Vaccines for Children Program Human Papillomavirus Virus (HPV) Vaccine Question and Answer December 2016

Q. What has changed in the new HPV vaccine recommendations?

A. CDC now recommends 2 doses of HPV vaccine for people starting the vaccination series before the 15th birthday. Three doses of HPV vaccine are recommended for people starting the vaccination series on or after the 15th birthday and for people with certain immunocompromising conditions.

CDC continues to recommend routine vaccination for males and females at 11 or 12 years of age. 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 22 through 26 years of age may be vaccinated.

Q. What is the recommended 2-dose HPV vaccination schedule?

A. For males and females 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).

Q. Who should still receive a 3-dose schedule?

A. 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).

Q. What is the recommendation for persons with immunocompromising conditions?

A. 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.

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Q. Why is the 2-dose schedule change recommended only for males and females aged 9–14 years?

A. ACIP makes recommendations based on the best available scientific evidence. Immunogenicity studies have shown 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.

Q. 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?

A. 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.

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

A. For 9 through 14 year olds, the 2-dose series provides the same protection as 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).

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

A. 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)

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

A. 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. A dose administered within 4 days before the 9th birthday can be counted as a valid first dose and does not need to be repeated. Also, if a patient presents in the office 4 or fewer days before their 9th birthday, and there is concern the patient may not return for a follow-up visit to get the HPV vaccine, administer a first dose of HPV vaccine.

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

A. 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 1st dose, and at least 12 weeks after the 2nd dose.

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

A. Yes. Even though every alternate schedule does not appear on Table 1 of the General Recommendations on Immunization, if an acceptable schedule exists, the CDC does allow the four-day grace period to be applied. If the 2 dose schedule is acceptable, and the 2nd dose is administered within 4 days before the completion of the 5 calendar-month interval, this dose should be counted as valid. Also, if a patient presents in the office 4 or fewer days before their 9th birthday, and there is concern the patient may not return for a follow-up visit to get the HPV vaccine, administer a first dose of HPV vaccine.

Q. 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?

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

Q. A 16-year-old, with a history of 1 dose of HPV vaccine at age 11 years, is in the clinic. Does this patient 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?

A. This adolescent needs one more dose to complete the series, because they initiated the HPV vaccination series before his 15th 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.

Q. A 13-year-old adolescent was administered 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?

A. 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.

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

- **A**. 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 15th 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 cell-mediated 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.

Q. 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?

A. ACIP makes recommendations based on the best available scientific evidence. Immunogenicity studies have shown 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.

Q. 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?

A. Yes. Adolescents and adults who initiated the HPV vaccine series prior to the 15th birthday, and who do not have certain immunocompromising conditions, are considered adequately vaccinated with one additional dose of HPV vaccine regardless of the fact that the second dose was given more than 12 months after the first dose and regardless of the age at which the second dose is given.