# Human Papillomavirus Vaccination

ACOG's toolkit for clinicians, with resources to inform and protect patients





### The American College of Obstetricians and Gynecologists

WOMEN'S HEALTH CARE PHYSICIANS

Vice President, Practice Activities Christopher M. Zahn, MD, FACOG

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Dear Colleague:

The American College of Obstetricians and Gynecologists (ACOG) is dedicated to increasing adult immunizations provided by obstetrician-gynecologists. As you know, we now have three vaccines that help prevent HPV-related cancers. The Human Papillomavirus (HPV) Vaccine is recommended for girls and young women, and boys and young men (see enclosed ACOG Committee Opinion #641 for specific recommendations). If your patient is a mother, talk to them about the importance of vaccinating their kids against HPV. This 3-dose vaccine has the potential to prevent up to 81% of cervical cancer cases. A physician recommendation for vaccination has been shown to be the most effective way to increase immunization rates among patients. If your patient does not accept your recommendation initially, continue to offer the vaccine to her on subsequent office visits. I highly encourage you to incorporate HPV vaccination into your routine well-woman care.

This toolkit includes evidence-based, tested messages to help you and your staff communicate with patients about the importance of receiving HPV Vaccination. The College's new Committee Opinion # 641, Human Papillomavirus Vaccination, has been updated along with ACOG's HPV resources to reflect changes in guidance from ACOG and ACIP including updated information regarding the use of the 9-valent HPV vaccine. If your patient has questions about receiving the HPV vaccine, please give her a sheet from the Frequently Asked Questions for Patients Concerning HPV Vaccination tear pad which includes ACOG's evidence based, tested messages. For tips on speaking to parents, adolescents, and young women about HPV Vaccination, refer to our Physician Script. In addition, federal law requires that each patient receive a vaccine information statement (VIS) before receiving a vaccine. The HPV VIS is included in this tool kit and may be copied and distributed to your patients.

Educate your entire practice team about the importance of HPV vaccination. For up-to-date information, please encourage your staff and patients to visit the ACOG immunization web page, Immunization for Women, at <u>www.immunizationforwomen.org</u>.

We hope the enclosed materials are helpful to you, your practice team, and your patients. If you have additional questions, please email us at <u>immunization@acog.org</u> or call 202-863-2489. If you would like additional materials, please visit us at sales.acog.org. Thank you for your time and attention.

Sincerely,

Christopher M. Zahn, MD Vice President, Practice Activities

The materials included in this tool kit were originally printed and mailed through an unrestricted educational grant from Merck, Inc in 2016. The American College of Obstetricians and Gynecologists reviews its publications regularly and has updated the contents within this toolkit to reflect newly published ACOG recommendations.



# **ACOG COMMITTEE OPINION**

Number 809

(Replaces Committee Opinion Number 704, June 2017)

#### **Committee on Adolescent Health Care**

Immunization, Infectious Disease, and Public Health Preparedness Expert Work Group

This Committee Opinion was developed by the Immunization, Infectious Disease, and Public Health Preparedness Expert Work Group and the Committee on Adolescent Health Care, with the assistance of Linda O'Neal Eckert, MD.

### **Human Papillomavirus Vaccination**

**ABSTRACT:** Human papillomavirus (HPV) causes significant morbidity and mortality in women and men. The HPV vaccine significantly reduces the incidence of anogenital cancer and genital warts in women and in men. Human papillomavirus vaccines are among the most effective vaccines available worldwide, with unequivocal data demonstrating greater than 99% efficacy when administered to women who have not been exposed to that particular type of HPV. Obstetrician–gynecologists and other health care professionals should strongly recommend HPV vaccination to eligible patients and stress the benefits and safety of the HPV vaccine. Further, obstetrician–gynecologists are encouraged to stock and administer HPV vaccines in their offices when feasible. Ideally, the HPV vaccine should be given in early adolescence because vaccination is most effective before exposure to HPV through sexual activity. Unvaccinated women age 26 years and younger should receive the HPV vaccine series regardless of sexual activity, prior exposure to HPV, or sexual orientation. The HPV vaccine is now licensed in the United States for women and men through age 45 years. For some women aged 27–45 years who are previously unvaccinated, obstetrician–gynecologists and other health care professionals may use shared clinical decision making regarding HPV vaccination, considering the patient's risk for acquisition of a new HPV infection and whether the HPV vaccine may provide benefit.

#### **Recommendations and Conclusions**

The American College of Obstetricians and Gynecologists (ACOG) makes the following recommendations and conclusions:

- The Advisory Committee on Immunization Practices and ACOG recommend routine human papillomavirus (HPV) vaccination for girls and boys at the target age of 11–12 years (but it may be given from the age of 9 years) as part of the adolescent immunization platform.
- Obstetrician-gynecologists and other health care professionals should strongly recommend HPV vaccination to eligible patients and stress the benefits and safety of the HPV vaccine.
- Obstetrician-gynecologists should assess and vaccinate adolescent girls and young women with the HPV vaccine during the catch-up period (ages 13–26 years), regardless of sexual activity, prior exposure to HPV, or sexual orientation, if they were not vaccinated in the target age of 11–12 years.

- Obstetrician-gynecologists and other health care professionals should educate parents in their decision making regarding vaccinations for their daughters and sons.
- For some women aged 27–45 years who are previously unvaccinated, obstetrician–gynecologists and other health care professionals may use shared clinical decision making regarding the HPV vaccination, considering the patient's risk for acquisition of a new HPV infection and whether the HPV vaccine may provide benefit.
- The American College of Obstetrician–Gynecologists does not recommend that an individual who received the quadrivalent HPV vaccine be revaccinated with 9-valent HPV vaccine, including those aged 27–45 years who previously completed some, but not all, of the vaccine series when they were younger.
- Obstetrician-gynecologists are encouraged to stock and administer HPV vaccine in their offices when feasible.

- Vaccination is recommended for women through age 26 years even if the patient is tested for HPV DNA and the results are positive.
- Testing for HPV DNA is not recommended before vaccination.
- Human papillomavirus vaccination is not recommended during pregnancy; however, routine pregnancy testing is not recommended before vaccination.
- The HPV vaccine can and should be given to breastfeeding women age 26 years and younger who have not previously been vaccinated.
- In children with a history of sexual abuse or assault, the HPV vaccine should be given as early as possible, starting at age 9 years

#### Background

Human papillomavirus (HPV) causes significant morbidity and mortality in women and men. Human papillomavirus infection is associated with anogenital cancer (including cervical, vaginal, vulvar, penile, and anal) and oropharyngeal cancer (back of tongue, tonsil) (see Table 1 Number of Human Papillomavirus–Associated and Estimated Number of Human Papillomavirus–Attributable Cancer Cases Per Year). Human papillomavirus also is associated with genital warts. Of the more than 150 HPV genotypes, 13 genotypes have been shown to cause cervical cancer (1). Despite the success of cervical cancer screening in the United States, each year cervical cancer is diagnosed in more than 13,000 women and nearly 4,000 die from the disease (2). Most cases of cervical cancer occur in women who have had inadequate screening. Approximately 90% of cases of genital warts are caused by HPV genotypes 6 and 11 (3). Human papillomavirus-associated cancer in men is increasing in the United States, as are HPV-associated anal and vulvar cancer in women (4).

Despite the benefits of HPV vaccines, only 54% of women and 49% of men in the recommended age groups have received all recommended doses (5). Compared with many other countries, HPV vaccination rates in the United States are unacceptably low (5). According to the Centers for Disease Control and Prevention, if health care professionals increase HPV vaccination rates in eligible recipients to 80% in the target age range, it is estimated that an additional 53,000 cases of cervical cancer could be prevented during the lifetimes of those younger than 12 (6). Furthermore, for every year that HPV vaccination rates do not increase, an additional 4,400 women will develop cervical cancer. For

 Table 1. Number of Human Papillomavirus–Associated and Estimated Number of Human Papillomavirus–Attributable Cancer Cases Per Year\*

Cancer Site	Average Number of Cases of Cancer Per Year in Sites Where HPV Often Is Found (HPV-Associated Cancer)	Percentage of Cases of Cancer Probably Caused by Any HPV Type <sup>†</sup>	Estimated Number of Cases of Cancer Probably Caused by Any HPV Type <sup>†</sup>
Cervix	12,015	91%	10,900
Vagina	862	75%	600
Vulva	4,009	69%	2,800
Penis	1,303	63%	800
Anus <sup>‡</sup>	6,810	91%	6,200
Female	4,539	93%	4,200
Male	2,270	89%	2,000
Oropharynx	19,000	70%	13,500
Female	3,460	63%	2,200
Male	15,540	72%	11,300
Total	43,999	<b>79</b> %	34,800
Women	24,886	83%	20,700
Men	19,113	74%	14,100

Abbreviation: HPV, human papillomavirus.

\*Estimates were rounded to the nearest 100. Estimated counts might not sum to total because of rounding.

<sup>†</sup>HPV types detected in genotyping study; most were high-risk HPV types known to cause cancer.

<sup>‡</sup>Includes anal and rectal squamous cell carcinomas.

Saraiya M, Unger ER, Thompson TD, Lynch CF, Hernandez BY, Lyu CW, et al. US assessment of HPV types in cancers: implications for current and 9-valent HPV vaccines. HPV Typing of Cancers Workgroup. J Natl Cancer Inst 2015;107:djv086.

information and resources on establishing an immunization program in your clinical practice, see the American College of Obstetricians and Gynecologists' (ACOG) guidance on Immunization Implementation Strategies for Obstetrician–Gynecologists at https://www.acog.org/ clinical/clinical-guidance/committee-opinion/articles/ 2019/03/immunization-implementation-strategies-forobstetrician-gynecologists.

#### **Human Papillomavirus Vaccination**

The U.S. Food and Drug Administration has approved three vaccines that prevent HPV infection. These vaccines cover 2, 4, or 9 HPV serotypes, respectively. Bivalent and quadrivalent vaccines are approved for women and men aged 9–26 years, and the 9-valent vaccine is approved for women and men aged 9–45 years. Currently, the 9-valent vaccine is the only HPV vaccine available in the United States (7).

The Advisory Committee on Immunization Practices and ACOG recommend routine HPV vaccination for girls and boys at the target age of 11–12 years (but it may be given from the age of 9 years) as part of the adolescent immunization platform to reduce the incidence of anogenital cancer and genital warts associated with HPV infection (8). Although obstetrician-gynecologists are not likely to care for many patients in the recommended HPV vaccination target population, they have the opportunity to provide catch-up vaccination for girls and women age 13 and older and to discuss HPV vaccination with parents of children in the target age. Obstetriciangynecologists should assess and vaccinate adolescent girls and young women with the HPV vaccine during the catch-up period (ages 13-26 years), regardless of sexual activity, prior exposure to HPV, or sexual orientation, if they were not vaccinated in the target age of 11–12 years. Further, obstetrician-gynecologists and other health care professionals should educate parents in their decision making regarding vaccinations for their daughters and sons. Finally, for some women age 27-45 years who are previously unvaccinated, obstetrician-gynecologists and other health care professionals may use shared clinical decision making regarding the HPV vaccination, considering the patient's risk for acquisition of a new HPV infection and whether the HPV vaccine may provide benefit (7, 9, 10).

#### Human Papillomavirus Vaccination Timing and Number of Doses

#### Children and Adolescents (9–14 years)

The target age for HPV vaccination is 11-12 years. For immunocompetent girls and boys who receive their first dose of HPV vaccine before 15 years of age, only two doses are needed because the immune response that develops at this age provides antibody levels equivalent to those in patients who receive three doses at the age of 15 years or older (11). The timing of the two doses is 0 (baseline) and 6–12 months. The 6-month interval between these two doses is critical for ensuring adequate immune titers and durability of protection. If the interval between the two doses is less than 5 months, a third dose is recommended (8). Studies show that two doses of HPV vaccine given 6 months apart in individuals aged 9–14 years resulted in antibody titers equal to those in individuals aged 15–26 years who were given three doses. Hence, only two doses, 6–12 months apart, are needed if HPV vaccination is initiated before 15 years of age in boys and girls (5, 8).

In addition to the ability to use two doses instead of three doses, earlier vaccination also is preferred because HPV vaccines are most effective when given before exposure and infection with HPV, which coincide with the onset of sexual activity. Statistics show that 20% of 9th graders and more than 55% of 12th graders have engaged in sexual intercourse (12, 13). In Sweden, vaccine effectiveness in preventing genital warts was 93% among girls vaccinated between 10 years of age and 13 years of age compared with 48% and 21% if vaccinated at ages 20-22 years and 23-26 years, respectively (14). All of these findings underscore the importance of vaccination at the target age (11-12 years), which is before the onset of potential exposure in the vast majority of adolescents. Human papillomavirus vaccination is not associated with an earlier onset of sexual activity (15, 16) or increased incidence of sexually transmitted infections (12).

#### Teens and Adults (15–26 years)

If girls or boys receive their first dose at age 15 years or older, three doses are needed and given at 0 (baseline), 1–2 months after the first dose, and 6 months after the first dose (8).

Unvaccinated women age 26 years and younger should receive the HPV vaccine series regardless of sexual activity, prior exposure to HPV, or sexual orientation. Although the vaccine is less effective in previously infected individuals, it is expected that some benefit will be experienced because prior exposure to all nine vaccine types is highly unlikely (17, 18). Vaccination is recommended for women through age 26 years even if the patient is tested for HPV DNA and the results are positive. Testing for HPV DNA is not recommended before vaccination.

#### Adults (27–45 years)

The HPV vaccine is now licensed in the United States for women and men through age 45 years. Although administration of the HPV vaccine is safe in patients aged 27–45, and can prevent new infections in women not previously exposed to the HPV-type protection generated by the vaccine, most women in this age range will have been exposed to HPV already. The overall public health benefit of HPV vaccination in women aged 27–45 years is markedly diminished compared with use in the target age range (7).

Ideally, the HPV vaccine should be given in early adolescence because vaccination is most effective before exposure to HPV through sexual activity. For some women aged 27-45 years who are previously unvaccinated, obstetrician-gynecologists and other health care professionals may use shared clinical decision making regarding HPV vaccination, considering the patient's risk for acquisition of a new HPV infection and whether the HPV vaccine may provide benefit. Those women aged 27-45 years who are most likely to benefit from vaccination are those at greater risk for HPV exposure or acquisition: younger women, women who are not in committed monogamous relationships, and women with recently diagnosed sexually transmitted infections. When counseling patients, clinicians should explain that women aged 27-45 years in long-term monogamous relationships are not likely at risk of acquiring a new HPV infection. It is not routinely recommended that these women receive the vaccine (7).

Clinicians should keep in mind that catch-up HPV vaccination is not recommended for all adults older than 26 years and that HPV vaccination does not need to be discussed with most adults older than 26 years. The American College of Obstetricians and Gynecologists does not recommend that an individual who received the quadrivalent HPV vaccine be revaccinated with 9-valent HPV vaccine, including those aged 27–45 years who previously completed some, but not all, of the vaccine series when they were younger. Further, having a new partner increases the risk of a new HPV infection at any age; however, with increasing age and more past exposure to HPV, it is less likely that vaccination provides benefit (7).

Typically, routine vaccine recommendations are made for specific at-risk populations (identified either by age group or underlying health-related conditions) after considering vaccination cost, availability, and public health impact. The 9-valent HPV vaccine is costly and in short supply globally. In addition, routine HPV vaccination of all women age 27–45 would be expected to have a very limited effect on the global fight to prevent cervical cancer. Thus, in this case, the shared clinical decision making approach is recommended by the Centers for Disease Control and Prevention and ACOG.

#### **Considerations for Special Populations**

Human papillomavirus vaccination is not recommended during pregnancy; however, routine pregnancy testing is not recommended before vaccination. When the vaccine has been inadvertently administered to a pregnant woman, safety data are reassuring, although the data are somewhat limited because the vaccine is not used routinely in pregnancy (19–21). Patients and obstetrician–gynecologists or other health care professionals are encouraged to register women exposed to the 9-valent HPV vaccine around the time the pregnancy began or during pregnancy by contacting the manufacturer (www.merckpregnancyregistries.com/ gardasil9.html). Pregnancy registries for the quadrivalent HPV vaccine and bivalent HPV vaccine have been closed. If a vaccine series is started and a patient then becomes pregnant, completion of the vaccine series should be delayed until that pregnancy is completed. It is not necessary to restart the series. The HPV vaccine can and should be given to breastfeeding women age 26 years and younger who have not previously been vaccinated. The HPV vaccine has not been shown to affect the safety of breastfeeding for these women or their infants (22).

The presence of immunosuppression, like that experienced in patients with human immunodeficiency virus infection or organ transplantation, is not a contraindication to HPV vaccination. However, the immune response may be less robust in an immunocompromised patient (23). Thus, the three-dose schedule is recommended for immunocompromised women and men, adults and adolescents, even if younger than 15 years.

In children with a history of sexual abuse or assault, the HPV vaccine should be given as early as possible, starting at age 9 years (8).

### Boosters, Revaccination, and Series Completion

The durability of the immune response (ie, how long protection lasts) of the HPV vaccine is being monitored in long-term studies, and currently there is no indication for a booster vaccine (24). The vaccine series does not need to be restarted in the case of a delay in administration of the second or third dose, regardless of the amount of time of the delay. Further, revaccination with the 9-valent HPV vaccine in individuals who previously completed the three-dose series with the quadrivalent HPV vaccine or the bivalent HPV vaccine is not a routine recommendation. The bivalent and quadrivalent vaccines have been shown to be extremely effective at preventing HPV-related disease (20; 25).

If obstetrician-gynecologists or other health care professionals do not know or do not have the same HPV vaccine product previously administered, or are in settings that are transitioning to the 9-valent HPV vaccine, any available HPV vaccine product may be used to continue or complete the series for women for protection against HPV genotypes 16 and 18; the 9-valent HPV vaccine or the quadrivalent HPV vaccine may be used to continue or complete the series for men (26).

#### Vaccine Safety

Safety data for all three HPV vaccines are reassuring. According to the Vaccine Adverse Events Reporting System, more than 270 million doses of HPV vaccine have been distributed worldwide since 2006, and there are no data to suggest that there are any severe adverse effects or adverse reactions linked to vaccination (27). The 9-valent and quadrivalent vaccines had similar safety profiles, except that the 9-valent HPV vaccine had a higher rate of injection site swelling and erythema than the quadrivalent HPV vaccine, and the rate increased after each successive dose of the 9-valent HPV vaccine (26). The Vaccine Adverse Events Reporting System reports from December 2014 to December 2017 demonstrated no additional or unexpected safety concerns related to the 9-valent HPV vaccine (28). Available data demonstrate no safety concerns in individuals who were vaccinated with the 9-valent HPV vaccine after having been vaccinated with the quadrivalent HPV vaccine (29, 30).

Anyone who has had a life-threatening allergic reaction to any component of the HPV vaccine, or to a previous dose of the HPV vaccine, should not get the vaccine. Obstetrician-gynecologists and other health care professionals should assess patients for severe allergies, including but not limited to an allergy to yeast or prior HPV vaccine dose. An individual with a moderate or severe febrile illness should wait until the illness improves before receiving a vaccine. Obstetrician-gynecologists and other health care professionals should counsel patients to expect mild local discomfort after the vaccination and that such discomfort is not a cause for concern. Syncope and site reactions are common after this vaccine, but serious adverse events are rare. Adolescents should be observed for at least 15 minutes after vaccination because of the risk of fainting.

#### Vaccine Efficacy

Human papillomavirus vaccines are among the most effective vaccines available worldwide, with unequivocal data demonstrating greater than 99% efficacy when administered to women who have not been exposed to that particular type of HPV (26). The HPV vaccine significantly reduces the incidence of anogenital cancer and genital warts in women and in men (31, 32). Additionally, HPV vaccination may decrease the incidence of oropharyngeal cancer. In the United States, the prevalence of vaccine-type HPV infection decreased 71% among women aged 14–19 years between 2006 (when the quadrivalent HPV vaccine was introduced) and 2014 (31). Additionally, a marked reduction in genital warts has occurred in countries with high HPV vaccine coverage (33).

The 9-valent HPV vaccine protects against more than 99% of HPV disease related to genotypes 6, 11, 16, and 18 and up to 96.7% for HPV disease related to genotypes 31, 33, 45, 52, and 58 (26). This includes prevention of cervical, vaginal, vulvar, and anal disease caused by these HPV types. The HPV vaccine is a prophylactive vaccine used to prevent disease. Studies are ongoing currently as to whether it may be helpful to prevent recurrent disease, but current data does not support its use as a therapeutic vaccine (34).

#### Patient Education and Vaccination Efforts

High rates of HPV vaccination will reduce the burden of HPV-related disease in the United States. Current vaccination rates are unacceptably low. Studies have shown that physicians' recommendations have the strongest influence in the acceptance of HPV vaccination by patients and parents of patients (35). Obstetriciangynecologists and other health care professionals should strongly recommend HPV vaccination to eligible patients and stress the benefits and safety of the HPV vaccine. Further, obstetrician-gynecologists are encouraged to stock and administer HPV vaccines in their offices when feasible. Obstetrician-gynecologists play a critical role and should assess and vaccinate adolescent girls age 11–12 years and previously unvaccinated young women during the catch-up period (ages 13–26 years). Health care professionals should use shared clinical decision making with previously unvaccinated women aged 27–45 years to assess the benefit of HPV vaccination.

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#### What is HPV?

Human papillomavirus (HPV) infection is the most common sexually transmitted infection (STI) in the United States. HPV infections can cause genital warts. HPV infections also can cause cell changes that can lead to cancer over time, including cancer of the cervix. There are more than 100 types of HPV, but only a few types can cause disease.

#### How common is HPV?

HPV infections are so common that 8 in 10 people who are sexually active will get at least one type of HPV in their lives. About 14 million people get a new HPV infection every year. This includes adults and teens.

#### Will I know if I have HPV?

Genital warts can be a sign of infection. When HPV infection affects the cervix, there are no symptoms. Usually, people with HPV infection do not know they have it. This is one reason why HPV spreads easily.

#### How long do HPV infections last?

The immune system fights most HPV infections and clears them from the body, usually within 2 years. But sometimes HPV infections can last longer. A longer infection with a "high-risk" HPV type can turn into cancer. It usually takes years for this to happen.

#### Do all women with HPV infections get cancer?

No. In most women, HPV infections are cleared from the body by the immune system. For women with ongoing infection, regular screening is done with Pap tests. The Pap test looks for abnormal cells in the cervix. Finding and treating cell changes early can help prevent cervical cancer.

#### Can HPV be prevented?

Yes. One way to protect against HPV infection is by getting the HPV vaccine. The vaccine is safe and effective and protects against the HPV types that are the most common cause of genital warts and cancer.

#### Is the HPV vaccine safe?

Yes. Studies show that the vaccine is safe and effective. Millions of people around the world have gotten the HPV vaccine without serious side effects. The vaccine does not contain live viruses, so it cannot cause an HPV infection. The Centers for Disease Control and Prevention monitors the HPV vaccine and its safety.

#### Is the HPV vaccine effective?

Yes, the HPV vaccine is highly effective, especially when given before a person has sex. The vaccine is given as a series of shots, and it can reduce the risk of HPV-related genital warts and cancer by up to 99 percent when all shots have been given. HPV vaccine is one of the most effective vaccines you can get.

#### Who should be vaccinated?

Vaccination works best when it is done before a person is sexually active and exposed to HPV. The best age for HPV vaccination of girls and boys is 11 or 12, but it can be given starting at age 9 and through age 26.

#### Why is HPV vaccination also recommended for boys?

Boys can get HPV-related infections of the penis, anus, mouth, and throat. No effective screening tests exist for anal cancer or throat cancer. Also, males who receive the HPV vaccine are less likely to infect future sexual partners.

#### Why is HPV vaccination recommended for children?

The body develops better protection against HPV when the vaccine is given between age 11 and 12. This may result in longer-lasting immunity to HPV-related diseases.

#### How is the HPV vaccine given?

The HPV vaccine is given as a series of shots:

- For those age 9 to 14, two shots of vaccine are recommended. The second shot should be given 6 to 12 months after the first one.
- For those age 15 through 26, three shots of vaccine are recommended. The second shot should be given 1 to 2 months after the first one. The third shot should be given 6 months after the first shot.

#### What happens if someone misses a shot?

If a child has not gotten all of the shots, they do not have to "start over." They can get the next shot that is due even if the time between them is longer than recommended. This is also true for adults who have not completed the number of recommended shots. Talk with your health care professional if you have questions about getting any shots you missed.

#### What if someone older than 26 wants the HPV vaccine?

If a person older than 26 has not been vaccinated and is at risk of a new HPV infection, they should talk with their health care professional about whether they need the HPV vaccine. The vaccine is approved for people through age 45.

#### Will vaccinating girls against HPV encourage them to become sexually active sooner?

No. Studies show that HPV vaccination has not been linked to girls having an earlier start to sexual activity or more sexual activity.

#### What are the side effects of the HPV vaccine?

The most common side effect of the HPV vaccine is soreness and redness where the shot is given. There have been no reports of severe side effects or bad reactions to the vaccine.

#### Can I get the shot if I have already had sex?

Yes. If you have had sex, you may already be infected with one or more types of HPV. But the vaccine may still protect you against HPV types you do not have yet.

#### **Resources from ACOG**

Cervical Cancer Screening www.acog.org/Patients-CervicalCancerScreening

#### **Cervical Cancer**

www.acog.org/Patients-CervicalCancer

#### Immunization

www.acog.org/topics/immunization

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Frequently Asked Questions for Obstetrician–Gynecologists and Other Health Care Professionals Human Papillomavirus

#### Why are HPV vaccines needed?

Human papillomavirus (HPV) vaccines reduce the occurrence of cervical, vaginal, vulvar, and anal cancer and may decrease the incidence of oropharyngeal cancer. An immediate effect of HPV vaccination is a reduction in HPV infection and genital warts. Approximately 79 million individuals in the United States have been infected with HPV, and 14 million new infections occur every year (1). Most infections are transient. However, those individuals with untreated HPV infection are at a high risk of developing HPV-associated cancer, of which cervical cancer in women is the most common. Approximately 13,000 cases of cervical cancer occur per year with more than 4,000 deaths annually (2). Approximately 300,000 cases of genital warts, 7,000 cases of anal cancer, and more than 12,000 cases of HPV-associated oropharyngeal cancer occur annually in women and men. The vaccine's role in preventing oropharyngeal (tonsil and base of tongue) and anal cancer is important because there are no screening tests for those types of cancer. Approximately 60% of cases of oral cancer, 66% of cases of cervical cancer, and approximately 80% of cases of anal cancer are associated with two of the highest risk HPV genotypes, HPV types 16 and 18 (2).

#### Who should get vaccinated?

Human papillomavirus vaccination is strongly recommended for girls and boys aged 11–12 years but can be given as early as age 9 years and as late as 13–26 years. The vaccines are U.S. Food and Drug Administration (FDA) approved for all females and males aged 9–26 years. Children are best protected from HPV before they are exposed through close genital skin-to-skin contact or sexual intercourse. Studies suggest a more robust immune response when the vaccine is given at younger ages. Although most obstetrician–gynecologists do not see 11–12-year-olds, they play a critical role in catch-up vaccination and should assess and vaccinate adolescent girls and young women during the catch-up period (ages 13–26 years), regardless of sexual activity, prior exposure to HPV, or sexual orientation. Obstetrician–gynecologists and other health care professionals also should educate parents and patients on the benefits and safety of HPV vaccination and offer HPV vaccination and offer HPV vaccines in their offices.

#### Should every woman aged 27-45 years be offered the 9-valent HPV vaccine?

No. Catch-up HPV vaccination is not recommended for all adults aged 27 years or older, and HPV vaccination does not need to be discussed with most adults aged 27 years or older. Women 27–45 years of age in long-term monogamous relationships are not at risk for acquiring a new HPV infection and are not recommended to routinely receive the vaccine. Having a new partner increases the risk for new HPV infection at any age; however, with increasing age and more past exposure to HPV, it is less likely that vaccination provides benefit.

However, for some women aged 27–45 years who are previously unvaccinated, obstetrician–gynecologists and other health care professionals may use shared clinical decision making, taking into account the patient's risk for acquisition of a new HPV infection and whether the HPV vaccine may have benefit.

# Why did the Centers for Disease Control and Prevention (CDC) and the American College of Obstetricians and Gynecologists (ACOG) recommend "shared clinical decision making" rather than routine vaccination for patients aged 27-45 years?

Typically, routine vaccine recommendations are made for specific at-risk populations (identified by age group or underlying health-related condition[s]) after considering vaccination cost, availability, and public health effect. The 9-valent HPV vaccine is costly and in short supply globally. In addition, routine HPV vaccination of all women aged 27–45 years would be expected to have limited effect on the global fight to prevent cervical cancer. Given these circumstances, routine vaccination of women in this age group was not recommended. However, the recommendation for "shared clinical decision making" does allow those individuals 27–45 years of age with no or few prior sexual partners (hence not likely to have prior HPV infection) and who are at risk of acquiring a new HPV infection, to discuss HPV vaccination with their obstetrician–gynecologist.



#### Which women in the 27-45-year age group are likely to accrue the greatest lifetime benefit from HPV vaccination?

Having a new partner increases the risk of new HPV infection at any age; however, with increasing age and more past exposure to HPV, it is less likely that HPV vaccination will provide benefit. Hence, younger women, or women not in committed monogamous relationships, who may have had fewer partners, hence less risk of past HPV exposure, are likely to be at greater risk of HPV exposure/acquisition with a new partner, and therefore most likely to have some benefit from vaccination.

# Should the 9-valent HPV vaccine be recommended/offered to women aged 27–45 years who have completed part (but not all) of the vaccine series when they were younger?

No.

#### Should the 9-valent HPV vaccine be recommended/offered to women older than 45?

No. The vaccine is not licensed in adults over 45 years of age.

#### How many doses are needed?

For girls and boys who receive their first dose of HPV vaccine before age 15 years, only two doses are needed. The interval between the two doses is 6–12 months. If these two doses are given at an interval of less than 5 months, a third dose is recommended. If females or males receive their first dose at 15 years or older, three doses are needed and given at 0 months (baseline), 1–2 months after the first dose, and 6 months after the first dose. Immunosuppressed individuals and individuals with HIV also should receive three doses, regardless of their age when the series is initiated.

#### Should HPV DNA testing be done before HPV vaccination?

No. Even if a patient is tested and the results are positive, vaccination still is recommended in the 9–26-year age range because the likelihood that a patient is positive for all vaccine-preventable HPV types is unlikely.

### Should I vaccinate a young woman if she previously had an abnormal Pap test result or has a history of genital warts?

Yes. Even if the patient has one or two HPV types causing the abnormal Pap test or genital warts, vaccination still is recommended in the 9–26-year age range because the likelihood that a woman is positive for all vaccine-preventable HPV types is unlikely.

#### How are the three available HPV vaccines (bivalent, quadrivalent, and 9-valent) different?

All three HPV vaccines protect against HPV types 16 and 18, which cause approximately 66% of cases of cervical cancer and the majority of other types of HPV-attributable cancer in the United States. The 9-valent HPV vaccine targets five additional cancer-causing HPV types (31, 33, 45, 52, and 58), which account for approximately 15% of all cervical cancer. The quadrivalent and 9-valent HPV vaccines also protect against HPV types 6 and 11, which cause genital warts. The bivalent vaccine and quadrivalent vaccine are no longer marketed in the United States.

### If a patient receives the quadrivalent HPV vaccine for the first dose, do I need to complete the series with the quadrivalent vaccine, or can I complete the series with the 9-valent vaccine?

If health care professionals do not know or do not have available the HPV vaccine product previously administered, the 9-valent HPV vaccine may be used to continue or complete the series.

### If a patient previously completed the quadrivalent HPV vaccine series, should they be revaccinated with the 9-valent HPV vaccine?

No. It is not a recommendation for an individual who received the quadrivalent HPV vaccine to be revaccinated with the 9-valent HPV vaccine, including those aged 27–45 years who previously completed some, but not all, of the vaccine series when they were younger.

#### Do the vaccines provide cross protection against other HPV types not in the vaccines?

There is evidence of some cross protection in all three vaccines to nonvaccine HPV types. However, the degree and duration of the cross protection is not reliable.

#### Will a booster dose be needed?

The need for a booster is still under study, but available information suggests a booster dose is not necessary and that protection lasts for at least 10 years.

#### Do I need to restart the series if a patient does not obtain the second or third dose on time?

No. Even if the interval for the second or third dose is much longer than recommended, it is not necessary to restart the series. Proceed with administering the next dose (whether it is the second or the third). Do strive to complete all doses, even if the time between doses exceeds the recommended time frame.

#### Is HPV vaccine recommended for pregnant women?

No. Although HPV vaccines are not recommended for use in pregnancy, studies have shown that vaccination during pregnancy causes no sequelae for the woman or her fetus. The vaccine contains no live virus particles, so it is not infectious.

#### Can girls and boys with HIV be vaccinated?

Yes. Studies show that HPV vaccination is safe, and the HPV vaccine is recommended for girls and boys with HIV. Girls and boys with HIV should receive three doses of HPV vaccine, regardless of the age at vaccine initiation.

#### Are there any contraindications to being vaccinated?

Yes. Anyone who has ever had a life-threatening allergic reaction to any component of the HPV vaccine, or to a previous dose of the HPV vaccine, should not get the vaccine. Health care professionals should assess patients for severe allergies, including an allergy to yeast. Vaccination should be postponed for individuals with a moderate or severe illness.

#### Can HPV vaccines be given to breastfeeding women?

Yes. The HPV vaccines can and should be given to breastfeeding women aged 26 years and younger who have not previously been vaccinated. If the HPV vaccine series was interrupted for pregnancy, the series should be resumed postpartum with the next dose.

#### Are the HPV vaccines safe?

Safety data for all three HPV vaccines are reassuring. According to the Vaccine Adverse Events Reporting System, more than 270 million doses of HPV vaccine have been distributed worldwide since 2006, and there are no data to suggest that there are any severe adverse effects or adverse reactions linked to vaccination. The vaccines do not contain live viruses; therefore, they cannot cause an HPV infection. Since the vaccine was licensed, adverse effects have been exceedingly rare (less than 0.0003% of patients). Frequently reported nonserious side effects include headache, nausea, dizziness, pain and redness, and low-grade fever. Studies have shown that the 9-valent HPV vaccine may result in fever and pain and redness at the injection site at a greater frequency than the quadrivalent HPV vaccine. Obstetrician–gynecologists and other health care professionals should counsel patients to expect mild local discomfort after vaccination and that such discomfort is not a cause for concern. The HPV vaccine was licensed by the FDA in 2006, and the CDC continues to closely monitor the vaccine and its safety. Adolescents should be observed for at least 15 minutes after vaccination because they are at higher risk for fainting.

#### What are effective messages for parents when talking about the HPV vaccine?

- HPV is a common disease that has potentially serious consequences such as cervical, vaginal, vulvar, penile, anal, mouth, and throat cancer, and genital warts.
- Studies of girls aged 11–12 years have found that HPV vaccination is not linked to increased sexual activity, and their antibody response was most robust if vaccination occurs during this time.
- Obstetrician-gynecologists and other health care professionals are making sure their own children get the HPV vaccine before they are at risk.
- Approximately 79 million individuals in the United States have been infected with HPV and 14 million new infections occur every year, leading to approximately 13,000 cases of cervical cancer per year with more than 4,000 deaths.
- An individual gets HPV from another person during sexual activity, including oral sex. HPV is so common that 80% of those who are sexually active will contract HPV during their lifetime.
- Parents are the key to preventing HPV-related cancer. Children should be vaccinated before they become sexually active to protect them and their future partners from contracting HPV.
- The HPV vaccine is not just for girls. Boys can benefit and stop the spread of HPV by getting vaccinated, too. Not only is a vaccinated boy protecting others, he also is preventing himself from being among the more than 10,000 males who receive a diagnosis of an HPV-related cancer each year.
- Compared with older adolescents and young adults, 11–12-year-olds have a twofold to threefold higher HPV protection after immunization.
- The HPV vaccine can reduce your son's or daughter's risk of certain HPV-related types of cancer by up to 99% when he or she is fully protected with all doses.
- Ongoing research shows the HPV vaccine's protection remains strong for 10 years. There is no evidence to suggest this level of protection changes over time.
- Since the vaccine was licensed, 0.0003% of patients have reported adverse effects—and most of those were nonserious, such as headache, nausea, and dizziness.
- The HPV vaccine was licensed by the FDA in 2006. The CDC continues to closely monitor the vaccine and its safety.
- It is required by law for obstetrician–gynecologists and other health care professionals to give their patients a Vaccine Information Statement before administering an immunization. Vaccine Information Statement forms can be found in multiple languages at <a href="https://www.immunize.org/vis">www.immunize.org/vis</a>.

#### References

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- 2. American Cancer Society. Cancer facts & figures 2020. Atlanta, GA: ACS; 2020. Available at: <u>https://www.cancer.org/</u> <u>content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2020/cancer-facts-and-figures-2020.pdf</u>. Retrieved April 3, 2020.

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# Physician Script: HPV Vaccination

HPV vaccine is a crucial part of ensuring your patients and their families are protected against human papillomavirus (HPV) and its serious consequences, including cervical, vaginal, vulvar, penile, anal, mouth and throat cancer, and genital warts.

Below are a few suggestions on how to recommend the vaccine to your patients and medical colleagues.



## 11 and 12 Year Olds

Human papillomavirus is a serious disease. In addition to several cancers in both men and women, it can also cause genital warts. It's unfortunately very common: Approximately 79 million people in the U.S. have been infected and 14 million new infections occur every year. It's important to protect your children before they become sexually active. At 11 or 12 years of age, your child will have the strongest response to, and thus protection from, the vaccine. The recommende doses will reduce your child's risk from certain HPV-related cancers by up to 99%. We know this vaccine is safe and effective. I have/will recommend it for my own children. Please talk to your child's doctor about getting the vaccine.



#### Patients in the Catch-up Population

Human papillomavirus is a serious disease. In addition to several cancers in both men and women, it can also cause genital warts. It's unfortunately very common: Approximately 79 million people in the U.S. have been infected and 14 million new infections occur every year. Even if you're already sexually active and possibly already exposed to HPV virus, the HPV vaccine offers protection against multiple strains of the virus. The recommended doses will reduce your risk from certain HPVrelated cancers by up to 99%. Your partner can also get vaccinated to protect himself/ herself as well as you. We know this vaccine is safe and effective. I have/will recommend it for my own children. Let's start the vaccine series today.

"



#### Pediatricians and Family Physicians

Human papillomavirus is a serious disease. Approximately 79 million people in the United States have been infected with HPV and 14 million new infections occur every year. It is important to protect children from HPV before they are at risk of exposure. The CDC, AAP, AAFP, and ACOG recommend that 11 and 12 year olds receive the HPV vaccine, prior to becoming sexually active. Statistics show that one in three 9th graders and two in three 12th graders have engaged in sexual intercourse. Recommend the HPV vaccine series for both girls and boys the same way you recommend the other adolescent vaccines. For example, you can say,

'Your child needs these vaccines today,' and name all of the vaccines – 'meningococcal, Tdap, and HPV' – recommended for the child's age. You can also share if you've had your own child vaccinated against the disease. Your recommendation is the number one reason why someone will get the HPV vaccine and be protected from HPV-associated cancers and disease.



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### Coding Information on HPV Vaccination

#### CPT Codes for Vaccine Administration

<b>Code</b> 90471	Method Injection	Route of Administration Percutaneous, intradermal, subcutaneous, or intramuscular	<b>Type of Service</b> Primary	<b>Reporting Rules</b> Report only one primary vaccine administration per encounter.
+90472	Injection	Percutaneous, intradermal, subcutaneous, or intramuscular	Additional	Report for secondary or subsequent vaccine administration. Report only with code 90460, 90471, or 90473.
90460	Any route	Percutaneous, intradermal, subcutaneous, or intramuscular	Primary	Report only one primary vaccine administration per encounter. Physician or other qualified health care professional also provides counseling. Patient is 18 years or younger.
90461	Any route	Percutaneous, intradermal, subcutaneous, or intramuscular	Additional	Report for each additional component in a vaccine administered in conjunction with 90460. Physician or other qualified health care professional also provides counseling. Patient is 18 years or younger.

#### HPV Vaccines Administered to Adolescents and Adults

Vaccine	Code for Vaccine Product	CPT Administration Code
HPV types 6, 11, 16, 18 (quadrivalent [4vHPV]), 3-dose schedule, intramuscular	90649	90460-90472
HPV types 16, 18 (bivalent [2vHPV]), 3-dose schedule, intramuscular	90650	90460-90472
HPV types 6, 11, 16, 18, 31, 33, 45, 52, 58 (nonavalent [9vHPV]) 3-dose schedule, intramuscular	90651	90460-90472

Abbreviation: HPV, human papillomavirus.

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For more information, please visit the Coding section on the Immunization for Women web page, www.immunizationforwomen.org/ practice\_management/coding.

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### Promoting Cervical Cancer Prevention by Incorporating Human Papillomavirus Vaccination Recommendations Into Existing Patient Communications

The American College of Obstetricians and Gynecologists recommends that all individuals aged 11–12 years receive the human papillomavirus (HPV) vaccine to help prevent cervical cancer. Your patients may have children in this age range or the vaccination "catch-up" age range (13–26 years). Your patients also may be in the catch-up age range themselves and need the HPV vaccine. The American College of Obstetricians and Gynecologists encourages obstetrician–gynecologists and other gynecologic care providers to take advantage of every occasion to recommend the HPV vaccine for patients and their family members to avoid missed opportunities to vaccinate and promote its importance in helping to prevent cervical cancer.

The sample letter below is intended to help you take advantage of current patient notifications that you already use in your practice as a way to recommend the HPV vaccine for patients and their family members. This wording and design can be adapted to add your logo and practice information. The letter can be used as a printed postcard as shown below or it can be incorporated into patient portal web sites, electronic health records, or both.

Dear \_\_\_\_\_,

I am pleased to inform you that your recent Pap test was normal and that your test for high-risk human papillomavirus (HPV, the virus that causes most cases of cervical cancer) was negative. If you have any questions about your Pap test or HPV test, please call and leave a message with the nurse in our office.

As your health care provider, I want to make sure you know that there are safe and effective vaccines available to protect you and your family against HPV infection, which can lead to cancer in males and females. Human papillomavirus vaccines are recommended for all males and females aged 9–26 years to prevent cancer caused by HPV. If you think you or any members of your family need to be vaccinated against HPV, please call a health care provider's office to schedule an appointment.

If you are younger than 27 years and have not received the HPV vaccine, please contact our office to schedule an appointment today for your first dose. You can find more information on the HPV vaccine at the American College of Obstetrician and Gynecologists' Immunization for Women web site: www.immunizationforwomen.org

Yours sincerely,





# HPV (Human Papillomavirus) Vaccine: What You Need to Know

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

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### Why get vaccinated?

**HPV (Human papillomavirus) vaccine** can prevent infection with some types of human papillomavirus.

HPV infections can cause certain types of cancers including:

- cervical, vaginal and vulvar cancers in women,
- penile cancer in men, and
- anal cancers in both men and women.

HPV vaccine prevents infection from the HPV types that cause over 90% of these cancers.

HPV is spread through intimate skin-to-skin or sexual contact. HPV infections are so common that nearly all men and women will get at least one type of HPV at some time in their lives.

Most HPV infections go away by themselves within 2 years. But sometimes HPV infections will last longer and can cause cancers later in life.

### 2 HPV vaccine

HPV vaccine is routinely recommended for adolescents at 11 or 12 years of age to ensure they are protected before they are exposed to the virus. HPV vaccine may be given beginning at age 9 years, and as late as age 45 years.

Most people older than 26 years will not benefit from HPV vaccination. Talk with your health care provider if you want more information.

Most children who get the first dose before 15 years of age need 2 doses of HPV vaccine. Anyone who gets the first dose on or after 15 years of age, and younger people with certain immunocompromising conditions, need 3 doses. Your health care provider can give you more information.

HPV vaccine may be given at the same time as other vaccines.

# 3 Talk with your health care provider

Tell your vaccine provider if the person getting the vaccine:

- Has had an allergic reaction after a previous dose of HPV vaccine, or has any severe, lifethreatening allergies.
- Is pregnant.

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In some cases, your health care provider may decide to postpone HPV vaccination to a future visit.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting HPV vaccine.

Your health care provider can give you more information.

### Risks of a vaccine reaction

• Soreness, redness, or swelling where the shot is given can happen after HPV vaccine.

• Fever or headache can happen after HPV vaccine.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

As with any medicine, there is a very remote chance of a vaccine causing a severe allergic reaction, other serious injury, or death.



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

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# What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at **www.vaers.hhs.gov** or call **1-800-822-7967**. VAERS is only for reporting reactions, and VAERS staff do not give medical advice.

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#### The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines. Visit the VICP website at www.hrsa.gov/vaccinecompensation or call 1-800-338-2382 to learn about the program and about filing a claim. There is a time limit to file a claim for compensation.

### 7 How can I learn more?

- Ask your health care provider.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
- Call 1-800-232-4636 (1-800-CDC-INFO) or
- Visit CDC's website at www.cdc.gov/vaccines

Vaccine Information Statement (Interim) HPV Vaccine



10/30/2019 | 42 U.S.C. § 300aa-26

Standing orders for other vaccines are available at www.immunize.org/standing-orders. NOTE: This standing orders template may be adapted per a practice's discretion without obtaining permission from IAC. As a courtesy, please acknowledge IAC as its source.

### STANDING ORDERS FOR Administering Human Papillomavirus Vaccine to Adults

#### Purpose

To reduce morbidity and mortality from human papillomavirus (HPV) infection by vaccinating all adults who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

#### Policy

Where allowed by state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess the need for and vaccinate adults who meet any of the criteria below.

#### Procedure

#### 1 Assess adults for need of vaccination against human papillomavirus infection based on the following criteria:

- Adults, age 26 years or younger
- Adults, age 27 through 45 years, based on shared clinical decision making. (Note: Although many adults ages 27–45 years have prior exposures to 1 or more HPV types, most have not been exposed to all 9 HPV types that are contained in the vaccine. Also, at any age, having a new sex partner is a risk factor for being exposed to a new HPV infection.)

#### 2 Screen for contraindications and precautions

#### Contraindication

Do not give HPV vaccine to an adult who has experienced a serious systemic or anaphylactic reaction to a prior dose of HPV vaccine or to any of its components (e.g., yeast). For information on vaccine components, refer to the manufacturers' package insert (www.immunize.org/fda), or go to

www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf or

www.fda.gov/vaccines-blood-biologics/vaccines/vaccines-licensed-use-united-states.

#### Precaution

- Moderate or severe acute illness with or without fever
- Pregnancy; delay vaccination until after completion of the pregnancy

#### **3** Provide Vaccine Information Statements

Provide all patients with a copy of the most current federal Vaccine Information Statement (VIS). Provide non-English speaking patients with a copy of the VIS in their native language, if one is available and desired; these can be found at www.immunize.org/vis. (For information about how to document that the VIS was given, see section 6 titled "Document Vaccination.")

#### 4 Prepare to Administer Vaccine

Choose the needle gauge, needle length, and injection site according to the following chart:

GENDER AND WEIGHT OF PATIENT	NEEDLE GAUGE	NEEDLE LENGTH	INJECTION SITE
Female or male less than 130 lbs	22–25	5/8*-1"	Deltoid muscle of arm
Female or male 130–152 lbs	22–25	ן"	Deltoid muscle of arm
Female 153–200 lbs	22–25	1–11⁄2"	Deltoid muscle of arm
Male 153–260 lbs	22–25	1–11⁄2"	Deltoid muscle of arm
Female 200+ lbs	22–25	11⁄2"	Deltoid muscle of arm
Male 260+ lbs	22–25	11⁄2"	Deltoid muscle of arm

\* A 5%" needle may be used in patients weighing less than 130 lbs (<60 kg) for IM injection in the deltoid muscle only if the skin is stretched tight, the subcutaneous tissue is not bunched, and the injection is made at a 90° angle to the skin.

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5 Administer HPV vaccine, 0.5 mL, via the intramuscular (IM) route, according to the following table:

HISTORY OF PREVIOUS HPV VACCINATION <sup>1</sup>	SCHEDULE FOR ADMINISTRATION OF HPV VACCINE
0 documented doses, or none known	Give 3 doses at 0, 1–2, and 6 months.
1 previous dose given before 15th birthday	Give dose #2 at least 5 months after dose #1; no further doses are indicated. <sup>2</sup>
1 previous dose given at 15 years or older	Give the 2nd dose 1–2 months (minimum of 4 weeks) after dose #1, then give the 3rd dose 6 months after dose 1 (minimum of 12 weeks after dose #2 and at least 5 months after dose #1).
2 previous doses with dose #1 given before 15th birth- day and dose #2 given at least 5 months after dose #1	No further doses are indicated. <sup>2</sup>
1 previous dose given before 15th birthday and dose #2 given 5 months later, after 15th birthday	No further doses are indicated. <sup>2</sup>
2 previous doses given at 15 years or older	Give the 3rd dose 6 months after dose #1 (minimum of 12 weeks after dose #2 and at least 5 months after dose #1).

<sup>1</sup> All previously administered doses of HPV vaccine (regardless of brand) count as valid doses if given at appropriate intervals.
 <sup>2</sup> Immunocompromised persons, including those with HIV infection, should receive a 3-dose schedule at 0, 1–2, and 6 months, regardless of age at vaccine initiation.

#### **6** Document Vaccination

Document each patient's vaccine administration information and follow-up in the following places:

*Medical record:* Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. You must also document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. If vaccine was not administered, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal). Discuss the need for vaccine with the patient at the next visit.

Personal immunization record card: Record the date of vaccination and the name/location of the administering clinic.

*Immunization Information System (IIS) or "registry":* Report the vaccination to the appropriate state/local IIS, if available.

#### 7 Be Prepared to Manage Medical Emergencies

Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications. For IAC's "Medical Management of Vaccine Reactions in Adult Patients in a Community Setting," go to www.immunize.org/catg.d/p3082.pdf. To prevent syncope, vaccinate patients while they are seated or lying down and consider observing them for 15 minutes after receipt of the vaccine.

#### 8 Report Adverse Events to VAERS

Report all adverse events following the administration of HPV vaccine to the federal Vaccine Adverse Event Reporting System (VAERS). To submit a VAERS report online (preferred) or to download a writable PDF form, go to https://vaers.hhs.gov/reportevent.html. Further assistance is available at (800) 822-7967.

#### **Standing Orders Authorization**

This policy and procedure shall remain in effect f	or all patients of the
until rescinded or until	
Medical Director's signature	Signature dateEffective date

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### STANDING ORDERS FOR Administering Human Papillomavirus Vaccine to Children and Teens

#### Purpose

To reduce morbidity and mortality from human papillomavirus (HPV) infection by vaccinating all children and teens who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

#### Policy

Where allowed by state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess the need for and vaccinate children and teens who meet any of the criteria below.

#### Procedure

- 1 Assess children and teens for need of vaccination against human papillomavirus infection based on the following criteria:
  - Age 11 years and older who have not completed an HPV vaccination series
  - Age 9 years and older with any history of sexual abuse or assault
  - Age 9 through 10 years, without a specific risk factor, whose parent/guardian wishes to have them vaccinated
- 2 Screen for contraindications and precautions

#### Contraindication

Do not give HPV vaccine to an child or teen who has experienced a serious systemic or anaphylactic reaction to a prior dose of HPV vaccine or to any of its components (e.g., yeast). For information on vaccine components, refer to the manufacturers' package insert (www.immunize.org/fda) or go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf.

#### Precaution

- Moderate or severe acute illness with or without fever
- Pregnancy; delay vaccination until after completion of the pregnancy

#### **3** Provide Vaccine Information Statements

Provide all patients (or, in the case of minors, their parent, or legal representative) with a copy of the most current federal Vaccine Information Statement (VIS). Provide non-English speaking patients with a copy of the VIS in their native language, if one is available and desired; these can be found at www.immunize.org/vis. (For information about how to document that the VIS was given, see section 6 titled "Document Vaccination.")

#### 4 Prepare to Administer Vaccine

Choose the needle gauge, needle length, and injection site according to the following chart:

AGE OF INFANT/CHILD	NEEDLE GAUGE	NEEDLE LENGTH	INJECTION SITE
9 through 10 years	22.25	5/8**-1"	Deltoid muscle of arm*
5 through to years	1 22-23	1–11⁄4"	Anterolateral thigh muscle
11 through 18 years	22.25	5/8**-1" Deltoid muscle of arm*	
	22-25	1–11⁄2"	Deltoid muscle of arm* Anterolateral thigh muscle Deltoid muscle of arm* Anterolateral thigh muscle

\* Preferred site.

\*\* A 5/8" needle may be used for children for IM injection in the deltoid muscle only if the skin is stretched tight, the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle.

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**5** Administer HPV vaccine, 0.5 mL, via the intramuscular (IM) route, according to the following tables: *Schedule for routine vaccination* 

TYPE OF VACCINE         AGE WHEN FIRST DOSE           IS ADMINISTERED <sup>1,2</sup> IS ADMINISTERED <sup>1,2</sup>		DOSE	SCHEDULE
	9 through 14 years	0.5 mL	Two doses, 6–12 months apart <sup>2</sup>
HPV (Gardasii 9)	15 years or older	0.5 mL	Three doses at 0, 1–2, and 6 months

*Note:* For individuals who failed to complete either the 2-dose or 3-dose schedule as stated above, do not start over. Simply follow the schedule shown below.

#### Schedule for catch-up vaccination

HISTORY OF PREVIOUS HPV VACCINATION	SCHEDULE FOR ADMINISTRATION OF HPV VACCINE
0 documented doses, or none known	Follow schedule as per above table.
1 previous dose when younger than age 15 years	Give dose #2 with minimum interval of 5 months <sup>2</sup>
2 previous doses given less than 5 months apart and dose #1 given when younger than age 15 years	Give dose #3 with minimum interval of 12 weeks after dose #2 and at least 5 months after dose #1.
1 previous dose when age 15 or older	Give dose #2 at least 4 weeks after dose #1, then give dose #3 at least 12 weeks after dose #2 and at least 5 months after dose #1.
2 previous doses when age 15 or older	Give dose #3 at least 12 weeks after dose #2 and at least 5 months after dose #1.

<sup>1</sup> Only two doses are recommended for anyone who begins the schedule before the 15th birthday, regardless of age at series completion.

<sup>2</sup>Immunocompromised persons, including those with HIV infection, should receive a 3-dose series at 0, 1–2, and 6 months, regardless of age at vaccine initiation.

#### 6 Document Vaccination

Document each patient's vaccine administration information and follow-up in the following places: *Medical record:* Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. You must also document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. Note that medical records/charts should be documented and retained in accordance with applicable state laws and regulations. If vaccine was not administered, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal). Discuss the need for vaccine with the patient (or, in the case of a minor, their parent or legal representative) at the next visit.

**Personal immunization record card:** Record the date of vaccination and the name/location of the administering clinic.

*Immunization Information System (IIS) or "registry"*: Report the vaccination to the appropriate state or local IIS, if available.

#### 7 Be Prepared to Manage Medical Emergencies

Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications. For IAC's "Medical Management of Vaccine Reactions in Children and Teens," go to www.immunize.org/catg.d/p3082a.pdf. For "Medical Management of Vaccine Reactions in Adult

Patients," go to www.immunize.org/catg.d/p3082a.pdf. For "Medical Management of Vaccine Reactions in Adult Patients," go to www.immunize.org/catg.d/p3082.pdf. To prevent syncope, vaccinate patients while they are seated or lying down and consider observing them for 15 minutes after receipt of the vaccine.

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#### **Standing Orders Authorization**

This policy and proc	edure shall remain in effect fo	or all pati	ents of the	
effective	until rescinded or until _	DATE		
Medical Director	PRINT NAME		/SIGNATURE	DATE