dose of HPV vaccine at age 11 years, is in our clinic. Does he need one or two doses to complete the series? If one dose, when should it be given? If two doses, when should the first dose be given, and what is the recommended spacing between the two doses?

He needs one more dose to complete the series, because he initiated the HPV vaccination series before his 15<sup>th</sup> birthday. In a 2-dose series, the second dose is recommended 6–12 months after the first dose. In this case, the first dose has already been given, and it has been more than 6 months since that dose was given, (he is already 16 years old, so it has been around five YEARS), so the second dose can be given as soon as possible (ASAP).

We gave a 13-year-old adolescent a second dose of 9vHPV vaccine 5 months after the first dose. Is she considered complete? If not, when should she return to receive the next dose?

She is considered complete, because the minimum interval between dose 1 and dose 2 of the two-dose series for adolescents 9 through 14 years of age is 5 months.

#### Are there any adolescents or adults who should NOT follow the 2-dose schedule for HPV vaccine?

The following adolescents or adults should receive 3 doses of HPV vaccine:

- Adolescents or adults who initiate the HPV vaccine series on or after the 15<sup>th</sup> birthday
- Adolescents or adults with certain immunocompromising conditions, regardless of age
  at initiation of the HPV vaccine series: persons who should receive 3 doses are those
  with primary or secondary immunocompromising conditions that might reduce cellmediated or humoral immunity, such as B lymphocyte antibody deficiencies, T
  lymphocyte complete or partial defects, HIV infection, malignant neoplasm,
  transplantation, or immunosuppressive therapy, since immune response to vaccination
  may be attenuated.

However, children aged <15 years with the following conditions can receive a 2-dose schedule of HPV vaccine: asplenia, asthma, chronic granulomatous disease, chronic liver disease, chronic lung disease, chronic renal disease, CNS anatomic barrier defects (e.g., cochlear implant), complement deficiency, diabetes, heart disease, or sickle cell disease.

Why do older adolescents and young adults who start the series 15 years of age and older still need a 3-dose series instead of a two-dose series?

ACIP makes recommendations based on the best available scientific evidence. Immunogenicity studies have shown that 2 doses of HPV vaccine given to 9–14 year-olds at least 6 months apart were as good, or better, than 3 doses given to older adolescents and young adults. Studies have not been done to show this in adolescents age 15 years or older.

If the second dose of the 2-dose series is delayed by over a year, and the child is still eligible for the 2-dose series, will the child be considered series complete with just one additional dose?

Yes. Adolescents and adults who initiated the HPV vaccine series prior to the 15<sup>th</sup> birthday, and who do not have certain immunocompromising conditions, are considered adequately vaccinated with one additional dose of HPV vaccine.