Talking to Parents about HPV Vaccine

Recommend HPV vaccination in the **same way** and on the **same day** as all adolescent vaccines. You can say, *"Now that your son is 11, he is due for vaccinations today to help protect him from meningitis, HPV cancers, and pertussis."* Remind parents of the follow-up shots their child will need and ask them to make appointments before they leave.

Why does my child need HPV vaccine?

HPV vaccine is important because it prevents infections that can cause cancer. That's why we need to start the shot series today.

Is my child really at risk for HPV?

HPV is a very common infection in women and men that can cause cancer. Starting the vaccine series today will help protect your child from the cancers and diseases caused by HPV.

Why do they need HPV vaccine at such a young age?

Like all vaccines, we want to give HPV vaccine earlier rather than later. If you wait, your child may need three shots instead of two.

I'm worried about the safety of HPV vaccine. Do you think it's safe?

Yes, HPV vaccination is very safe. Like any medication, vaccines can cause side effects, including pain, swelling, or redness where the shot was given. That's normal for HPV vaccine too and should go away in a day or two.

Sometimes kids faint after they get shots and they could be injured if they fall from fainting. We'll protect your child by having them stay seated after the shot.

Would you get HPV vaccine for your kids?

Yes, I gave HPV vaccine to my child (or grandchild, etc.) when he was 11, because it's important for preventing cancer.

Why do boys need HPV vaccine?

HPV vaccination can help prevent future infection that can lead to cancers of the penis, anus, and back of the throat in men.

What diseases are caused by HPV?

Some HPV infections can cause cancer—like cancer of the cervix or in the back of the throat—but we can protect your child from these cancers in the future by getting the first HPV shot today.

How do you know the vaccine works?

Studies continue to prove HPV vaccination works extremely well, decreasing the number of infections and HPV precancers in young people since it has been available.

I'm worried my child will think that getting this vaccine makes it OK to have sex.

Studies tell us that getting HPV vaccine doesn't make kids more likely to start having sex. I recommend we give your child her first HPV shot today.

Can HPV vaccine cause infertility in my child?

There is no known link between HPV vaccination and the inability to have children in the future. However, women who develop an HPV precancer or cancer could require treatment that would limit their ability to have children.

What vaccines are actually required?

I strongly recommend each of these vaccines and so do experts at the CDC and major medical organizations. School entry requirements are developed for public health and safety, but don't always reflect the most current medical recommendations for your child's health.

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

HPV VACCINE IS CANCER PREVENTION

December, 2016 | CS269453B

HPV Vaccine is Safe — (Gardasil)

04/08/2016 CS256663A

What are HPV Vaccines?

HPV vaccines protect against certain cancers caused by human papillomavirus (HPV) infection. HPV infection can cause cervical, vaginal, and vulvar cancers in women and penile cancer in men. HPV can also cause anal cancer, throat (oropharyngeal) cancer, and genital warts in both men and women. There are currently three HPV vaccines available for use in the United States. This fact sheet summarizes what we know about the safety of Gardasil, one of the available HPV vaccines.

How Do I Know HPV Vaccine is Safe?

As with all approved vaccines, CDC and the Food and Drug Administration (FDA) closely monitor the safety of HPV vaccine to identify **adverse events** and **side effects**. Pre-licensure clinical trials and data collected after the vaccine was made available show that it is very safe.

Adverse event: a health problem that happens after vaccination that may or may not be caused by a vaccine.

Side effect: a health problem that has been shown to be linked to a vaccine by scientific studies.

What Are the Side Effects?

HPV vaccine is very safe, and it is effective at protecting against some HPV types that cause cancer. Vaccines, like any medicine, can have side effects. Many people who get HPV vaccine have no side effects at all. Some people report having very mild side effects, like a sore arm from the shot. The most common side effects are usually mild.

Common Side Effects of HPV Vaccines

- Pain, redness, or swelling in the arm where the shot was given
- Fever
- Headache or feeling tired
- Nausea
- Muscle or joint pain

Understanding HPV Vaccine Safety Studies and Monitoring

It is important to understand the following when reading about HPV vaccine safety studies:

Anyone can report side effects and adverse events.
CDC and FDA maintain a vaccine safety monitoring system called the Vaccine Adverse Event Reporting System (VAERS). VAERS accepts reports from anyone, including doctors, patients, and parents. While VAERS provides useful information on vaccine safety, the data have limitations. It is generally not possible to use VAERS to determine whether a vaccine caused an adverse event.

HPV vaccine has many of the same, mild side effects as other vaccines.
Common, mild side effects reported during HPV vaccine safety studies include pain in the arm where the shot was given, fever, dizziness and nausea. These are similar to side effects seen with other vaccines.
Some preteens and teens might faint after getting the HPV vaccine or any shot. People should sit or lie down for about 15 minutes after getting a shot. This can help prevent fainting.

CDC has carefully studied the risks of HPV vaccination.
HPV vaccination is recommended because the benefits, such as prevention of cancer, far outweigh the risks of possible side effects.

Benefits	Potential Risks
Cancer Prevention	Chance of fainting
Cervical, vaginal, and vulvar cancer in women	Pain, redness, or swelling in the arm where the shot was given
Anal cancer in men and women	
Likely penile cancer in men	
Likely oropharyngeal cancer in women and men	

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What Do the Studies Say?

Scientists at CDC and FDA continuously monitor the safety of HPV vaccine. While monitoring activities help identify possible side effects and adverse events, they do not prove the side effects were caused by Gardasil.

- Monitoring by CDC and FDA in 2009 revealed most side effects reported after receiving HPV vaccine were non-serious, including: fainting; dizziness; nausea; headache; and pain, swelling, or redness in the arm where the shot was given.

Formal studies have also looked at whether or not specific adverse events can be linked to Gardasil:

- A 2011 study found women and girls who received Gardasil were no more at risk of allergic reactions, anaphylaxis (severe allergic reaction), Guillain–Barré Syndrome (GBS), stroke, blood clots, appendicitis, or seizures than those who were unvaccinated or who received other vaccines.
- A 2012 study that looked at when adverse events occur found Gardasil may be associated with skin infections where the shot is given during the two weeks after vaccination and fainting on the day the shot is received.
- A 2013 study that included almost 1 million girls found Gardasil was not associated with blood clots or adverse events related to the autoimmune and brain systems.
- A 2014 study that included over 1 million women found Gardasil was not associated with venous thromboembolism, also called VTE or blood clots.

Several studies have shown that there is no relationship between Gardasil and autoimmune disorders:

- A 2012 study and a 2014 study both found women and girls who received the Gardasil shot were not more likely to develop autoimmune disorders than those who were unvaccinated.
- A 2015 study found women and girls who received Gardasil were not more likely than those who were unvaccinated to develop multiple sclerosis (MS) or other similar diseases.

Gardasil is not recommended during pregnancy. However, some women may receive the Gardasil shot before realizing they are pregnant. There have been several studies that found pregnant women who received Gardasil did not experience any problems:

- A 2015 study found no safety concerns for pregnant women who received Gardasil, or for their babies.
- The Gardasil Pregnancy Registry, maintained by the manufacturer, received many reports of pregnant women who were vaccinated, and found no evidence that the vaccine affects fertility, pregnancy, or the health of the baby.

Related Scientific Articles

Arnheim-Dahlström L, Pasternak B, Svanström H, Sparén P, Hviid A. Autoimmune, neurological, and venous thromboembolic adverse events after immunisation of adolescent girls with quadrivalent human papillomavirus vaccine in Denmark and Sweden: Cohort study. *BMJ.* 2013 Oct;347:f5906.

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Slade BA, Leidel L, Vellozzi C, Woo EJ, Hua W, Sutherland A, et al. Postlicensure safety surveillance for quadrivalent human papillomavirus recombinant vaccine. *JAMA.* 2009; 302(7):750-7

The Centers for Disease Control and Prevention, American Academy of Family Physicians, and American Academy of Pediatrics strongly recommend children receive all vaccines according to the recommended schedule.

HPV Vaccine Information for Clinicians

CDC recommends HPV vaccination for girls and boys at ages 11 or 12 years to protect against cancers caused by HPV infections. CDC encourages clinicians to recommend HPV vaccination the same way and same day they recommend other routinely recommended vaccines for adolescents.

Background

Human papillomaviruses (HPV) are a very common family of viruses that infect epithelial tissue. More than 120 HPV types have been identified. Most HPV types infect cutaneous epithelial cells and cause common warts, such as those that occur on the hands and feet. Approximately 40 HPV types can infect mucosal epithelial cells, such as those on the genitals, mouth, and throat. Although most HPV infections are asymptomatic and resolve spontaneously or become undetectable, some HPV infections can persist and lead to cancer.

Persistent infections with high-risk (oncogenic) HPV types can cause cervical, vaginal and vulvar cancers in women; penile cancers in men; and oropharyngeal and anal cancers in both men and women. The most common high-risk types are HPV 16 and 18.

Infection with low-risk (non-oncogenic) HPV types can cause genital warts and rarely laryngeal papillomas. These types can also cause benign or low-grade cervical cell abnormalities. The most common low-risk types are HPV 6 and 11.

About 79 million Americans are infected with genital HPV. Approximately 14 million people become newly infected each year, mostly teens and young adults. Almost every person will acquire an HPV infection at some time in their life.

Every year in the United States, an estimated 19,200 women and 11,600 men are diagnosed with a cancer caused by HPV infection.

Of women diagnosed with an HPV cancer, cervical cancer is the most common with almost 12,000 women diagnosed annually in the United States; subsequently about 4,400 women die every year from cervical cancer in the country.

Of the men in the United States diagnosed with an HPV cancer, oropharyngeal cancer is the most common. Around 9,100 U.S. men each year are diagnosed with oropharyngeal cancer caused by HPV infection. There is no screening test for oropharyngeal cancers, making prevention of infection a priority.

HPV Vaccines

Three HPV vaccines have been licensed by the U.S. Food and Drug Administration (FDA) since 2006. HPV vaccine is recommended for routine vaccination of adolescents (including girls and boys) at age 11 or 12 years, and can be started at age 9 years.

	Bivalent/2vHPV (Cervarix)	Quadrivalent/4vHPV (Gardasil)	9-valent/9vHPV (Gardasil 9)
Manufacturer	GlaxoSmithKline	Merck	Merck
Year Licensed	October 2009 - females	June 2006 - females; October 2009 - males	December 2014 - males and females
HPV types in vaccine	16 and 18	6, 11, 16, and 18	6, 11, 16, 18, 31, 33, 45, 52, and 58
Adjuvant in vaccine	AS04: 500 µg aluminum hydroxide 50 µg 3-*O*-desacyl-4′-monophosphoryl lipid A	AAHS: 225 µg amorphous aluminum hydroxyphosphate sulfate	AAHS: 500 µg amorphous aluminum hydroxyphosphate sulfate
Recommended for…	• Females ages 11-12 (can start at age 9 years) • Females ages 13 through 26 who were not adequately vaccinated previously	• Females and males ages 11-12 (can start at age 9 years) • Females ages 13 through 26 and males ages 13 through 21 who were not adequately vaccinated previously • Males ages 22 through 26 with certain immunocompromising conditions; gay, bisexual, and other men who have sex with men (MSM); and transgender persons who were not adequately vaccinated previously	• Females and males ages 11-12 (can start at age 9 years) • Females ages 13 through 26 and males ages 13 through 21 who were not adequately vaccinated previously • Males ages 22 through 26 with certain immunocompromising conditions; gay, bisexual, and other men who have sex with men (MSM); and transgender persons who were not adequately vaccinated previously
Contraindicated for…	People with anaphylaxis caused by latex	People with immediate hypersensitivity to yeast	People with immediate hypersensitivity to yeast

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Bivalent HPV vaccine protects against two types of HPV, quadrivalent HPV vaccine protects against four types of HPV, and 9-valent HPV vaccine protects against nine types of HPV. Bivalent, quadrivalent, and 9-valent HPV vaccine all protect against HPV 16 and 18, the HPV types that cause about 66% of cervical cancers and the majority of other HPV-attributable cancers in the United States. Quadrivalent and 9-valent HPV vaccine also protect against HPV 6 and 11, the HPV types that cause anogenital warts. In addition, 9-valent HPV vaccine targets five additional cancer-causing types, which account for another 15% of cervical cancers (12).

The additional five types in 9-valent HPV vaccine account for a higher proportion of HPV-associated cancers in women compared with men, and also cause cervical precancers in women. Therefore, the additional protection from 9-valent HPV vaccine will mostly benefit women.

After the end of 2016, only 9-valent HPV vaccine will be available in the United States.

HPV Vaccine Recommendations

HPV vaccine is routinely recommended for adolescents at age 11 or 12 years. Vaccination is also recommended for females ages 13 through 26 years and males ages 13 through 21 years who were not adequately vaccinated when they were younger. Vaccination is also recommended for gay, bisexual, and other men who have sex with men, transgender people, and persons with certain immunocompromising conditions ages 22 through 26 years who were not adequately vaccinated when they were younger.

Ideally, adolescents should be vaccinated before they are exposed to HPV. However, people who have already been infected with one or more HPV types can still get protection from other HPV types in the vaccine.

HPV vaccines *can* safely be given to…

- Patients with minor acute illnesses, such as diarrhea or mild upper respiratory tract infections, with or without fever.
- Women who have had an unclear or abnormal Pap test, a positive HPV test, or genital warts. However, these patients should be advised that the vaccine may not have any therapeutic effect on existing Pap test abnormalities, HPV infection, or genital warts.
- Patients with immunocompromising conditions, including certain diseases or medications. However, the immune response to vaccination and effectiveness of the vaccine might be less than in people with a normally functioning immune system.
- Women who are breastfeeding.

HPV vaccines should *not* be given to…

- Patients with a history of allergies to any vaccine component. Quadrivalent vaccine (4vHPV) and nine-valent vaccine (9vHPV) are not recommended for people with immediate hypersensitivity to yeast. Bivalent vaccine (2vHPV) is not recommended for people with anaphylaxis caused by latex.
- Patients with moderate or severe acute illnesses. In these cases, patients should wait until the illness improves before getting vaccinated.
- Pregnant women. However, HPV vaccines have not been shown to cause any adverse pregnancy outcomes or adverse events for the mother or her developing fetus.
  - If a woman is found to be pregnant after starting the HPV vaccine series, second and/or third doses should be delayed, and given after she is no longer pregnant.
  - Pregnancy testing is not needed before vaccination. If a pregnant woman does receive HPV vaccine, no intervention is needed.
  - Exposure to 9vHPV vaccine during pregnancy can be reported to the manufacturer. Pregnancy registries for 4vHPV and 2vHPV were closed after >6 years, with FDA concurrence.

HPV Vaccine Safety

HPV vaccines are very safe. Scientific research shows the benefits of HPV vaccination far outweigh the potential risks. Like all medical interventions, vaccines can have some side effects. Nearly 90 million doses of HPV vaccines have been distributed in the United States since the first HPV vaccine was introduced in 2006. The most common side effects associated with HPV vaccines are mild, and include pain, redness, or swelling in the arm where the shot was given.

All vaccines used in the United States, including HPV vaccines, are required to go through years of extensive safety testing before they are licensed by the U.S. Food and Drug Administration (FDA). During clinical trials conducted before they were licensed:

- 9-valent HPV vaccine was studied in more than 15,000 males and females
- Quadrivalent HPV vaccine was studied in more than 29,000 males and females
- Bivalent HPV vaccine was studied in more than 30,000 females
- Each HPV vaccine was found to be safe and effective.

Syncope (fainting) can occur after any medical procedure, including vaccination. Recent data suggest that syncope after any vaccination is more common in adolescents. Adolescents and adults should be seated or lying down during vaccination, and remain that way for 15 minutes after vaccination, under clinician observation. This is to prevent any injuries that could occur from a fall during a syncopal event.

Adverse events occurring after administration of any vaccine should be reported to the Vaccine Adverse Event Reporting System (VAERS). Additional information about VAERS is available by telephone (1-800-822-7967) or online (https://vaers.hhs.gov).

HPV Vaccine Effectiveness

HPV vaccines work extremely well. HPV vaccine was first recommended in 2006 in the United States, and by 2010, quadrivalent type HPV infections in teen girls decreased by 56%, and decreases in prevalence were also observed in women in their early 20s. Research has also shown that fewer U.S. teens are getting genital warts since HPV vaccines have been in use. Also, decreases in vaccine-type prevalence, genital warts, and cervical dysplasia have been observed in other countries with HPV vaccination programs.

There are no data to suggest HPV vaccines will treat existing diseases or conditions caused by HPV. However, people who already have HPV-associated diseases or conditions can still get protection from other HPV types covered by the vaccines.

Cervical cancer screening is recommended for women beginning at age 21 years and continuing through age 65 years for both vaccinated and unvaccinated women. Women who have received any HPV vaccine should still be screened for cervical cancer beginning at age 21 years, in accordance with currently published cervical cancer screening guidelines. There are no screening recommendations for other cancers caused by HPV.

Duration of Vaccine Protection

Studies suggest that HPV vaccines offer long-lasting protection against HPV infection and therefore disease caused by HPV infection. Studies of the bivalent and quadrivalent vaccines have followed vaccinated individuals for around ten years, and so far have found no evidence of protection decreasing over time. Duration of protection provided by HPV vaccination will continue to be studied.

HPV Vaccine Dosing Schedules

- If the first dose of any HPV vaccine is 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 HPV vaccine is 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).
- In a 2-dose schedule of HPV vaccine, the minimum interval is 5 months between the first and second dose. If the second dose is administered at a shorter interval, a third dose should be administered a minimum of 12 weeks after the second dose and a minimum of 5 months after the first dose.
- In a 3-dose schedule of HPV vaccine, the minimum intervals are 4 weeks between the first and second dose, 12 weeks between the second and third dose, and 5 months between the first and third dose. If a vaccine dose is administered at a shorter interval, it should be re-administered after another minimum interval has been met since the most recent dose.

Although minimum intervals are stated in the dosing schedule, there is no maximum interval. There is no reason to restart the vaccine series if the HPV vaccine schedule is interrupted; patients who have exceeded the minimum interval for the next dose by months or even years, may be given the next dose needed. 9-valent HPV vaccine may be used to continue or complete a vaccination series started with quadrivalent or bivalent HPV vaccines.

There is no ACIP recommendation regarding additional 9-valent HPV vaccine doses for persons who have been adequately vaccinated with bivalent or quadrivalent HPV vaccine.

HPV vaccine can safely be administered at the same visit as other vaccines recommended for adolescents at ages 11 or 12 years, such as tetanus toxoid, reduced diphtheria toxoid and acellular pertussis (Tdap) vaccine, quadrivalent meningococcal conjugate (MenACWY) vaccine, and influenza vaccine. Administering all indicated vaccines at a single visit at ages 11 or 12 years increases the likelihood that patients receive their vaccinations on schedule.

As mentioned previously, patients should be observed for 15 minutes after receiving any shot, including HPV vaccine.

Paying for HPV Vaccine

As with all vaccines recommended by the Advisory Committee on Immunization Practices (ACIP), HPV vaccines are covered by insurance. For patients that need assistance paying for HPV vaccine, the Vaccines for Children (VFC) program may be able to help. VFC provides vaccines for children ages 18 years and younger who are uninsured, Medicaid-eligible, or American Indian/Alaska Native. Learn more about the VFC program at www.cdc.gov/Features/VFCprogram.

Related Resources

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Clinician FAQ: CDC Recommendations for HPV Vaccine 2-Dose Schedules

After the October 2016 ACIP meeting, CDC now recommends that 11 or 12 year olds receive 2 doses of HPV vaccine instead of 3. Parents may have questions about this change. This resource helps explain the reasons for changing the HPV vaccine recommendation, and provides tips for talking with the parents of your patients about the change.

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 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 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 years for females and through age 21 years for males. Males age 22–26 years 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).

Answering parents' questions: *We now recommend 2 doses of HPV vaccine for your son or daughter, instead of 3, if your child starts the series before their 15th birthday. I still recommend your child start the vaccination series by age 11 or 12 years for best protection against HPV. He or she will need a second dose 6-12 months after the first dose.*

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).

Answering parents' questions: *If your child starts the series after his or her 15th birthday or has certain health problems that weaken his or her immune system, he or she will still need the 3-dose series. We will give the second dose 1–2 months after the first, and the last dose 6 months after the first dose.*

Why did CDC make the recommendation change to a 2-dose schedule?

Over the past year, CDC and the Advisory Committee on Immunization Practices (ACIP) have been reviewing data on 2-dose schedules, including results from studies of HPV vaccines that compared the antibody responses after 2 doses and 3 doses. These studies showed that the antibody response after 2 doses given at least 6 months apart to 9–14 year-olds was as good or better than the antibody response after 3 doses given to older adolescents and young adults, the age group in which efficacy was demonstrated in clinical trials.

Answering parents' questions: *CDC and ACIP (a group of experts that make vaccine recommendations) have been reviewing data on 2-dose HPV vaccination schedules for several months. The evidence showed that 2 doses of HPV vaccine given at least 6 months apart in younger adolescents were as good or better than 3 doses. These updated recommendations are an example of using the latest available evidence to provide your child with the best possible protection against serious diseases.*

Answering parents' questions: *Since your child received his/her first dose of the HPV vaccine before he/she was 15 years old, we'll only need to give 1 more dose.*

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CS HCVG15-PTT-106 11/30/2016

Why is the 2-dose schedule change recommended only for girls and boys age 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, 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.

Answering parents' questions: *The data we currently have from scientific studies (clinical trials) showed that 2 doses of HPV vaccine given at least 6 months apart were as good or better than 3 doses in children 9–14 years of age. Older adolescents haven't been studied in the same way, so we don't have information available for that age group. For that reason, the recommendation for number of doses has not been changed for older adolescents.*

What is the recommendation for persons with immunocompromising conditions?

CDC recommends 3 doses of HPV vaccine (0, 1–2, 6 months) for immunocompromised people age 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.

Answering parents' questions: *Even though CDC has recommended just 2 doses of HPV for kids under 15 years, we'll need to give your child 3 doses because he/she has a health problem that weakens his or her immune system.*

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.

If a girl or boy received 2 doses of HPV vaccine less than 5 months apart, do they need a third HPV vaccine dose?

Yes. In a 2-dose schedule of HPV vaccine, the recommended interval is 6–12 months, and the minimum interval is 5 months between the first and second dose. If the second dose is given earlier than 5 months, a third dose should be administered.

Answering parents' questions: *The recommended schedule is 2 doses given 6 to 12 months apart. The minimum amount of time between those doses is 5 months. Because your child received 2 doses less than 5 months apart, we'll need to give your child a third dose.*

If someone is age 15 years or older and started the vaccination series at age 11 but only received 1 dose, how many more doses do they need?

This person needs 1 more dose to complete a 2-dose series, which is recommended because the vaccination was started before turning 15 years old. In a 2-dose series, the second dose is recommended 6–12 months after the first dose. In this case, the first dose was given several years ago, so the second dose can be given right away.

Is the 9-valent HPV vaccine approved by FDA for use as a 2-dose schedule?

Yes, in October 2016, FDA approved a 2-dose schedule (0, 6–12 months) of 9-valent HPV vaccine for use in girls and boys age 9–14 years in the United States.

What HPV vaccines are currently available in the United States?

Three HPV vaccines are licensed for use in the United States: 9-valent HPV vaccine, quadrivalent HPV vaccine, and bivalent HPV vaccine. However, after the end of 2016, only 9-valent HPV vaccine will be sold in the United States.

Supplemental information and guidance for vaccination providers regarding use of 9-valent HPV

A 9-valent human papillomavirus (HPV) vaccine (9vHPV, Gardasil 9, Merck & Co.) was licensed for use in females and males in December 2014.[1,2,3,4] The 9vHPV was the third HPV vaccine licensed in the United States by the Food and Drug Administration (FDA); the other vaccines are bivalent HPV vaccine (2vHPV, Cervarix, GlaxoSmithKline), licensed for use in females, and quadrivalent HPV vaccine (4vHPV, Gardasil, Merck & Co.), licensed for use in females and males.[5] In February 2015, the Advisory Committee on Immunization Practices (ACIP) recommended 9vHPV as one of three HPV vaccines that can be used for routine vaccination of females and one of two HPV vaccines for routine vaccination of males.[6] After the end of 2016, only 9vHPV will be distributed in the United States.

In October 2016, ACIP updated HPV vaccination recommendations regarding dosing schedules.[7] CDC now recommends two doses of HPV vaccine (0, 6–12 month schedule) for persons starting the vaccination series before the 15th birthday. Three doses of HPV vaccine (0, 1–2, 6 month schedule) continue to be recommended for persons starting the vaccination series on or after the 15th birthday and for persons with certain immunocompromising conditions.

Guidance is needed for persons who started the series with 2vHPV or 4vHPV and may be completing the series with 9vHPV. The information below summarizes some of the recommendations included in ACIP Policy Notes and provides additional guidance.[5-7]

Information about the vaccines

What are some of the similarities and differences between the three HPV vaccines?

- Each of the three HPV vaccines is a noninfectious, virus-like particle (VLP) vaccine.
- 2vHPV, 4vHPV and 9vHPV all target HPV 16 and 18, types that cause approximately 66% of cervical cancers and the majority of other HPV-associated cancers in both women and men in the United States.[8] Both 4vHPV and 9vHPV also protect against HPV 6 and 11, types that cause anogenital warts. In addition, 9vHPV also targets five additional cancer causing types (HPV 31, 33, 45, 52, and 58) which cause about 15% of cervical cancers.
- 4vHPV and 9vHPV are licensed and recommended for use in females and males; 2vHPV is licensed and recommended for use in females.

How many HPV-associated cancers newly diagnosed each year are caused HPV 16/18 and by the five additional types in 9vHPV?

- An estimated 24,600 HPV-associated cancers are caused by HPV 16 or 18, and 3,800 by the five additional types prevented by 9vHPV. Almost all of the cancers caused by the five additional types occur in women (3,100).[8]

Information for persons who started an HPV vaccination series with 4vHPV or 2vHPV

If a series was started with 4vHPV or 2vHPV, can it be completed with 9vHPV?

- Yes, ACIP recommendations state that 9vHPV may be used to continue or complete a series started with a different HPV vaccine product.

Are additional 9vHPV doses recommended for a person who started a series with 4vHPV or 2vHPV and completed the series with one or two doses of 9vHPV?

- There is no ACIP recommendation for additional 9vHPV doses for persons who started the series with 4vHPV or 2vHPV and completed the series with 9vHPV.

National Center for Immunization and Respiratory Diseases
Office of the Director

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If a series was started with 4vHPV or 2vHPV and will be completed with 9vHPV, what are the intervals for the remaining doses in a three-dose or two-dose series?

- If the first dose of any HPV vaccine was given before the 15th birthday, vaccination should be completed according to a two-dose schedule. In a two-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 HPV vaccine was given on or after the 15th birthday, vaccination should be completed according to a three-dose schedule. In a three-dose series, the second dose is recommended 1–2 months after the first dose, and the third dose is recommended six 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. Number of recommended doses is based on age at administration of the first dose.

If a person desires protection against the five additional types prevented by 9vHPV and has started a series with another HPV vaccine product, what issues should be considered?

- The majority of all HPV-associated cancers that can be prevented by vaccination are caused by HPV 16 and HPV 18. These HPV types are prevented by all three vaccines: 2vHPV, 4vHPV and 9vHPV.
- The benefit of protection against the five additional types targeted by 9vHPV is mostly limited to females for prevention of cervical cancers and precancers. This is because only a small percentage of HPV-associated cancers in males is due to the five additional types prevented by 9vHPV.
- Available data show no serious safety concerns in persons who were vaccinated with 9vHPV after having received a three-dose series of 4vHPV at least 12 months earlier.
- Cervical cancer screening is recommended beginning at age 21 years and continuing through age 65 years for both vaccinated and unvaccinated women.[5]

What data are available on the number of doses of 9vHPV needed for protection against the 5 additional types for a series started with 4vHPV and completed with 9vHPV?

- There are no data on efficacy or immunogenicity of one, two or three doses of 9vHPV among persons who have already received only one or two doses of 4vHPV.
- In an immunogenicity and safety clinical trial, three doses of 9vHPV (administered at 0, 2, and 6 months) were given to females who had already received three doses of 4vHPV; the first dose of 9vHPV was administered 12–36 months later.[9]
  - After three doses of 9vHPV, over 98% of vaccinees developed antibodies to all five additional types. Antibody was also measured after the first dose of 9vHPV; most but not all vaccinees in the trial developed antibody against all five additional types. Antibody titers were higher after the third dose than after the first dose. Antibody was not measured after the second dose.
  - In a cross-study comparison, geometric mean antibody titers for the five additional HPV types among persons who received three doses of 9vHPV after three doses of 4vHPV were lower than those of persons who received three doses of 9vHPV without prior HPV vaccination. The clinical significance of the lower antibody titers is not known because there is no established minimum antibody level that correlates with protection.
- An immunogenicity trial of two doses of 9vHPV has been conducted in HPV vaccine-naïve adolescents aged 9–14 years. In this trial, the two doses were separated by an interval of 6 or 12 months.[1]
  - Results from this trial demonstrated non-inferior immunogenicity in adolescents age 9–14 years who received a two-dose schedule of HPV vaccine at a 0, 6 month schedule or a 0, 12 month schedule, compared to a three-dose schedule at 0, 2, and 6 months among women in the age group in which efficacy has been demonstrated in clinical trials.
  - Results from this trial support the use of a two-dose schedule in younger adolescents but do not directly address additional 9vHPV vaccination in persons who already received 4vHPV.

What data are available on the safety of 9vHPV vaccination after a series started with another HPV vaccine product?

- In an immunogenicity and safety clinical trial, 9vHPV was compared with placebo in females aged 12–26 years who had previously received three doses of 4vHPV. Among the 608 females evaluated who received 9vHPV, there was an acceptable safety profile.[9]
- Compared to persons in other studies who were vaccinated with 9vHPV and had never received any HPV vaccination, those who received 9vHPV after a three-dose 4vHPV series had higher rates of injection site swelling and redness. Otherwise, safety profiles of 9vHPV given to HPV vaccine naïve persons and 9vHPV given to persons who had previously completed a three-dose 4vHPV series were generally similar.

Information for persons who previously completed a three-dose or two-dose HPV vaccination series

Is additional vaccination with 9vHPV recommended for persons who have completed a three-dose or two-dose series of either 4vHPV or 2vHPV?

- There is no ACIP recommendation for additional 9vHPV doses for persons who previously completed a series of 4vHPV or 2vHPV.

If a person desires protection against the five additional types prevented by 9vHPV and has completed a series of 4vHPV, what issues should be considered?

- The majority of all HPV-associated cancers that can be prevented by vaccination are caused by HPV 16 or 18. These HPV types are prevented by all three HPV vaccines: 2vHPV, 4vHPV and 9vHPV.
- The benefit of protection against the five additional types targeted by 9vHPV would be mostly limited to females for prevention of cervical cancers and precancers. This is because only a small percentage of HPV-associated cancers in males is due to the five additional types prevented by 9vHPV.
- Available data show no serious safety concerns in persons who were vaccinated with 9vHPV after having received three doses of 4vHPV.
- Cervical cancer screening is recommended beginning at age 21 years and continuing through age 65 years for both vaccinated and unvaccinated women.5

What data are available on efficacy and immunogenicity of 9vHPV when administered after a complete three-dose series of another HPV vaccine product?

- In an immunogenicity and safety clinical trial, three doses of 9vHPV (administered in 0, 2, 6 month schedule) were given to females who had received three doses of 4vHPV; the first dose of 9vHPV was administered 12 to 36 months later.[9]
  - After three doses of 9vHPV, over 98% of vaccinees developed antibodies to all 5 additional types. Antibody was also measured after the first dose of 9vHPV; most but not all of the vaccinees in this trial developed antibody against all five additional types. Antibody titers were higher after the third dose than after the first dose. Antibody was not measured after the second dose.
  - In a cross study comparison, geometric antibody titers for the five additional types among persons who received three doses of 9vHPV after three doses of 4vHPV were lower than those of persons who received three doses of 9vHPV without prior HPV vaccination. The significance of the lower antibody titers is not known because there is no immune correlate of protection.
- There are no data on immunogenicity or efficacy of 9vHPV when administered after a two-dose series of another HPV vaccine product.

What data are available on the safety of 9vHPV when administered after a complete three-dose series of another HPV vaccine product?

- In an immunogenicity and safety clinical trial, 9vHPV was compared with placebo in females aged 12–26 years who had previously received three doses of 4vHPV. Among the 608 females evaluated who received 9vHPV, there was an acceptable safety profile.[9]
- Compared to persons in other studies who were vaccinated with 9vHPV and had never received any HPV vaccination, those who received 9vHPV after a three-dose 4vHPV series had higher rates of injection site swelling and redness. Otherwise, safety profiles of 9vHPV given to HPV vaccine naïve persons and 9vHPV given to persons who had previously completed a three-dose 4vHPV series were generally similar.

What is the cost effectiveness of 3 additional doses of 9vHPV for persons who already have received a complete two-dose or three-dose HPV vaccination series?

- The estimated cost per quality-adjusted life year (QALY) gained for giving an additional three doses of 9vHPV to females aged 13–18 years who have already received three doses of 4vHPV is over $100,000. Even for giving an additional two doses, the cost per QALY is close to $100,000.[10]
- The potential benefit would be lower, and the cost per QALY gained higher, in females older than 18 years and in males of any age.
- In contrast, routine 9vHPV vaccination in the United States is cost-saving, compared with routine 4vHPV vaccination.

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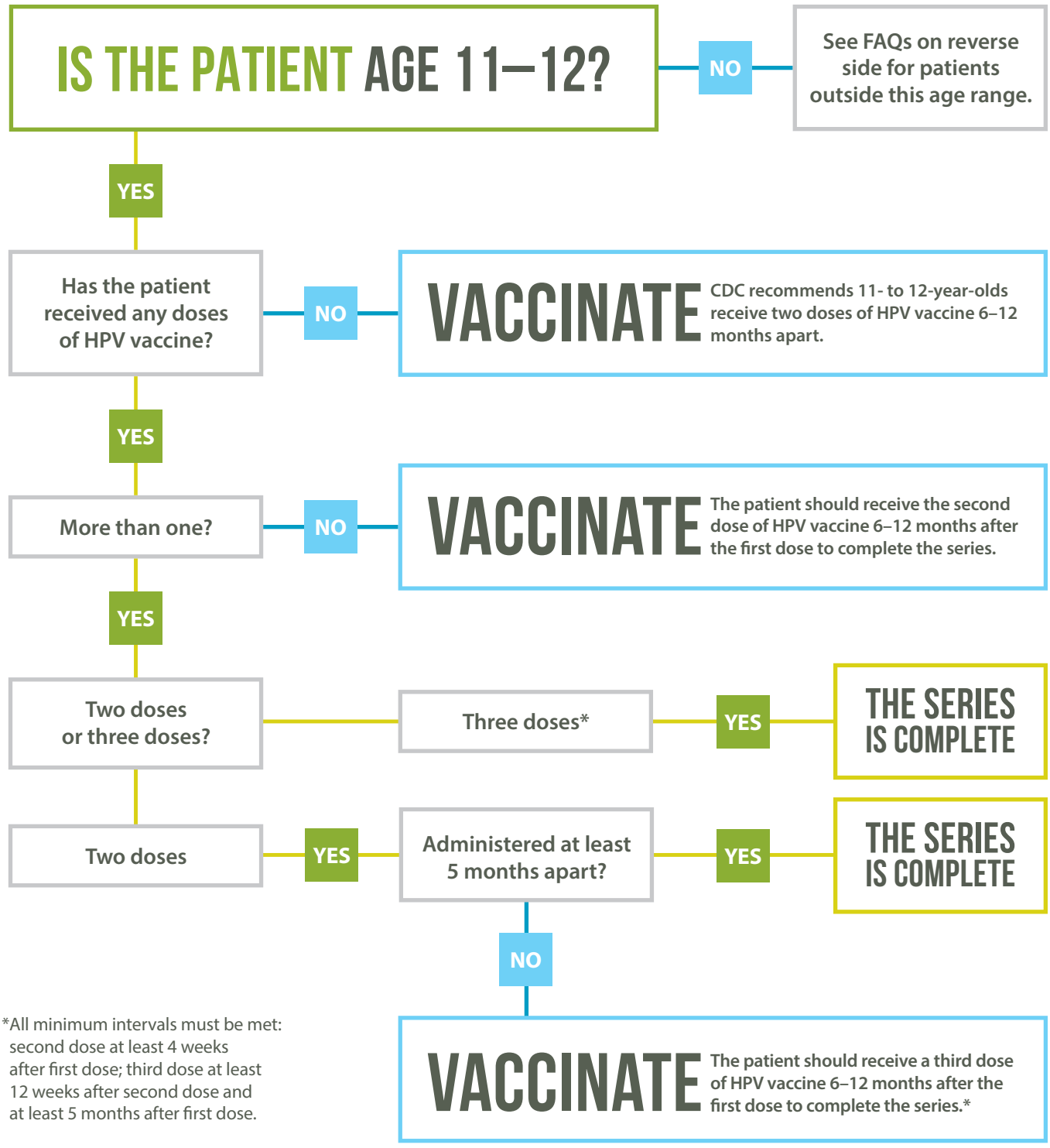
PREVENTING CANCER JUST GOT EASIER

HPV vaccine protects against cancers and other diseases caused by human papillomavirus (HPV). Follow the chart below to determine whether your patient needs two or three doses of HPV vaccine.



*All minimum intervals must be met: second dose at least 4 weeks after first dose; third dose at least 12 weeks after second dose and at least 5 months after first dose.

CDC RECOMMENDS TWO HPV DOSES FOR YOUNGER ADOLESCENTS

The Centers for Disease Control and Prevention (CDC) now routinely recommends two doses of HPV vaccine for 11- or 12-year-olds to prevent HPV cancers. This recommendation makes it easier for parents to protect their children by reducing the number of doses and trips to the doctor. HPV vaccination is an important cancer prevention tool and two doses of HPV vaccine will provide safe, effective, and long-lasting protection. Some specifics of the recommendation include:

- A two-dose schedule is recommended for adolescents starting the schedule at ages 9 through 14 years. For this age group, follow the decision tree on the reverse side.
- 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. The third dose should be given 6–12 months after the first dose to complete the series.
- A three-dose schedule is recommended for teens and young adults who start the series at ages 15 through 26 years. Under this schedule, the second dose of HPV vaccine should be given 1–2 months after the first dose, and the third dose should be given 6 months after the first dose.
- Three doses are recommended for people aged 9–26 years with certain immunocompromising conditions.

Read the full policy note:
www.cdc.gov/mmwr/volumes/65/wr/mm6549a5.htm

TALKING TO PATIENTS AND THEIR PARENTS ABOUT 2-DOSE SCHEDULES FOR HPV VACCINATION

With patients aged 11–12 years, start the vaccine discussion with their parents by making the following recommendation: *"Now that your child is 11 (or 12) years old, they are due for three vaccines today to help protect them from the infections that cause meningitis, HPV cancers, and pertussis—or whooping cough."*
Many parents are accepting of this bundled recommendation because it demonstrates that HPV vaccination is a normal part of adolescent vaccination. Parents may be interested in vaccinating, yet still have questions. Some parents might just need additional information from you, the clinician they trust. Clarify the parent's question or what additional information they need.

For parents who have a question or need more information about "why now/why 11–12?"
"As with all vaccine-preventable diseases, we want to protect your child early. If we start now, it's one less thing for you to worry about. Also, your child will only need two doses of HPV vaccine at this age. If you wait, your child may need three doses in order to get complete protection. We'll give the first dose today and then you'll need to bring your child back in 6 to 12 months from now for the second dose."

If a parent asks, or needs more information about "How long can we wait and still give just two doses?"
"The two-dose schedule is recommended if the series is started before the 15th birthday. However, I don't recommend waiting to give this cancer-preventing vaccine. As children get older and have busier schedules, it becomes more difficult to get them back in. I'd feel best if we started the series today to get your child protected as soon as possible."

For patients aged 9–14 who have already had two doses given less than 5 months apart
"The recommended schedule is two doses given 6 to 12 months apart. The minimum amount of time between those doses is 5 months. Because your child received two doses less than 5 months apart, we'll need to give your child a third dose."

For parents asking about the duration of protection or how well the vaccine will work with just two doses
"Studies have shown that two doses of HPV vaccine work very well in younger adolescents and we expect the same long-lasting protection with two doses that we expect with three doses." You can also access guidance on answering parents' questions about HPV vaccine by using our tip sheet, *Talking to Parents about HPV Vaccine,* at **www.cdc.gov/HPV.**

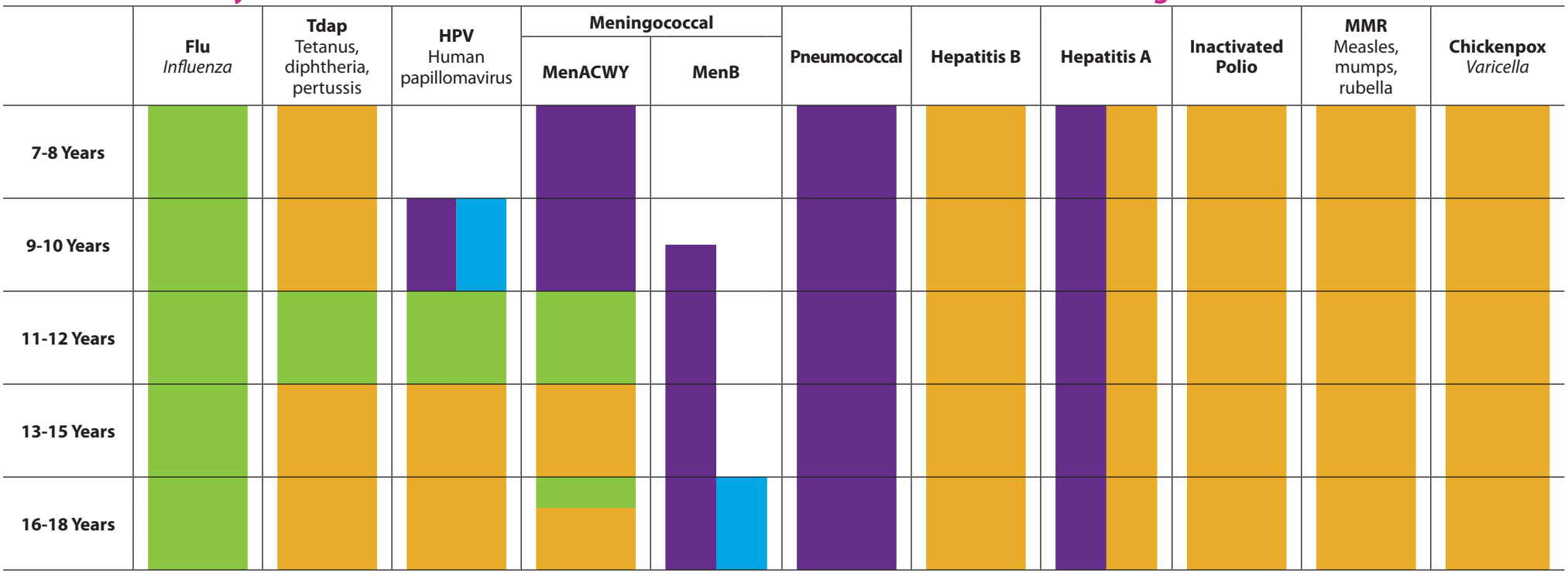
HPV VACCINE
IS CANCER PREVENTION

MARCH 2017

INFORMATION FOR PARENTS

2017 Recommended Immunizations for Children 7-18 Years Old

Talk to your child's doctor or nurse about the vaccines recommended for their age.



More information:

- **Flu:** Preteens and teens should get a flu vaccine every year.
- **Tdap:** Preteens and teens should get one shot of Tdap at age 11 or 12 years.
- **HPV:** All 11-12 year olds should get a 2-shot series of HPV vaccine at least 6 months apart. A 3-shot series is needed for those with weakened immune systems and those age 15 or older.
- **MenACWY:** All 11-12 year olds should get a single shot of a quadrivalent meningococcal conjugate vaccine (MenACWY). A booster shot is recommended at age 16.
- **MenB:** Teens, 16-18 years old, **may** be vaccinated with a MenB vaccine.

These shaded boxes indicate when the vaccine is recommended for all children unless your doctor tells you that your child cannot safely receive the vaccine.

These shaded boxes indicate the vaccine should be given if a child is catching-up on missed vaccines.

These shaded boxes indicate the vaccine is recommended for children with certain health or lifestyle conditions that put them at an increased risk for serious diseases. See vaccine-specific recommendations at www.cdc.gov/vaccines/pubs/ACIP-list.htm.

This shaded box indicates the vaccine is recommended for children not at increased risk but who wish to get the vaccine after speaking to a provider.

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

American Academy of Pediatrics
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Vaccine-Preventable Diseases and the Vaccines that Prevent Them

Diphtheria (Can be prevented by Tdap vaccination)

Diphtheria is a very contagious bacterial disease that affects the respiratory system, including the lungs. Diphtheria bacteria can be passed from person to person by direct contact with droplets from an infected person's cough or sneeze. When people are infected, the bacteria can produce a toxin (poison) in the body that can cause a thick coating in the back of the nose or throat that makes it hard to breathe or swallow. Effects from this toxin can also lead to swelling of the heart muscle and, in some cases, heart failure. In serious cases, the illness can cause coma, paralysis, and even death.

Hepatitis A (Can be prevented by HepA vaccination)

Hepatitis A is an infection in the liver caused by hepatitis A virus. The virus is spread primarily person-to-person through the fecal-oral route. In other words, the virus is taken in by mouth from contact with objects, food, or drinks contaminated by the feces (stool) of an infected person. Symptoms can include fever, tiredness, poor appetite, vomiting, stomach pain, and sometimes jaundice (when skin and eyes turn yellow). An infected person may have no symptoms, may have mild illness for a week or two, may have severe illness for several months, or may rarely develop liver failure and die from the infection. In the U.S., about 100 people a year die from hepatitis A.

Hepatitis B (Can be prevented by HepB vaccination)

Hepatitis B causes a flu-like illness with loss of appetite, nausea, vomiting, rashes, joint pain, and jaundice. Symptoms of acute hepatitis B include fever, fatigue, loss of appetite, nausea, vomiting, pain in joints and stomach, dark urine, grey-colored stools, and jaundice (when skin and eyes turn yellow).

Human Papillomavirus (Can be prevented by HPV vaccination)

Human papillomavirus is a common virus. HPV is most common in people in their teens and early 20s. It is the major cause of cervical cancer in women and genital warts in women and men. The strains of HPV that cause cervical cancer and genital warts are spread during sex.

Influenza (Can be prevented by annual flu vaccination)

Influenza is a highly contagious viral infection of the nose, throat, and lungs. The virus spreads easily through droplets when an infected person coughs or sneezes and can cause mild to severe illness. Typical symptoms include a sudden high fever, chills, a dry cough, headache, runny nose, sore throat, and muscle and joint pain. Extreme fatigue can last from several days to weeks. Influenza may lead to hospitalization or even death, even among previously healthy children.

Measles (Can be prevented by MMR vaccination)

Measles is one of the most contagious viral diseases. Measles virus is spread by direct contact with the airborne respiratory droplets of an infected person. Measles is so contagious that just being in the same room after a person who has measles has already left can result in infection. Symptoms usually include a rash, fever, cough, and red, watery eyes. Fever can persist, rash can last for up to a week, and coughing can last about 10 days. Measles can also cause pneumonia, seizures, brain damage, or death.

Meningococcal Disease (Can be prevented by meningococcal vaccination)

Meningococcal disease is caused by bacteria and is a leading cause of bacterial meningitis (infection around the brain and spinal cord) in children. The bacteria are spread through the exchange of nose and throat droplets, such as when coughing, sneezing or kissing. Symptoms include sudden onset of fever, headache, and stiff neck. Meningococcal bacteria also cause blood infections. About one of every ten people who get the disease dies from it. Survivors of meningococcal disease may lose their arms or legs, become deaf, have problems with their nervous systems, become developmentally disabled, or suffer seizures or strokes.

Mumps (Can be prevented by MMR vaccination)

Mumps is an infectious disease caused by the mumps virus, which is spread in the air by a cough or sneeze from an infected person. A child can also get infected with mumps by coming in contact with a contaminated object, like a toy. The mumps virus causes swollen salivary glands under the ears or jaw, fever, muscle aches, tiredness, abdominal pain, and loss of appetite. Severe complications for children who get mumps are uncommon, but can include meningitis (infection of the covering of the brain and spinal cord), encephalitis (inflammation of the brain), permanent hearing loss, or swelling of the testes, which rarely results in decreased fertility.

Pertussis (Whooping Cough) (Can be prevented by Tdap vaccination)

Pertussis is caused by bacteria spread through direct contact with respiratory droplets when an infected person coughs or sneezes. In the beginning, symptoms of pertussis are similar to the common cold, including runny nose, sneezing, and cough. After 1-2 weeks, pertussis can cause spells of violent coughing and choking, making it hard to breathe, drink, or eat. This cough can last for weeks. Pertussis is most serious for babies, who can get pneumonia, have seizures, become brain damaged, or even die. About half of children under 1 year of age who get pertussis must be hospitalized.

Pneumococcal Disease (Can be prevented by pneumococcal vaccination)

Pneumonia is an infection of the lungs that can be caused by the bacteria called pneumococcus. This bacteria can cause other types of infections too, such as ear infections, sinus infections, meningitis (infection of the covering around the brain and spinal cord), and bacteremia (bloodstream infection). Sinus and ear infections are usually mild and are much more common than the more serious forms of pneumococcal disease. However, in some cases pneumococcal disease can be fatal or result in long-term problems, like brain damage and hearing loss. Pneumococcal disease spreads when people cough or sneeze. Many people have the bacteria in their nose or throat at one time or another without being ill—this is known as being a carrier.

Polio (Can be prevented by IPV vaccination)

Polio is caused by a virus that lives in an infected person's throat and intestines. It spreads through contact with the stool of an infected person and through droplets from a sneeze or cough. Symptoms typically include sore throat, fever, tiredness, nausea, headache, or stomach pain. In about 1% of cases, polio can cause paralysis. Among those who are paralyzed, About 2 to 10 children out of 100 die because the virus affects the muscles that help them breathe.

Rubella (German Measles) (Can be prevented by MMR vaccination)

Rubella is caused by a virus that is spread through coughing and sneezing. In children rubella usually causes a mild illness with fever, swollen glands, and a rash that lasts about 3 days. Rubella rarely causes serious illness or complications in children, but can be very serious to a baby in the womb. If a pregnant woman is infected, the result to the baby can be devastating, including miscarriage, serious heart defects, mental retardation and loss of hearing and eye sight.

Tetanus (Lockjaw) (Can be prevented by Tdap vaccination)

Tetanus is caused by bacteria found in soil, dust, and manure. The bacteria enters the body through a puncture, cut, or sore on the skin. When people are infected, the bacteria produce a toxin (poison) that causes muscles to become tight, which is very painful. Tetanus mainly affects the neck and belly. This can lead to "locking" of the jaw so a person cannot open his or her mouth, swallow, or breathe. Complete recovery from tetanus can take months. One to two out of 10 people people who get tetanus die from the disease.

Varicella (Chickenpox) (Can be prevented by varicella vaccination)

Chickenpox is caused by the varicella zoster virus. Chickenpox is very contagious and spreads very easily from infected people. The virus can spread from either a cough, sneeze. It can also spread from the blisters on the skin, either by touching them or by breathing in these viral particles. Typical symptoms of chickenpox include an itchy rash with blisters, tiredness, headache and fever. Chickenpox is usually mild, but it can lead to severe skin infections, pneumonia, encephalitis (brain swelling), or even death.

If you have any questions about your child's vaccines, talk to your healthcare provider.

Last updated on 01/10/2017 • *CS273685-A*