

# Human Papillomavirus Vaccination

**2016**

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



The American College of  
Obstetricians and Gynecologists  
WOMEN'S HEALTH CARE PHYSICIANS



**IMMUNIZATION** *for* **WOMEN**  
Immunization Information for Ob-Gyns and Their Patients



# The American College of Obstetricians and Gynecologists

WOMEN'S HEALTH CARE PHYSICIANS

*Vice President, Practice Activities*  
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April 2016

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 [www.immunizationforwomen.org](http://www.immunizationforwomen.org).

We hope the enclosed materials are helpful to you, your practice team, and your patients. If you have additional questions, please email us at [immunization@acog.org](mailto:immunization@acog.org) or call 202-863-2489. If you would like additional materials, please visit us at [sales.acog.org](http://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 printed and mailed through an unrestricted educational grant from Merck, Inc. ACOG does not allow companies to influence its educational programs, publications, or advocacy positions.

## Why is HPV vaccination recommended at such young ages?

The HPV vaccines prevent infection but cannot treat infection. They work best if given before any exposure to HPV infection, which occurs with sexual activity. It is best to get the vaccine at your or your child's health care visit (at age 11–12 years). Compared with older adolescents and young adults, children between the ages of 11 years and 12 years develop a twofold to threefold higher level of the protective antibody that the body generates after immunization. This may result in longer-lasting immunity; however, sexually active individuals still may benefit from vaccination because they are unlikely to have been infected with all HPV types that are prevented by the vaccines.

## What is the recommended timing of the three HPV vaccine doses?

Each of the three types of HPV vaccine are given as shots in the arm in three doses over 6 months.

## If I am late for my second or third dose, do I have to start over with all three doses?

No. Starting over is not necessary. Get the next dose, whether it is the second or the third. Complete all three doses, even if the time between doses is longer than recommended.

## Can women older than 26 years be vaccinated against HPV?

At this time, HPV vaccination is only recommended for individuals aged 9–26 years. The vaccines work best if given before exposure to HPV through sexual activity. Vaccination does not appear to be harmful if given after age 26 years, but it may not be as effective. Many women older than 26 years may already have been exposed to HPV.

## Will vaccinating my daughter against HPV encourage her 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.

## Are the HPV vaccines safe?

Yes. Studies show that all three vaccines are very safe and effective. They do not contain live viruses, so they cannot cause an HPV infection. The vaccines have been given to millions of people around the world without serious adverse effects. In the 8 years since the first vaccine was licensed, 0.0003% of patients reported adverse effects, and most of those were nonserious symptoms such as headache, nausea, and dizziness. The Centers for Disease Control and Prevention continues to closely monitor the vaccine and its safety.

## Do the HPV vaccines work?

Yes. The vaccines are highly effective at preventing cancer and other HPV-associated diseases when administered before sexual activity begins. The HPV vaccine can reduce your son or daughter's risk of certain HPV-related cancer by up to 99% when he or she is fully protected with three doses. Clinical trials and ongoing research have shown that the HPV vaccine's protection remains strong for at least 8–10 years. There is no evidence to suggest this level of protection changes over time. Two of the vaccines also can reduce the risk of getting genital warts by 90%.

## RESOURCES

American College of Obstetricians and Gynecologists  
Immunization for Women  
[www.immunizationforwomen.org](http://www.immunizationforwomen.org)

Centers for Disease Control and Prevention  
HPV Vaccine—Questions and Answers  
<http://www.cdc.gov/hpv/parents/questions-answers.html>



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WOMEN'S HEALTH CARE PHYSICIANS

# COMMITTEE OPINION

Number 641 • September 2015

(This Committee Opinion Replaces Committee Opinion Number 588)

## Committee on Adolescent Health Care Immunization Expert Work Group

*This Committee Opinion reflects emerging clinical and scientific advances as of the date issued and is subject to change. This information should not be construed as dictating an exclusive course of treatment or procedure to be followed.*

## Human Papillomavirus Vaccination

**ABSTRACT:** Human papillomavirus (HPV) is associated with the development of anogenital cancer (including cervical, vaginal, vulvar, penile, and anal), oropharyngeal cancer, and genital warts. Human papillomavirus vaccination can significantly reduce the incidence of anogenital cancer and genital warts. Despite the benefits of HPV vaccines, only approximately one third of girls in the recommended age group have received all three vaccines. Compared with other vaccines recommended in the same age bracket, HPV vaccination rates in the United States are unacceptably low. It is crucial that obstetrician–gynecologists and other providers educate parents and patients on the benefits and safety of HPV vaccination. The Centers for Disease Control and Prevention and the American College of Obstetricians and Gynecologists recommend routine vaccination with HPV vaccine for girls and boys. The 9-valent HPV vaccine is recommended by the Advisory Committee on Immunization Practices and was licensed by the U.S. Food and Drug Administration in December 2014 for girls and boys aged 11–12 years.

### Summary of Recommendations

- It is crucial that obstetrician–gynecologists and other providers educate parents and patients on the benefits and safety of human papillomavirus (HPV) vaccination.
- The Centers for Disease Control and Prevention (CDC) and the American College of Obstetricians and Gynecologists (the College) recommend routine vaccination with HPV vaccine for girls and boys. Despite this recommendation, only approximately 50% of girls aged 13–17 years in the United States have received at least one vaccine dose; only 33% have received all three doses.
- The target age for vaccination is 11–12 years for girls and boys.
- The 9-valent HPV vaccine has been added to the Advisory Committee on Immunization Practices (ACIP) recommendations for girls and boys at the target age of 11–12 years with catch-up for females and males through age 26 years if not vaccinated in the target age.
- Testing for HPV DNA is not recommended before vaccination in any group and if the patient is tested for HPV DNA and the results are positive, vaccination is still recommended.

Human papillomavirus is associated with the development of anogenital cancer (including cervical, vaginal, vulvar, penile, and anal), oropharyngeal cancer, and genital warts. Of the more than 100 HPV genotypes, 13 have been shown to cause cervical cancer (1). Most cases of all HPV-associated cancer are caused by HPV genotypes 16 and 18 (2–4). In the United States, HPV genotypes 16 and 18 account for 66% of cases of cervical cancer and HPV genotypes 31, 33, 45, 52, and 58 account for an additional 15% of cases of cervical cancer (4). For cervical intraepithelial neoplasia (CIN) 2+, 50–60% of cases are caused by HPV genotypes 16 and 18 and 25% of cases are caused by HPV genotypes 31, 33, 45, 52, and 58 (5). Approximately 90% of cases of genital warts are caused by HPV genotypes 6 and 11 (6).

Despite cervical cytology screening in the United States, each year cervical cancer is diagnosed in more than 12,000 women and nearly 4,000 die from the disease. Additionally, nearly 2.8 million abnormal Pap test results are identified annually (7).

Human papillomavirus vaccination can significantly reduce the incidence of anogenital cancer and genital warts. Additionally, HPV vaccination may decrease the incidence of oropharyngeal cancer as well as maternal passage of HPV to infants, which results in recurrent laryngeal papillomatosis, although definitive prevention

trials have not been completed for these two disease endpoints (8). In the United States, the prevalence of vaccine-type HPV decreased 56% among females aged 14–19 years between 2006 when the quadrivalent HPV vaccine was introduced and 2010 (9). Despite the benefits of HPV vaccines, only approximately one third of girls in the recommended age group have received all three vaccines. Compared with other vaccines recommended in the same age bracket, HPV vaccination rates in the United States are unacceptably low (10).

## **Human Papillomavirus Vaccines**

The U.S. Food and Drug Administration (FDA) has approved three vaccines shown to be effective at preventing HPV infection. All three vaccines are given in a three-dose series with a schedule of 0, 1–2, and 6 months. The durability of the immune response (ie, how long protection lasts) is being monitored in various long-term studies, and there currently is no indication for a booster vaccine (11). The series does not need to be restarted if there is a delay in administration of the second or third dose.

Although obstetrician–gynecologists are not likely to care for many patients in the initial HPV vaccination target group, they have the opportunity to educate mothers about the importance of vaccinating their children at the recommended age. Furthermore, obstetrician–gynecologists play a critical role in vaccinating adolescent girls and young women during the catch-up period. Vaccination is not associated with an earlier onset of sexual activity (12) or increased incidence of sexually transmitted infections (13).

### **Timing of Vaccination**

The Advisory Committee on Immunization Practices and the College recommend HPV vaccination for girls and boys at the target age of 11–12 years as part of the adolescent immunization platform in order to help reduce the incidence of anogenital cancer and genital warts associated with HPV infection. Bivalent, quadrivalent, and 9-valent vaccines are recommended for females aged 9–26 years and quadrivalent and 9-valent vaccines are recommended for males aged 9–26 years. Human papillomavirus vaccination of girls at an earlier age (9–14 years versus 15–26 years) results in higher antibody levels. Although it is not known whether this more robust immune response correlates with greater vaccine efficacy, this may be another reason supporting earlier vaccination of girls aged 9–14 years. Earlier vaccination also is preferred because the vaccines are most effective when given before the onset of sexual activity and statistics show that one in three 9th graders and two in three 12th graders have engaged in sexual intercourse (13, 14).

In Sweden, vaccine effectiveness in preventing genital warts was 93% among girls vaccinated between ages 10 years and 13 years compared with 48% and 21% if vaccinated at ages 20–22 years and 23–26 years, respec-

tively (15). All of these findings underscore the importance of vaccination at the target age (11–12 years) and before the onset of sexual activity. Although a reduced two-dose schedule is recommended by the World Health Organization (WHO) for those aged 9–13 years, this dosage schedule currently is not recommended by the ACIP or the College for any age.

Vaccination is recommended regardless of sexual activity or exposure to HPV. Although the vaccine may be less effective in sexually active individuals, it is expected that some benefit will be experienced because prior sexual exposure to all vaccine types is unlikely (16, 17). Vaccination is recommended even if the patient is tested for HPV DNA and the results are positive. Testing for HPV DNA is not recommended before vaccination in any group.

### **9-valent Human Papillomavirus Vaccine**

The 9-valent HPV vaccine is recommended by ACIP and was licensed by the FDA in December 2014 for girls and boys aged 11–12 years. Catch-up vaccination for females and males through age 26 years is recommended for those not vaccinated at the target age of 11–12 years. In a phase III efficacy trial comparing the 9-valent HPV vaccine with the quadrivalent HPV vaccine among approximately 14,000 females aged 16–26 years, the 9-valent HPV vaccine had high efficacy for prevention of greater than or equal to CIN 2, vulvar intraepithelial neoplasia (VIN) 2 or 3, and vaginal intraepithelial neoplasia 2 or 3 due to HPV genotypes 31, 33, 45, 52, and 58 (see Table 1) (18). The antibody titer against HPV genotypes 6, 11, 16, and 18 was not reduced with the addition of the other five HPV genotypes (18).

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 currently is not a routine recommendation. If obstetrician–gynecologists or other providers do not know or do not have available the 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 females 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 males (18).

### **Safety**

Safety data for all three HPV vaccines are reassuring. According to the Vaccine Adverse Events Reporting System, more than 60 million doses of HPV vaccine have been distributed, and there are no data to suggest that there are any severe adverse effects or adverse reactions linked to vaccination (19). 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

**Table 1.** Uses and Efficacy of the Bivalent, Quadrivalent, and 9-valent Human Papillomavirus Vaccines

Vaccine	HPV Types	Disease Reduction	Efficacy*
Bivalent	16 and 18	HPV genotypes 16 and 18-related cervical cancer, CIN 1, CIN 2/3, and adenocarcinoma in situ	HPV disease related to genotypes 16 and 18; 98.1% <sup>††</sup>
Quadrivalent	6, 11, 16, and 18	HPV genotypes 6, 11, 16, and 18-related cervical, vulvar, and vaginal cancer; CIN 1; CIN 2/3; adenocarcinoma in situ; VIN 2/3; and vaginal intraepithelial neoplasia 2/3 in females  Penile intraepithelial neoplasia 1/2/3 and penile cancer in males  Warts, anal intraepithelial neoplasia, and anal cancer in males and females	HPV disease related to genotypes 6, 11, 16, and 18; up to 100% <sup>§  </sup>  External genital disease in men; 90.4% <sup>  </sup>
9-valent	6, 11, 16, 18, 31, 33, 45, 52, and 58	HPV genotypes 6, 11, 16, 18, 31, 33, 45, 52, and 58-related cervical, vulvar, and vaginal cancer; CIN 2/3; adenocarcinoma in situ; VIN 2/3; and vaginal intraepithelial neoplasia 2/3 in females  Penile intraepithelial neoplasia 1/2/3 and penile cancer in males <sup>¶</sup>  Warts, anal intraepithelial neoplasia, and anal cancer in males and females	HPV disease related to genotypes 6, 11, 16, and 18; greater than 99%  HPV related to genotypes 31, 33, 45, 52, and 58; 96.7% <sup>¶</sup>

Abbreviations: CIN, cervical intraepithelial neoplasia; HPV, human papillomavirus; VIN, vulvar intraepithelial neoplasia.

\*Efficacy rates based recipient being naive to the vaccine HPV genotypes at the time of vaccination.

<sup>†</sup>Paavonen J, Naud P, Salmeron J, Wheeler CM, Chow SN, Apter D, et al. Efficacy of human papillomavirus (HPV)-16/18 AS04-adjuvanted vaccine against cervical infection and precancer caused by oncogenic HPV types (PATRICIA): final analysis of a double-blind, randomised study in young women. HPV PATRICIA Study Group [published erratum appears in Lancet 2010;376:1054]. Lancet 2009;374:301–14.

<sup>††</sup>Donovan B, Franklin N, Guy R, Grulich AE, Regan DG, Ali H, et al. Quadrivalent human papillomavirus vaccination and trends in genital warts in Australia: analysis of national sentinel surveillance data. Lancet Infect Dis 2011;11:39–44.

<sup>§</sup>Munoz N, Kjaer SK, Sigurdsson K, Iversen OE, Hernandez-Avila M, Wheeler CM, et al. Impact of human papillomavirus (HPV)-6/11/16/18 vaccine on all HPV-associated genital diseases in young women. J Natl Cancer Inst 2010;102:325–39.

<sup>||</sup>Giuliano AR, Palefsky JM, Goldstone S, Moreira ED Jr, Penny ME, Aranda C, et al. Efficacy of quadrivalent HPV vaccine against HPV Infection and disease in males [published erratum appears in N Engl J Med 2011;364:1481]. N Engl J Med 2011;364:401–11.

<sup>¶</sup>Petrosky E, Bocchini JA Jr, Hariri S, Chesson H, Curtis CR, Saraiya M, et al. Use of 9-valent human papillomavirus (HPV) vaccine: updated HPV vaccination recommendations of the advisory committee on immunization practices. Centers for Disease Control and Prevention (CDC). MMWR Morb Mortal Wkly Rep 2015;64:300–4.

dose of the 9-valent HPV vaccine (18). Obstetrician–gynecologists or other providers should counsel patients to expect discomfort after vaccination and that such

discomfort is not a cause for concern. 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 (20). 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. Obstetrician–gynecologists or other providers should assess patients for severe allergies, including an allergy to yeast. Individuals with a moderate or severe illness should wait until their illness improves before receiving a vaccine.

### Considerations for Special Populations

Although HPV vaccination in pregnancy is not recommended, neither is routine pregnancy testing before vaccination. Available safety data regarding the inadvertent administration of the vaccine during pregnancy are reassuring (21, 22). Patients and obstetrician–gynecologists or other providers are encouraged to register women exposed to the 9-valent HPV vaccine around the time of conception or during pregnancy by contacting the manufacturer (20). Pregnancy registries for the quadrivalent HPV vaccine and bivalent HPV vaccine have been closed. Exposure to these vaccines can be reported by calling the manufacturer (23, 24). 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. Lactating women can receive any HPV vaccine because inactivated vaccines like HPV do not affect the safety of breastfeeding for mothers or infants (25).

The presence of immunosuppression, like that experienced in patients with human immunodeficiency virus (HIV) infection or organ transplantation, is not a contraindication to HPV vaccination. However, the immune response may be less robust in the immunocompromised patient (26).

Human papillomavirus vaccines are not currently licensed in the United States for women older than 26 years. Off-label use may be indicated on a case-by-case basis (27).

### 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 play a crucial role in the acceptance of HPV vaccination by patients and parents of patients (28). It is crucial that obstetrician–gynecologists and other providers educate parents and patients on the benefits and safety of HPV vaccination and offer HPV vaccines in their offices.

According to the CDC, if health care providers increase HPV vaccination coverage to 80%, it is estimated that an additional 53,000 cases of cervical cancer could be prevented during the lifetime of those younger than 12 years (29). Furthermore, for every year that coverage does not increase, an additional 4,400 women will develop cervical cancer.

### For More Information

*These resources are for information only and are not meant to be comprehensive. Referral to these resources does not imply the American College of Obstetricians and Gynecologists' endorsement of the organization, the organization's web site, or the content of the resource. The resources may change without notice.*

ACOG has identified additional resources on topics related to this document that may be helpful for ob-gyns, other health care providers, and patients. You may view these resources at: [www.acog.org/More-Info/HPV](http://www.acog.org/More-Info/HPV).

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## Frequently Asked Questions for Patients Concerning HPV Vaccination

### What is HPV?

Human papillomavirus (HPV) is a common viral infection that has potentially serious consequences such as genital warts and cervical, vaginal, vulvar, penile, anal, mouth, and throat cancer. Approximately 79 million people in the United States have been infected with HPV and 14 million new infections occur every year, which leads to approximately 12,000 cases of cervical cancer per year with more than 4,000 deaths. An individual gets HPV from another person during sexual activity. Human papillomavirus is so common that 80% of those who are sexually active will contract HPV during their lifetime.

### Will I know if I have HPV?

Most people with HPV will not know that they have an HPV infection. Genital warts are a sign of HPV infection. However, an infection of the cervix usually has no symptoms. With or without symptoms, an infected person can spread HPV to others.

### How long do HPV infections last?

The immune system fights most HPV infections and clears them from the body in a few years. Infections that are not cleared from the body are called “persistent infections.” They may cause precancerous cells and cancer.

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

No. In most women, HPV infections are cleared from the body in a few years. For women with persistent infections, regular screening is done with Pap tests. The Pap test looks for cells in the cervix that could be precancerous. This early detection and treatment of precancerous cells can prevent deaths due to cervical cancer.

### Can HPV be prevented?

Yes. Several types of HPV can be prevented by vaccination.

### What HPV vaccines are currently available?

There are three types of HPV vaccines. All three vaccines are effective in protecting against the two HPV types (16 and 18) that most commonly cause cancer and precancer. Talk to your obstetrician–gynecologist or other gynecologic care provider about the HPV vaccine for you or your child today.

### Who should be vaccinated?

The ideal age for HPV vaccination is 11 years or 12 years in girls and boys. However, the vaccines can be given to children as young as age 9 years. Boys and girls who did not get vaccinated at age 11 years or 12 years can be vaccinated up to age 26 years. The HPV vaccine is not just for girls; boys can stop the spread of HPV by getting vaccinated too. Each year, 9,300 men receive a diagnosis of an HPV-related cancer. Males who receive the HPV vaccine are not only protecting their sexual partners, but also themselves.

*(see reverse)*

# 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.



## Mothers of 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 recommended three 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 three doses will reduce your risk from certain HPV-related 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.



The American College of  
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WOMEN'S HEALTH CARE PHYSICIANS



IMMUNIZATION for WOMEN  
Immunization Information for Ob-Gyns and Their Patients



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WOMEN'S HEALTH CARE PHYSICIANS

## Coding Information on HPV Vaccination

### CPT Codes for Vaccine Administration

Code	Method	Route of Administration	Type of Service	Reporting Rules
90471	Injection	Percutaneous, intradermal, subcutaneous, or intramuscular	Primary	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.

*This information is provided by the American College of Obstetricians and Gynecologists for educational purposes only. It is not intended to represent the only, or necessarily the best, coding format or method for the situations discussed, but rather as an approach, view, statement, or opinion that may be helpful to persons responsible for diagnosis and procedure coding. The statements made in this document should not be construed as the American College of Obstetricians and Gynecologists' policy or procedure or as standards of care. The American College of Obstetricians and Gynecologists makes no representations or warranties, expressed or implied, regarding the accuracy of the information contained in this document and disclaims any liability or responsibility for any consequences resulting from or otherwise related to any use of, or reliance on, this information.*

For more information, please visit the Coding section on the Immunization for Women web page, [www.immunizationforwomen.org/practice\\_management/coding](http://www.immunizationforwomen.org/practice_management/coding).

## 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](http://www.immunizationforwomen.org)

Yours sincerely,



The American College of  
Obstetricians and Gynecologists  
WOMEN'S HEALTH CARE PHYSICIANS



# If you...

Have a child age 11 or 12 **or** are 13–26 years old

You should know about the HPV, or human papillomavirus, vaccine.

Approximately 79 million people in the United States have been infected with HPV and 14 million new infections occur every year, leading to around 12,000 cases of cervical cancer per year with over 4,000 deaths.

## HPV CAN CAUSE:

- Cervical, vaginal, vulvar, penile, anal, mouth, and throat cancers
- Genital warts

The vaccine is most effective when given at age 11 or 12, before a person becomes sexually active. However, even if a person is already sexually active and possibly already exposed to HPV virus, the HPV vaccine offers protection against multiple strains of the virus that can lead to HPV-related cancers and diseases. After you receive your first dose, you will receive the second dose 1-2 months later and the third one 6 months after the first dose. If you receive the first dose today, be sure to make follow-up appointments to receive the next doses on schedule.

Talk to your or your child's health care provider about the HPV vaccine. You are the key to HPV cancer prevention.

## HPV Vaccination Schedule

PATIENT NAME

DATE

	DATE DUE	ADMINISTERED ON
DOSE #1		
DOSE #2 (1-2 months later)		
DOSE #3 (6 months after 1st dose)		



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WOMEN'S HEALTH CARE PHYSICIANS



**IMMUNIZATION for WOMEN**  
Immunization Information for Ob-Gyns and Their Patients

IF YOU ARE 19-26 YEARS OLD AND HAVE NOT RECEIVED THE HPV VACCINE, PLEASE READ:

# PROTECT YOURSELF — with the — HPV VACCINE

## HPV is a common disease and can have **SERIOUS CONSEQUENCES**

In the U.S. Approximately  
**79 million**  
people have been infected with HPV

**14 million**  
new HPV infections occur  
**EVERY YEAR**

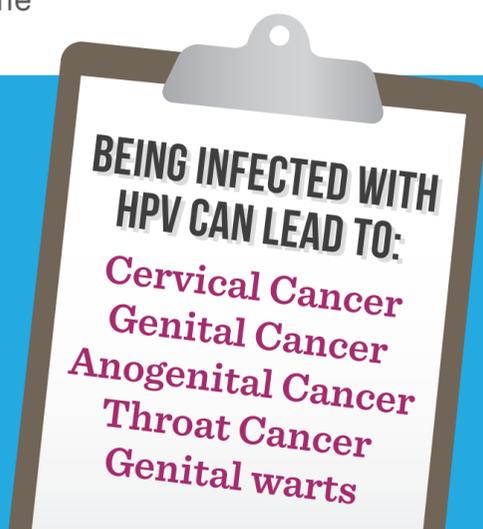
**80%** of sexually active people will contract HPV over their lifetime

You can contract HPV even if you've had just

- ✓ one sexual partner and
- ✓ do not show any symptoms of being sick

The virus can be spread through

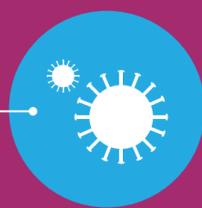
- ✓ oral sex and other sexual encounters, not just intercourse



## THE HPV VACCINE

Even if you have been sexually active, and possibly already exposed to HPV, the HPV vaccine...

Offers protection against multiple strains of the virus that can lead to several types of cancer and other HPV-related diseases



Reduces your risk of certain HPV-related cancers by up to 99% when you are fully protected with 3 doses

## THE HPV VACCINE CAN PROTECT both you and your partner from cancer



EACH YEAR, THERE ARE  
**12,000**  
CASES OF CERVICAL CANCER  
LEADING TO OVER  
4,000 DEATHS IN WOMEN

EACH YEAR, THERE ARE  
**9,300**  
HPV-RELATED CANCERS  
IN MEN



Getting vaccinated will also prevent you and your partner from  
**SPREADING HPV IN THE FUTURE**

## The HPV vaccine is **SAFE AND EFFECTIVE**

Clinical trials and ongoing research have shown the HPV vaccine's protection remains strong for at least

**10 years.**

There is no evidence to suggest this level of protection changes over time.



In the past eight years since the vaccine was licensed, only

**0.00003%**

of patients reported side effects – and most of those were “non-serious” symptoms such as headache, nausea and dizziness.

## YOU ARE THE KEY TO HPV CANCER PREVENTION.

Make sure you are protected by receiving all three doses of the HPV vaccine.



# Protect Your Family with THE HPV VACCINE

HPV IS A COMMON DISEASE AND CAN HAVE  
*serious consequences*

IN THE US...



Approximately

**79 MILLION**

people have been infected with HPV



**14 MILLION**

new HPV infections occur every year



**80%**

of sexually active people will contract HPV over their lifetime

BEING INFECTED WITH  
HPV CAN LEAD TO...



## PROTECT BOTH YOUR SONS AND DAUGHTERS FROM CANCER WITH THE HPV VACCINE

### PROTECT YOUR DAUGHTER

Each year, there are  
**12,000 CASES OF CERVICAL CANCER**  
leading to  
**OVER 4,000 DEATHS IN WOMEN**

### PROTECT YOUR SON

Each year, there are  
**9,300 CASES OF HPV-RELATED  
CANCERS IN MEN**

## THE HPV VACCINE

It is important to protect your child from the disease early.

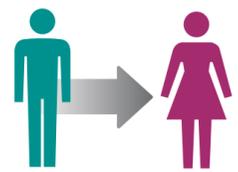
### THE HPV VACCINE CAN...



**ONLY PREVENT**  
infections,  
**NOT TREAT THEM**



Reduce Risk of  
HPV-related cancers  
**BY UP TO 99%**  
when fully protected  
with 3 doses



Prevent your child from  
**SPREADING HPV**  
to future sexual partners

The recommended age to receive the HPV vaccine is 11 or 12, however it is not too late for 13-26 year olds to get vaccinated as well.

**11-12**  
YEAR OLDS

develop a higher level of the protective antibody that the body generates after immunization, compared with older adolescents and young adults. This may result in longer lasting immunity.

## THE HPV VACCINE IS SAFE AND EFFECTIVE

Clinical trials and ongoing research have shown the HPV vaccine's protection remains strong for at least

**10 YEARS.**

There is no evidence to suggest this level of protection changes over time.

In the past eight years since the vaccine was licensed,

**ONLY 0.0003%**

of patients reported side effects – and most of those were “non-serious” symptoms such as headache, nausea and dizziness.

*You are the key to HPV cancer prevention.*

Get your child vaccinated at the recommended age of 11 or 12, to protect them and their future partners from contracting HPV.

## VACCINE INFORMATION STATEMENT

# HPV Vaccine Gardasil®-9 (Human Papillomavirus)

## What You Need to Know

Many Vaccine Information Statements are available in Spanish and other languages. See [www.immunize.org/vis](http://www.immunize.org/vis)

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite [www.immunize.org/vis](http://www.immunize.org/vis)

### 1 Why get vaccinated?

Gardasil-9 prevents many cancers caused by human papillomavirus (HPV) infections, including:

- **cervical cancer** in females,
- **vaginal and vulvar cancers** in females, and
- **anal cancer** in females and males.

In addition to these cancers, Gardasil-9 also prevents **genital warts** in both females and males.

In the U.S., about 12,000 women get cervical cancer every year, and about 4,000 women die from it. Gardasil-9 can prevent most of these cancers.

HPV infection usually comes from sexual contact, and most people will become infected at some point in their life. About 14 million Americans get infected every year. Many infections will go away and not cause serious problems. But thousands of women and men get cancer and diseases from HPV.

### 2 HPV vaccine

Gardasil-9 is one of three FDA-approved HPV vaccines. It is recommended for both males and females. It is routinely given at 11 or 12 years of age, but it may be given beginning at age 9 years through age 26 years.

Three doses of Gardasil-9 are recommended with the second and third dose 1-2 months and 6 months after the first dose.

*Vaccination is not a substitute for cervical cancer screening. This vaccine does not protect against all HPV types that can cause cervical cancer. Women should still get regular Pap tests.*

### 3 Some people should not get this vaccine

- Anyone who has had a severe, life-threatening allergic reaction to a dose of HPV vaccine should not get another dose.

Anyone who has a severe (life threatening) allergy to any component of HPV vaccine should not get the vaccine.

*Tell your doctor if you have any severe allergies that you know of, including a severe allergy to yeast.*

- HPV vaccine is not recommended for pregnant women. If you learn that you were pregnant when you were vaccinated, there is no reason to expect any problems for you or the baby. Any woman who learns she was pregnant when she got this HPV vaccine is encouraged to contact the manufacturer's registry for HPV vaccination during pregnancy at 1-800-986-8999. Women who are breastfeeding may be vaccinated.
- If you have a mild illness you can probably get the vaccine today. If you are moderately or severely ill, you should probably wait until you recover. Your doctor can advise you.



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Control and Prevention

## 4 Risks of a vaccine reaction

With any medicine, including vaccines, there is a chance of side effects. These are usually mild and go away on their own, but serious reactions are also possible.

Most people who get HPV vaccine do not have any problems with it.

### Mild or moderate problems following Gardasil-9

- Reactions in the arm where the shot was given:
  - Pain (about 9 people in 10)
  - Redness or swelling (about 1 person in 3)
- Fever:
  - Mild (100°F) (about 1 person in 10)
  - Moderate (102°F) (about 1 person in 65)
- Other problems:
  - Headache (about 1 person in 3)

### Problems that could happen after any vaccine:

- People sometimes faint after a medical procedure, including vaccination. Sitting or lying down for about 15 minutes can help prevent fainting, and injuries caused by a fall. Tell your doctor if you feel dizzy, or have vision changes or ringing in the ears.
- Some people get severe pain in the shoulder and have difficulty moving the arm where a shot was given. This happens very rarely.
- Any medication can cause a severe allergic reaction. Such reactions from a vaccine are very rare, estimated at about 1 in a million doses, and would happen within a few minutes to a few hours after the vaccination.

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

The safety of vaccines is always being monitored. For more information, visit: [www.cdc.gov/vaccinesafety/](http://www.cdc.gov/vaccinesafety/)

## 5 What if there is a serious reaction?

### What should I look for?

- Look for anything that concerns you, such as signs of a severe allergic reaction, very high fever, or unusual behavior.

Signs of a **severe allergic reaction** can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness. These would usually start a few minutes to a few hours after the vaccination.

### What should I do?

- If you think it is a **severe allergic reaction** or other emergency that can't wait, call 9-1-1 or get to the nearest hospital. Otherwise, call your doctor.
- Afterward, the reaction should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your doctor might file this report, or you can do it yourself through the VAERS web site at [www.vaers.hhs.gov](http://www.vaers.hhs.gov), or by calling **1-800-822-7967**.

*VAERS does not give medical advice.*

## 6 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.

Persons who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling **1-800-338-2382** or visiting the VICP website at [www.hrsa.gov/vaccinecompensation](http://www.hrsa.gov/vaccinecompensation). *There is a time limit to file a claim for compensation.*

## 7 How can I learn more?

- Ask your doctor. He or she can give you the vaccine package insert or suggest other sources of information.
- 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/hpv](http://www.cdc.gov/hpv)

Vaccine Information Statement (Interim)  
**HPV Vaccine** (Gardasil-9)

4/15/2015

42 U.S.C. § 300aa-26

Office Use Only



## VACCINE INFORMATION STATEMENT

# HPV Vaccine Gardasil® (Human Papillomavirus)

## What You Need to Know

Many Vaccine Information Statements are available in Spanish and other languages. See [www.immunize.org/vis](http://www.immunize.org/vis)

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite [www.immunize.org/vis](http://www.immunize.org/vis)

### 1 What is HPV?

Genital **human papillomavirus (HPV)** is the most common sexually transmitted virus in the United States. More than half of sexually active men and women are infected with HPV at some time in their lives.

About 20 million Americans are currently infected, and about 6 million more get infected each year. HPV is usually spread through sexual contact.

Most HPV infections don't cause any symptoms, and go away on their own. But HPV can cause **cervical cancer** in women. Cervical cancer is the 2nd leading cause of cancer deaths among women around the world. In the United States, about 12,000 women get cervical cancer every year and about 4,000 are expected to die from it.

HPV is also associated with several less common cancers, such as vaginal and vulvar cancers in women, and anal and oropharyngeal (back of the throat, including base of tongue and tonsils) cancers in both men and women. HPV can also cause genital warts and warts in the throat.

There is no cure for HPV infection, but some of the problems it causes can be treated.

### 2 HPV vaccine: Why get vaccinated?

The HPV vaccine you are getting is one of two vaccines that can be given to prevent HPV. It may be given to both males and females.

This vaccine can prevent most cases of cervical cancer in females, if it is given before exposure to the virus. In addition, it can prevent vaginal and vulvar cancer in females, and genital warts and anal cancer in both males and females.

Protection from HPV vaccine is expected to be long-lasting. But vaccination is not a substitute for cervical cancer screening. Women should still get regular Pap tests.

### 3 Who should get this HPV vaccine and when?

*HPV vaccine is given as a 3-dose series*

1st Dose	Now
2nd Dose	1 to 2 months after Dose 1
3rd Dose	6 months after Dose 1

Additional (booster) doses are not recommended.

#### Routine vaccination

- This HPV vaccine is recommended for girls and boys **11 or 12 years of age**. It *may* be given starting at age 9.

#### Why is HPV vaccine recommended at 11 or 12 years of age?

HPV infection is easily acquired, even with only one sex partner. That is why it is important to get HPV vaccine before any sexual contact takes place. Also, response to the vaccine is better at this age than at older ages.

#### Catch-up vaccination

This vaccine is recommended for the following people who have not completed the 3-dose series:

- Females 13 through 26 years of age.
- Males 13 through 21 years of age.

This vaccine *may* be given to men 22 through 26 years of age who have not completed the 3-dose series.

It is *recommended* for men through age 26 who have sex with men or whose immune system is weakened because of HIV infection, other illness, or medications.

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



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

## 4 Some people should not get HPV vaccine or should wait.

- Anyone who has ever had a life-threatening allergic reaction to any component of HPV vaccine, or to a previous dose of HPV vaccine, should not get the vaccine. Tell your doctor if the person getting vaccinated has any severe allergies, including an allergy to yeast.
- HPV vaccine is not recommended for pregnant women. However, receiving HPV vaccine when pregnant is not a reason to consider terminating the pregnancy. Women who are breast feeding may get the vaccine.
- People who are mildly ill when a dose of HPV vaccine is planned can still be vaccinated. People with a moderate or severe illness should wait until they are better.

## 5 What are the risks from this vaccine?

This HPV vaccine has been used in the U.S. and around the world for about six years and has been very safe.

However, any medicine could possibly cause a serious problem, such as a severe allergic reaction. The risk of any vaccine causing a serious injury, or death, is extremely small.

Life-threatening allergic reactions from vaccines are very rare. If they do occur, it would be within a few minutes to a few hours after the vaccination.

Several **mild** to **moderate** problems are known to occur with this HPV vaccine. These do not last long and go away on their own.

- Reactions in the arm where the shot was given:
  - Pain (about 8 people in 10)
  - Redness or swelling (about 1 person in 4)
- Fever:
  - Mild (100° F) (about 1 person in 10)
  - Moderate (102° F) (about 1 person in 65)
- Other problems:
  - Headache (about 1 person in 3)
- Fainting: Brief fainting spells and related symptoms (such as jerking movements) can happen after any medical procedure, including vaccination. Sitting or lying down for about 15 minutes after a vaccination can help prevent fainting and injuries caused by falls. Tell your doctor if the patient feels dizzy or light-headed, or has vision changes or ringing in the ears.

Like all vaccines, HPV vaccines will continue to be monitored for unusual or severe problems.

## 6 What if there is a serious reaction?

### What should I look for?

- Look for anything that concerns you, such as signs of a severe allergic reaction, very high fever, or behavior changes.

Signs of a severe allergic reaction can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness. These would start a few minutes to a few hours after the vaccination.

### What should I do?

- If you think it is a severe allergic reaction or other emergency that can't wait, call 9-1-1 or get the person to the nearest hospital. Otherwise, call your doctor.
- Afterward, the reaction should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your doctor might file this report, or you can do it yourself through the VAERS web site at [www.vaers.hhs.gov](http://www.vaers.hhs.gov), or by calling **1-800-822-7967**.

*VAERS is only for reporting reactions. They do not give medical advice.*

## 7 The National Vaccine Injury Compensation Program

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  - Visit CDC's website at [www.cdc.gov/vaccines](http://www.cdc.gov/vaccines)

## Vaccine Information Statement (Interim) HPV Vaccine (Gardasil)

5/17/2013

42 U.S.C. § 300aa-26

Office Use Only



## VACCINE INFORMATION STATEMENT

# HPV Vaccine Cervarix<sup>®</sup> (Human Papillomavirus)

## What You Need to Know

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About 20 million Americans are currently infected, and about 6 million more get infected each year. HPV is usually spread through sexual contact.

Most HPV infections don't cause any symptoms, and go away on their own. But HPV can cause **cervical cancer** in women. Cervical cancer is the 2nd leading cause of cancer deaths among women around the world. In the United States, about 10,000 women get cervical cancer every year and about 4,000 are expected to die from it.

HPV is also associated with several less common cancers, such as vaginal and vulvar cancers in women and other types of cancer in both men and women. It can also cause genital warts and warts in the throat.

There is no cure for HPV infection, but some of the problems it causes can be treated.

### 2 HPV vaccine: Why get vaccinated?

HPV vaccine is important because **it can prevent most cases of cervical cancer** in females, if it is given before a person is exposed to the virus.

Protection from HPV vaccine is expected to be long-lasting. But vaccination is not a substitute for cervical cancer screening. Women should still get regular Pap tests.

The vaccine you are getting is one of **two HPV vaccines that can be given to prevent cervical cancer**. It is given to females only.

The other vaccine may be given to both males and females. It can also prevent most genital warts. It has also been shown to prevent some vaginal, vulvar and anal cancers.

### 3 Who should get this HPV vaccine and when?

#### Routine vaccination

- HPV vaccine is recommended for girls **11 or 12 years of age**. It may be given to girls starting at age 9.

#### Why is HPV vaccine given to girls at this age?

It is important for girls to get HPV vaccine **before** their first sexual contact—because they won't have been exposed to human papillomavirus.

Once a girl or woman has been infected with the virus, the vaccine might not work as well or might not work at all.

#### Catch-up vaccination

- The vaccine is also recommended for girls and women **13 through 26 years of age** who did not get all 3 doses when they were younger.

#### HPV vaccine is given as a 3-dose series

1st Dose:	Now
2nd Dose:	1 to 2 months after Dose 1
3rd Dose:	6 months after Dose 1

Additional (booster) doses are not recommended.

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

### 4 Some people should not get HPV vaccine or should wait

- Anyone who has ever had a life-threatening allergic reaction to any component of HPV vaccine, or to a previous dose of HPV vaccine, should not get the vaccine. Tell your doctor if the person getting vaccinated has any severe allergies, including an allergy to latex.
- HPV vaccine is not recommended for **pregnant women**. However, receiving HPV vaccine when pregnant is not a reason to consider terminating the pregnancy. Women who are breast feeding may get the vaccine.



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Control and Prevention

Any woman who learns she was pregnant when she got this HPV vaccine is encouraged to contact the manufacturer's **HPV in pregnancy registry** at 888-452-9622. This will help us learn how pregnant women respond to the vaccine.

- People who are mildly ill when a dose of HPV vaccine is planned can still be vaccinated. People with a **moderate or severe illness** should wait until they are better.

## 5 What are the risks from this vaccine?

This HPV vaccine has been in use around the world for several years and has been very safe.

However, any medicine could possibly cause a serious problem, such as a severe allergic reaction. The risk of any vaccine causing a serious injury, or death, is extremely small.

Life-threatening allergic reactions from vaccines are very rare. If they do occur, it would be within a few minutes to a few hours after the vaccination.

Several **mild to moderate problems** are known to occur with HPV vaccine. These do not last long and go away on their own.

- Reactions where the shot was given:
  - Pain (about 9 people in 10)
  - Redness or swelling (about 1 person in 2)
- Other mild reactions:
  - Fever of 99.5°F or higher (about 1 person in 8)
  - Headache or fatigue (about 1 person in 2)
  - Nausea, vomiting, diarrhea, or abdominal pain (about 1 person in 4)
  - Muscle or joint pain (up to 1 person in 2)
- Fainting:

Brief fainting spells and related symptoms (such as jerking movements) can happen after any medical procedure, including vaccination. **Sitting or lying down for about 15 minutes after a vaccination can help prevent fainting and injuries caused by falls.** Tell your doctor if the patient feels dizzy or light-headed, or has vision changes or ringing in the ears.

Like all vaccines, HPV vaccines will continue to be monitored for unusual or severe problems.

## 6 What if there is a serious reaction?

### What should I look for?

- Look for anything that concerns you, such as signs of a severe allergic reaction, very high fever, or behavior changes.

Signs of a severe allergic reaction can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness. These would start a few minutes to a few hours after the vaccination.

### What should I do?

- If you think it is a severe allergic reaction or other emergency that can't wait, call 9-1-1 or get the person to the nearest hospital. Otherwise, call your doctor.
- Afterward, the reaction should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your doctor might file this report, or you can do it yourself through the VAERS web site at [www.vaers.hhs.gov](http://www.vaers.hhs.gov), or by calling **1-800-822-7967**.

*VAERS is only for reporting reactions. They do not give medical advice.*

## 7 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.

Persons who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling **1-800-338-2382** or visiting the VICP website at [www.hrsa.gov/vaccinecompensation](http://www.hrsa.gov/vaccinecompensation).

## 8 How can I learn more?

- Ask your doctor.
- 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](http://www.cdc.gov/vaccines)

Vaccine Information Statement (Interim)  
Human Papillomavirus (HPV) Cervarix

5/3/2011

Office Use Only



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# Standing Orders for Administering Human Papillomavirus Vaccine to Adults

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**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.

**Policy:** Under these standing orders, eligible nurses and other healthcare professionals (e.g., pharmacists), where allowed by state law, may vaccinate adults who meet the criteria below.

## Procedure

1. Identify adults in need of vaccination against human papillomavirus (HPV) based on the following criteria:
  - a. Female, age 26 years or younger
  - b. Male, age 21 years or younger
  - c. Male, age 22 through 26 years meeting any of the following conditions:
    - i. Immunocompromised as a result of infection (including HIV), disease, or medications
    - ii. Has sex with other males
    - iii. Wants to be vaccinated and lacks any of the above criteria
2. Screen all patients for contraindications and precautions to HPV vaccine:
  - a. **Contraindication:** a history of a severe allergic reaction (e.g., anaphylaxis) after a previous dose of HPV vaccine or to a HPV vaccine component (e.g., yeast for quadrivalent or 9-valent HPV vaccine [4vHPV or 9vHPV: Gardasil, Merck] or latex for bivalent HPV vaccine [2vHPV: Cervarix, GSK]). For information on vaccine components, refer to the manufacturers’ package insert ([www.immunize.org/packageinserts](http://www.immunize.org/packageinserts)) or go to [www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf](http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf).
  - b. **Precautions:**
    - Moderate or severe acute illness with or without fever
    - Pregnancy; delay vaccination until after completion of the pregnancy
3. Provide all patients with a copy of the most current federal Vaccine Information Statement (VIS). You must 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. Provide non-English speaking patients with a copy of the VIS in their native language, if available and preferred; these can be found at [www.immunize.org/vis](http://www.immunize.org/vis).
4. Provide 1) either 2vHPV, 4vHPV, or 9vHPV to women or 2) 4vHPV or 9vHPV to men. Provide either vaccine in a 3-dose schedule at 0, 1–2, and 6 calendar months. Administer 0.5 mL HPV vaccine intramuscularly (22–25g, 1–1½" needle) in the deltoid muscle; the anterolateral thigh muscle may be used if deltoid is inadequate. (Note: a ⅝" needle may be used for adults weighing less than 130 lbs [60 kg] for injection in the deltoid muscle *only* if the subcutaneous tissue is not bunched and the injection is made at a 90° angle.)
5. For adults who have not received HPV vaccine at the intervals specified in #4, administer subsequent doses of HPV vaccine to complete each patient’s 3-dose schedule by observing a minimum interval of 4 weeks between the first and second doses, 12 weeks between the second and third dose, and at least 24 weeks between the first and third doses. Men age 27 years and older who meet the criteria of 1.c.i. or 1.c.ii. above and women age 27 years and older who have received at least 1 dose before their 27<sup>th</sup> birthday should complete the 3-dose series as soon as feasible. Men age 22 years and older who have received at least 1 dose before their 22<sup>nd</sup> birthday should also complete the 3-dose series as soon as feasible.
6. Document each patient’s vaccine administration information and follow up in the following places:
  - a. **Medical chart:** 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. If vaccine was not administered, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).
  - b. **Personal immunization record card:** Record the date of vaccination and the name/location of the administering clinic.
7. 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, go to [www.immunize.org/catg.d/p3082.pdf](http://www.immunize.org/catg.d/p3082.pdf). To prevent syncope, vaccinate patients while seated or lying down and consider observing them for 15 minutes after receipt of the vaccine.
8. Report all adverse reactions following the administration of HPV vaccine to the federal Vaccine Adverse Event Reporting System (VAERS) at [www.vaers.hhs.gov](http://www.vaers.hhs.gov) or by calling (800) 822-7967. VAERS report forms are available at [www.vaers.hhs.gov](http://www.vaers.hhs.gov).

This policy and procedure shall remain in effect for all patients of the \_\_\_\_\_ until rescinded or until \_\_\_\_\_ (date). (name of practice or clinic)

Medical Director’s signature: \_\_\_\_\_ Effective date: \_\_\_\_\_

For standing orders for other vaccines, go to [www.immunize.org/standing-orders](http://www.immunize.org/standing-orders)

Technical content reviewed by the Centers for Disease Control and Prevention

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# Standing Orders for Administering Human Papillomavirus Vaccine to Children and Teens

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**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.

**Policy:** Under these standing orders, eligible nurses and other healthcare professionals (e.g., pharmacists), where allowed by state law, may vaccinate children and teens who meet the criteria below.

## Procedure

1. Identify all children and teens ages 11 years and older who have not completed the HPV vaccination series.
2. Screen all patients for contraindications and precautions to HPV vaccine:
  - a. **Contraindication:** a history of a serious allergic reaction (e.g., anaphylaxis) after a previous dose of HPV vaccine or to a HPV vaccine component (e.g., yeast for quadrivalent or 9-valent HPV vaccine [4vHPV or 9vHPV: Gardasil, Merck] or latex for bivalent HPV vaccine [2vHPV: Cervarix, GSK]). For information on vaccine components, refer to the manufacturers’ package insert ([www.immunize.org/packageinserts](http://www.immunize.org/packageinserts)) or go to [www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf](http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf).
  - b. **Precautions:**
    - Moderate or severe acute illness with or without fever
    - Pregnancy; delay vaccination until after completion of the pregnancy
3. Provide all patients (or, if minors, their parent or legal representative) with a copy of the most current federal Vaccine Information Statement (VIS). You must 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 (parent/legal representative). Provide non-English speaking patients with a copy of the VIS in their native language, if available and preferred; these can be found at [www.immunize.org/vis](http://www.immunize.org/vis).
4. Provide 1) either 2vHPV, 4vHPV, or 9vHPV to girls or 2) 4vHPV4 or 9vHPV to boys. Provide either vaccine in a 3-dose schedule at 0, 1–2, and 6 calendar months. Provide routine vaccination with HPV vaccine to girls and boys at age 11 or 12 years; vaccine may be administered to girls or boys as young as age 9 years. Administer 0.5 mL HPV vaccine intramuscularly (22–25g, 1–1½" needle) in the deltoid muscle; the anterolateral thigh muscle may be used if deltoid is inadequate. (Note: a 5/8" needle may be used for children and teens weighing less than 130 lbs [60 kg] for injection in the deltoid muscle *only* if the subcutaneous tissue is not bunched and the injection is made at a 90° angle.)
5. For children and teens who have not received HPV vaccine at the ages and/or intervals specified in #4, administer one dose at the earliest opportunity and then schedule subsequent doses to complete the 3-dose schedule by observing a minimum interval of 4 weeks between the first and second doses, 12 weeks between the second and third doses, and at least 24 weeks between the first and third doses.
6. Document each patient’s vaccine administration information and follow up in the following places:
  - a. **Medical chart:** 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. If vaccine was not administered, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).
  - b. **Personal immunization record card:** Record the date of vaccination and the name/location of the administering clinic.
7. 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](http://www.immunize.org/catg.d/p3082a.pdf). To prevent syncope, vaccinate patients while seated or lying down and consider observing them for 15 minutes after receipt of the vaccine.
8. Report all adverse reactions following the administration of HPV vaccine to the federal Vaccine Adverse Event Reporting System (VAERS) at [www.vaers.hhs.gov](http://www.vaers.hhs.gov) or by calling (800) 822-7967. VAERS report forms are available at [www.vaers.hhs.gov](http://www.vaers.hhs.gov).

This policy and procedure shall remain in effect for all patients of the \_\_\_\_\_ until rescinded or until \_\_\_\_\_ (date).  
(name of practice or clinic)

Medical Director’s signature: \_\_\_\_\_ Effective date: \_\_\_\_\_

For standing orders for other vaccines, go to [www.immunize.org/standing-orders](http://www.immunize.org/standing-orders)

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