

Human Papillomavirus Vaccination

2014



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

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Vice President, Practice Activities

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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 a vaccine that helps prevent cancer in many cases. Human papillomavirus (HPV) vaccination is recommended for girls, young women, and boys (see the enclosed ACOG Committee Opinion No. 588, *Human Papillomavirus Vaccination*, for specific recommendations). If your patient is a mother, talk to her about the importance of vaccinating her child(ren) against HPV. This three-dose vaccine series has the potential to prevent up to 70% of cases of cervical cancer. It has been shown that the most effective way to increase immunization rates among patients is for the physician to directly recommend the vaccines. If your patient does not accept your recommendation initially, continue to offer immunizations to her on subsequent office visits. I highly encourage you to incorporate HPV vaccination into your routine well-woman care.

This toolkit includes materials to help you and your staff communicate with patients about the importance of receiving the HPV vaccine. The recently revised Committee Opinion No. 588 provides guidance on the recommendations of HPV vaccination and how to integrate this vaccine into routine care. 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. For tips on speaking to patients about HPV vaccination, refer to our *Physician Script Concerning HPV Vaccination*, which also includes useful coding information on the back. 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 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 site, *Immunization for Women*, at www.immunizationforwomen.org.

We hope the enclosed materials are helpful to you, your practice team, and your patients. If you have additional questions, please e-mail us at immunization@acog.org or call 202-863-2453. If you would like additional materials, please visit us at sales.acog.org. Thank you for your time and attention.

Sincerely,

Gerald F. Joseph Jr, MD, FACOG
Vice President, Practice Activities



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Frequently Asked Questions for Patients Concerning HPV Vaccination

What is HPV?

Human papillomavirus (HPV) is a group of more than 120 different viruses. Some types of HPV are primarily sexually transmitted. One person can spread HPV to another person by genital–genital contact, oral–genital contact, or sexual intercourse. The oral, anal, or genital areas of men and women can become infected. Human papillomavirus types 6 and 11 cause 90% of genital warts. However, 13 additional serious types of HPV have been shown to cause cervical cancer. Of these, HPV types 16 and 18 cause about 70% of all cases of cervical cancer.

Will I know if I have HPV?

Genital warts are a sign of HPV infection. However, an infection of the cervix usually has no symptoms. With no symptoms, an infected person can spread HPV to another person without knowing.

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 infection 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 cervical cancer deaths.

What HPV vaccines are currently available?

There are two types of HPV vaccines: bivalent and quadrivalent. The bivalent HPV vaccine is indicated to prevent cervical cancer and cervical intraepithelial neoplasia caused by HPV types 16 and 18. The quadrivalent HPV vaccine is indicated to prevent cancer and intraepithelial neoplasia and genital warts associated with HPV types 6, 11, 16, and 18.

Who should get vaccinated?

Human papillomavirus vaccination is recommended for girls and boys aged 11 years or 12 years. However, the vaccines can be given to children as young as age 9 years. Those who were not vaccinated at the target age can be vaccinated from ages 13 years to 26 years.

(see reverse)

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. Also, research shows that the vaccines produce a better immune response when given at younger ages. However, sexually active individuals may still benefit from vaccination because they are unlikely to have been infected with all HPV types that are prevented by the vaccines. Hence, vaccination is recommended up to age 26 years.

What is the recommended timing of the three HPV doses?

Both vaccines 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. Even if the time before the second or third dose is longer than recommended, starting over is not necessary. Go and 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 get vaccinated against HPV?

At this time, HPV vaccination is only approved for ages 9 years to 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?

Studies show that HPV vaccination is not linked to more or earlier sexual activity.

Are the HPV vaccines safe?

Studies show that both 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 side effects. Common, mild side effects include pain where the shot was given, fever, headache, and nausea. As with all vaccines, the safety of HPV vaccines is monitored carefully.

Do the HPV vaccines work?

The vaccines are highly effective when given before sexual activity begins. They can reduce the chance of developing precancerous cells from HPV types 16 and 18 that are in the vaccines by 100%. This means the risk of cervical cancer is reduced by 70%. It is not 100% because cervical cancer can still be caused by other types of HPV not in the vaccines. This is why getting regular Pap tests is important. The quadrivalent vaccine, which also protects from HPV types 6 and 11, reduces the risk of getting genital warts by 90%.

RESOURCE

The American College of Obstetricians and Gynecologists
Human papillomavirus vaccination. Committee Opinion No. 588. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2014;123:712–8.



The American College of
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Physician Script Concerning HPV Vaccination

Human papillomavirus (HPV) vaccination is recommended for all female and male patients aged 9–26 years with a target age for vaccination at age 11 years to 12 years. Two HPV vaccines are currently available. These vaccines are bivalent, which is approved for use in girls and protects against HPV types 16 and 18 (the most common cause of cervical cancer) and quadrivalent, which is approved for use in boys and girls and protects against HPV types 16 and 18 as well as HPV types 6 and 11 (associated with genital warts).

The vaccines are highly effective and produce a robust immune response and persistent immune memory. Studies of both HPV vaccines have shown that among participants who had not been exposed to the vaccine genotypes, the vaccines are nearly 100% effective in preventing cervical intraepithelial neoplasia (CIN) 2,3 related to the HPV types 16 and 18. The quadrivalent vaccine has also shown to be nearly 100% effective in preventing vaginal and vulvar intraepithelial neoplasia and genital warts caused by HPV genotypes 6 and 11. These vaccines can prevent significant amounts of serious health problems when given to a patient who has not been exposed to HPV because 70% of cervical cancer is associated with HPV types 16 and 18 and 90% of genital warts are associated with HPV types 6 and 11 (included in the quadrivalent vaccine). In the United States, cervical cancer is the seventh leading cause of mortality among women, and there are approximately 1 million cases of precancerous cells or lesions and 360,000 cases of genital warts each year.

The vaccines are not recommended during pregnancy. If inadvertently administered during pregnancy, HPV vaccination has not shown to be harmful. It is safe to administer postpartum, during breastfeeding, and to family members. Pregnancy testing is not required prior to vaccination.

It is required by law for you to give your patients a Vaccine Information Statement upon receiving an immunization. Vaccine Information Statement forms can be found in multiple languages at www.immunize.org/vis/.

Multiple studies show that the most effective way to increase your patients' vaccination acceptance rate is for you to directly recommend and provide the vaccine. Talk to your patients or their parents about HPV vaccination today. Here is a script for your consideration when talking to a parent with a child in the target age range or age-eligible females:

"I strongly recommend human papillomavirus vaccination to all of my patients who are 9- to 26-years-old. I also recommend it to my patients who have children or grandchildren in that age range. Vaccination reduces the chances of cervical, vaginal, vulvar, anal, and oral cancer in females and penile, anal, and oral cancer in males. It also reduces the number of abnormal Pap test results, which saves women from having examinations they do not need. Human papillomavirus is extremely common—80% of people are exposed to the virus during their lifetime. Even having only one lifetime partner can expose you to the virus and put you at risk. This is why prevention is so important. Both HPV vaccines are safe and effective. I recommend vaccination at age 11 years to 12 years. If that doesn't happen, I recommend 'catch-up' vaccination for up to age 26 years."

RESOURCES

The American College of Obstetricians and Gynecologists

Human papillomavirus vaccination. Committee Opinion No. 588. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2014;123:712–8.

Center for Disease Control and Prevention

cdc.gov/vaccinesafety/vaccines/HPV/index.html



Coding Information on HPV Immunization

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 day. Report for administration of first vaccine if more than one was provided. Physician or other Qualified Health Professional also provides counseling. Patient is 18 years of age or younger.
90461	Any route	Percutaneous, intradermal, subcutaneous, or intramuscular	Additional	Report for secondary or subsequent vaccine administration. Physician or other Qualified Health Professional also provides counseling. Patient is 18 years of age or younger.

HPV Vaccines Administered to Adolescents and Adults

Vaccine	Code for Vaccine Product	CPT Administration Code
HPV types 6, 11, 16, 18 (quadrivalent), 3-dose schedule, intramuscular	90649	90460-90472
HPV types 16, 18 (bivalent), 3-dose schedule, intramuscular	90650	90460-90472

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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.



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

COMMITTEE OPINION

Number 588 • March 2014

(Replaces Committee Opinion Number 467, September 2010)

Committee on Adolescent Health Care

This Committee Opinion was developed with the assistance of the Immunization Expert Work Group. The document 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: The Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention recommends that human papillomavirus (HPV) vaccination routinely be targeted to females and males aged 11 years or 12 years as part of the adolescent immunization platform to help reduce the incidence of anogenital cancers and genital warts associated with HPV infection. The quadrivalent HPV vaccine is approved for use in males and females, whereas the bivalent HPV vaccine is approved for use only in females. For those not vaccinated at the target age, catch-up vaccination is recommended up to age 26 years. The American College of Obstetricians and Gynecologists endorses these recommendations. 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 and are critical to vaccinating adolescent girls and young women during the catch-up period. Obstetrician–gynecologists should advise patients and parents that HPV vaccines are most effective in preventing genital cancers when administered before the onset of sexual activity. However, sexually active individuals can receive some benefit from the vaccination because exposure to all HPV types prevented by the vaccines is unlikely in persons aged 13 years through 26 years. Although HPV vaccination in pregnancy is not recommended, neither is routine pregnancy testing before vaccination. Lactating women can receive either HPV vaccine. The need for ongoing cervical cytology screening should be emphasized in all women aged 21 years and older, even those who received HPV vaccination before the onset of sexual activity.

Human papillomavirus (HPV) is a group of more than 120 different viruses. Infection with HPV is associated with the development of anogenital cancers (including cervical, vaginal, vulvar, and anal), oropharyngeal cancer, and genital warts. Approximately 40 HPV genotypes are primarily sexually transmitted from person to person (eg, genital–genital contact, oral–genital contact, and sexual intercourse) and infect the oral, anal, or genital areas of men and women. However, only 13 genotypes have been shown to cause cervical cancer (1). Approximately 70% of all cases of cervical cancer are caused by HPV genotypes 16 and 18, and 90% of cases of genital warts are caused by HPV genotypes 6 and 11 (2).

Each year in the United States, cervical cancer is diagnosed in more than 12,000 women, and nearly 4,000 die from the disease (3). In addition, there are more than 1 million cases of abnormal cytology screening results that

require evaluation (4, 5). Although the implementation of cervical cytology screening programs and treatment of precancerous lesions has led to a decrease in deaths from cervical cancer in the United States, such deaths still occur. Approximately one half of all cases of cervical cancer are found in women who have never had a Pap test, and another 10% occur in patients who have not had one within the past 5 years (6). Both ongoing cervical cytology screening and HPV vaccination are needed to help reduce these deaths.

Human papillomavirus vaccination can also help reduce the incidence of other anogenital cancers and genital warts and may decrease the incidence of oropharyngeal cancer. Each year in the United States, HPV is believed to cause approximately 2,600 cases of vulvar and vaginal cancer, 4,300 cases of anal cancer, 360,000 cases of genital warts, and more than 8,400 cases of oropharyngeal

cancer (7). Approximately 35% of all cases of anal cancer and 80% of all cases of oropharyngeal cancer are in men (7).

Human Papillomavirus Vaccines

The U.S. Food and Drug Administration (FDA) has approved two vaccines shown to be effective at preventing HPV infection. The quadrivalent HPV vaccine is indicated to prevent cancers and intraepithelial neoplasias of the cervix, anus, vulva, and vagina and genital warts associated with HPV genotypes 6, 11, 16, and 18 (8). The FDA has approved administration of the quadrivalent three-dose vaccine to females and males aged 9–26 years. The bivalent three-dose HPV vaccine has FDA approval for administration to females aged 9–25 years for the prevention of cervical cancer, cervical intraepithelial neoplasia (CIN) 2 or worse and adenocarcinoma in situ, and CIN 1 caused by oncogenic HPV genotypes 16 and 18 (9).

Efficacy

Studies of the quadrivalent HPV vaccine have shown that among participants who were naive to the vaccine genotypes and who followed protocol, the vaccine was nearly 100% effective in preventing CIN 2, CIN 3, and condylomatous vulvar disease related to the HPV genotypes covered by the vaccine (8). Similarly, clinical trials in men showed an efficacy of 90.4% in preventing external genital lesions associated with the HPV genotypes covered by the vaccine (10). In a substudy of men who have sex with men, the quadrivalent vaccine was 77.5% effective in preventing anal intraepithelial neoplasia related to HPV genotypes 6, 11, 16, and 18, leading to FDA approval of the quadrivalent vaccine for the prevention of anal cancer and associated precancerous lesions that are caused by these HPV genotypes (11). Results of studies of the bivalent HPV vaccine indicate that it offers protection similar to the quadrivalent vaccine against CIN 2 and CIN 3 in adolescent and young women who are naive to the vaccine's HPV genotypes 16 and 18 (12, 13). The bivalent vaccine does not protect against lower genital tract condyloma caused by low-risk HPV genotypes 6 and 11 (ie, associated with genital warts). There is evidence that each vaccine provides some minor degree of cross-protection against other nonvaccine HPV genotypes that are associated with disease (14).

To be maximally effective, vaccination with either vaccine should be given during the target ages (11 years and 12 years) or before the onset of sexual activity. If the vaccine is given after the onset of sexual activity, patients may have already been infected with HPV. Data from Australia, where coverage is more than 75% in the target age group (females only), showed that the diagnosis of genital warts in females decreased by 73% within 3 years of vaccine introduction (13). There also was a significant decrease in the diagnosis of genital warts in heterosexual men, suggesting herd immunity. In Sweden, data that linked multiple population registers showed that 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, respectively (15). Data from the United States show that 1 month after the completion of HPV vaccination, girls aged 10–14 years generally have higher antibody levels than young women aged 15–26 years and retain these higher levels for several years (16, 17). All of these findings underscore the importance of vaccination during the target age or before the onset of sexual activity.

In the United States, the prevalence of vaccine-type HPV has decreased 56% among females aged 14–19 years since the quadrivalent vaccine was introduced in 2006 (18). The observed decrease in vaccine-associated HPV prevalence is likely due to the protection induced by a single vaccine dose, at least in the short term. According to the Centers for Disease Control and Prevention (CDC), slightly more than 50% of 13–17-year-olds in the United States have received at least one vaccine dose, and only 33% have received all three doses (19). Recent data demonstrate that individuals who received two doses of the quadrivalent vaccine at 0 and 6 months had similar antibody responses within 6 months as those receiving three doses (16). However, at 24–36 months, those who received two doses showed a lower level of antibody response than those who received three doses (16). Thus, reduced dose schedules are not currently recommended.

The need for booster doses remains to be demonstrated but is unlikely (13). The current three-dose vaccine series is designed to maximize the primary immune response and enhance long-term protection. The durability of the immune response (ie, how long protection lasts) is being monitored in various long-term studies, and there is currently no indication for a booster vaccine.

Safety

Safety data for both HPV vaccines are reassuring. According to the Vaccine Adverse Events Reporting System, more than 57 million doses of HPV vaccine have been distributed, and there are no data to suggest that there are any severe side effects or adverse reactions linked to vaccination (20). Ongoing surveillance of HPV vaccine side effects—which include syncope, nausea, headache, dizziness, and local pain and redness—shows no new, unexpected adverse reactions (20). Although there was an observed increase of venous thromboembolism in those vaccinated, on review it was determined that this finding was not statistically significant because all five patients had prior known risks of venous thromboembolism (21). The CDC continues to consider HPV vaccines safe.

Vaccination of Specific Populations

The following are recommendations for HPV vaccination of specific groups. Testing for HPV DNA is not required or recommended before vaccination in any group. If the patient is tested for HPV DNA and the results are positive, vaccination is still recommended because the

chance that the patient has been exposed to all vaccine-preventable HPV genotypes is low.

In all states, minors are allowed to give consent for the diagnosis and treatment of sexually transmitted infections. However, many of the laws that authorize them to provide such consent may only permit it after they have reached a specific age. Furthermore, these laws do not mention vaccinations (22). Clinicians should be familiar with state and local statutes regarding the rights of minors to consent to health care services and the federal and state laws that affect confidentiality.

Girls and Boys, Adolescents, and Young Women and Men

The Advisory Committee on Immunization Practices of the CDC recommends that HPV vaccination routinely be targeted to females and males aged 11 years or 12 years as part of the adolescent immunization platform to help reduce the incidence of anogenital cancer and genital

warts associated with HPV infection. The quadrivalent HPV vaccine is approved for use in males and females, whereas the bivalent HPV vaccine is approved for use only in females. Depending on the circumstances, the vaccine can be given to individuals as young as 9 years. For those not vaccinated at the target age, catch-up vaccination is recommended up to age 26 years (see Box 1) (2). Once the vaccination series has begun, there is no evidence to suggest that the series needs to be restarted if there is a delay in administration of subsequent vaccine doses.

The American College of Obstetricians and Gynecologists endorses these recommendations. During a health care visit with a girl, adolescent, or a young woman in the age range for vaccination, obstetrician–gynecologists should assess the patient’s HPV vaccine status, discuss HPV and the potential benefit of HPV vaccination, offer vaccination as needed, and document this information in the patient’s medical record.

Box 1. Key Information Regarding the Bivalent and Quadrivalent Human Papillomavirus Vaccines*

Dosage

Administered intramuscularly as three separate 0.5-mL doses based on the following schedule:

1. First dose: at elected date
2. Second dose: 1–2 months after the first dose
3. Third dose: 6 months after the first dose

Minimum interval between first and second dose is 4 weeks, between second and third dose is 12 weeks, and between first and third dose is 24 weeks. If the vaccine schedule is interrupted, the series does not need to be restarted, regardless of the length of time between doses. Whenever possible, the same vaccine product should be used for all doses in the series.

Recommended Age

- Target population: females and males[†] aged 11 years or 12 years (can be started as early as age 9 years)
- Females and males[†] who did not receive the vaccination at the target age can be vaccinated from age 13 years through 26 years

Contraindications

Individuals who develop symptoms indicative of hypersensitivity to the active substances or to any of the components of either vaccine after receiving a dose of vaccine should not receive further doses of the product. Safety and effectiveness of the two formulations have not been established in pregnant women. Any exposure to it during pregnancy should be reported to the manufacturer by calling 1-877-888-4231 for the quadrivalent vaccine and 1-888-452-9622 for the bivalent vaccine.

Precautions

As with any vaccine, vaccination may not protect all vaccine recipients. Neither vaccine is intended to be used for treatment of active disease (ie, genital warts, cervical cancer, cervical intraepithelial neoplasia, vulvar intraepithelial neoplasia, or vaginal intraepithelial neoplasia). Human papillomavirus (HPV) vaccines can be administered simultaneously or at any time before or after a different inactivated or live vaccine administration. Because vaccinated individuals may develop syncope, sometimes resulting in falling with injury, health care providers should consider observing patients for 15 minutes after vaccine administration.

Storage

Both formulations should be refrigerated at 2–8°C (36–46°F), should not be frozen, and should be protected from light.

Vaccine Adverse Event Reporting

To report an adverse event associated with administration, go to <http://vaers.hhs.gov>.

(continued)

Box 1. Key Information Regarding the Bivalent and Quadrivalent Human Papillomavirus Vaccines* (continued)

Advisory Committee on Immunization Practices Recommendations

For current recommendations by the Advisory Committee on Immunization Practices, go to <http://www.cdc.gov/vaccines/recs/acip/default.htm>.

Current Procedural Terminology Code[†]

The American Medical Association has established a Current Procedural Terminology code of 90649 for quadrivalent HPV vaccination and 90650 for bivalent HPV vaccine.

*Note that the U.S. Food and Drug Administration labeling for the bivalent vaccine indicates it is for use in females aged 9–25 years. In addition, the U.S. Food and Drug Administration approved dosage intervals for the quadrivalent and bivalent vaccines to be 0 months, 2 months, and 6 months and 0 months, 1 month, and 6 months, respectively.

[†]The U.S. Food and Drug Administration has approved the quadrivalent vaccine for use in males aged 9–26 years for the prevention of genital warts.

[‡]Current Procedural Terminology (CPT) copyright 2012 American Medical Association. All rights reserved. CPT is a registered trademark of the American Medical Association.

Data from Centers for Disease Control and Prevention. FDA licensure of bivalent human papillomavirus vaccine (HPV2, Cervarix) for use in females and updated HPV vaccination recommendations from the Advisory Committee on Immunization Practices (ACIP). *MMWR Morb Mortal Wkly Rep* 2010;59:626–9.

Sexually Active Adolescents and Young Women

Sexually active adolescents and young women can receive either the quadrivalent or bivalent HPV vaccine. These patients should be counseled that the vaccine may be less effective in individuals who have been exposed to HPV before vaccination than in individuals who were HPV naive at the time of vaccination (8, 12). However, sexually active individuals can receive some benefit from the vaccination because exposure to all HPV types prevented by the vaccines is unlikely in persons aged 13 years through 26 years. The need for ongoing cervical cytology screening should be emphasized in all women aged 21 years and older, even those vaccinated before the onset of sexual activity.

Adolescents and Young Women With Previous Cervical Intraepithelial Neoplasia or Genital Warts

The HPV vaccines can be given to patients with previous CIN or genital warts. Health care providers need to emphasize that the benefits may be limited and cervical cytology screening and corresponding management based on College recommendations must continue. The HPV vaccines are not intended to be treatment for cervical cytologic abnormalities, genital warts, or a positive HPV DNA test result. Patients with these conditions should undergo the appropriate evaluation and treatment (23, 24).

Pregnant and Lactating Women

Both the quadrivalent and bivalent HPV vaccines have been classified by the FDA as pregnancy category B. Although HPV vaccination in pregnancy is not recommended, neither is routine pregnancy testing before

vaccination. Currently, there are few data on HPV vaccine administration in pregnancy; however, the available safety data regarding the inadvertent administration of the vaccine during pregnancy are reassuring (25, 26). In clinical studies, the proportion of pregnancies with adverse outcomes was comparable in women who received the HPV vaccine and in women who received a placebo (9, 27). However, it is wise to remind patients to use contraception during the period when they are receiving the vaccination series. The manufacturer should be contacted if pregnancy is detected during the vaccination schedule (see Box 1). Completion of the vaccine series should be delayed until pregnancy is completed. Lactating women can receive either HPV vaccine because inactivated vaccines, such as these vaccines, do not affect the safety of breastfeeding for mothers or infants (28).

Immunosuppressed Patients

The presence of immunosuppression, like that experienced in patients with HIV infection or organ transplantation, is not a contraindication to HPV vaccination. However, the immune response may be less robust in the immunocompromised patient (29).

Women Older Than 26 Years

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 because vaccination may provide some marginal benefit (16).

Patient Education and Vaccination Efforts

Obstetrician–gynecologists are encouraged to discuss the benefits of HPV vaccination with patients aged

11–26 years and to offer initial vaccination and catch-up vaccination as needed. 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 and are critical to vaccinating adolescent girls and young women during the catch-up period. It is important for health care providers to educate patients and parents of children in the target age range for HPV vaccination about HPV-related disease and be prepared to respond to questions regarding HPV vaccination, including its benefits, limitations, and safety, as discussed earlier. Studies have shown that physicians' recommendations play a crucial role in the acceptance of HPV vaccination by patients and parents of patients (30). Many parents think that HPV vaccination is not needed and are concerned about safety and adverse reactions (31). Obstetrician–gynecologists should advise patients and parents that HPV vaccines are most effective in preventing genital cancers when administered before the onset of sexual activity, although HPV can be contracted without sexual activity. In addition, patients and parents can be counseled that HPV vaccines are safe and associated with few side effects, none of which are severe. An additional concern among some parents is that HPV vaccination may cause an increase in sexual activity among adolescents. However, health care providers can reassure parents that this is not the case. A study of 1,398 girls aged 11–12 years found that HPV vaccination was not associated with increased sexual activity outcomes that included pregnancy, sexually transmitted infection testing or diagnosis, or contraceptive counseling (32).

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 (19). Furthermore, for every year that coverage does not increase, an additional 4,400 women will develop cervical cancer. These data highlight the overwhelming importance of HPV vaccination efforts, including discussions with patients and parents of children and adolescents about the benefit of HPV immunization for cancer prevention (19).

American College of Obstetricians and Gynecologists' Resources

American College of Obstetricians and Gynecologists. *Cómo prevenir las enfermedades de transmisión sexual* [Spanish]. Patient Education Pamphlet SP009. Washington, DC: American College of Obstetricians and Gynecologists; 2013.

American College of Obstetricians and Gynecologists. *How to prevent sexually transmitted diseases*. Patient Education Pamphlet AP009. Washington, DC: American College of Obstetricians and Gynecologists; 2013.

American College of Obstetricians and Gynecologists. *Human papillomavirus infection*. Patient Education

Pamphlet AP073. Washington, DC: American College of Obstetricians and Gynecologists; 2013.

American College of Obstetricians and Gynecologists. *Infección del virus del papiloma humano* [Spanish]. Patient Education Pamphlet SP073. Washington, DC: American College of Obstetricians and Gynecologists; 2013.

American College of Obstetricians and Gynecologists. *Human papillomavirus*. In: *Tool kit for teen care*. 2nd ed. Washington, DC: ACOG; 2009.

American College of Obstetricians and Gynecologists. *Immunization for women*. Available at: <http://www.immunizationforwomen.org>. Retrieved January 10, 2013.

Screening for cervical cancer. Practice Bulletin No. 131. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2012;120:1222–38.

Other Resources

The following list is for information purposes only. Referral to these sources and web sites does not imply the endorsement of the American College of Obstetricians and Gynecologists. This list is not meant to be comprehensive. The exclusion of a source or web site does not reflect the quality of that source or web site. Please note that web sites are subject to change without notice.

American Cancer Society
250 Williams Street, NW
Atlanta, GA 30303
1-800-227-2345
<http://www.cancer.org>

American Sexual Health Association
PO Box 13827
Research Triangle Park, NC 27709
(919) 361-8400
<http://www.ashastd.org>

American Society for Colposcopy and Cervical Pathology
1530 Tilco Drive, Suite C
Frederick, MD 21704
(301) 733-3640
1-800-787-7227
<http://www.asccp.org>

Center for Young Women's Health
333 Longwood Avenue, 5th floor
Boston, MA 02115
(617) 355-2994
<http://www.youngwomenshealth.org>

Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, GA 30333
1-800-CDC-INFO (1-800-232-4636)
<http://www.cdc.gov>

Planned Parenthood Federation of America
434 West 33rd Street
New York, NY 10001
(212) 541-7800
1-800-230-7526
<http://www.plannedparenthood.org>

Society for Adolescent Health and Medicine
111 Deer Lake Road, Suite 100
Deerfield, IL 60015
(847) 753-5226
<http://www.adolescenthealth.org>

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
1-888-INFO-FDA (1-888-463-6332)
<http://www.fda.gov>

References

- Centers for Disease Control and Prevention. Basic information about HPV-associated cancers. Available at: http://www.cdc.gov/cancer/hpv/basic_info. Retrieved November 4, 2013.
- FDA licensure of bivalent human papillomavirus vaccine (HPV2, Cervarix) for use in females and updated HPV vaccination recommendations from the Advisory Committee on Immunization Practices (ACIP). Centers for Disease Control and Prevention (CDC) [published erratum appears in *MMWR Morb Mortal Wkly Rep* 2010;59:1184]. *MMWR Morb Mortal Wkly Rep* 2010;59:626–9.
- U.S. Cancer Statistics Working Group. United States cancer statistics: 1999–2010 incidence and mortality web-based report. Atlanta (GA); Bethesda (MD): Centers for Disease Control and Prevention; National Cancer Institute; 2013. Available at: <http://apps.nccd.cdc.gov/uscs>. Retrieved November 4, 2013.
- Centers for Disease Control and Prevention. Cervical cancer screening with the HPV test and the pap test in women ages 30 and older. Available at: http://www.cdc.gov/cancer/hpv/basic_info/screening/cervical_cancer.htm. Retrieved November 4, 2013.
- Insinga RP, Glass AG, Rush BB. The health care costs of cervical human papillomavirus-related disease. *Am J Obstet Gynecol* 2004;191:114–20.
- Cervical cancer. NIH Consens Statement 1996;14:1–38; quiz 4p.
- Centers for Disease Control and Prevention. Genital HPV infection - fact sheet. Available at: <http://www.cdc.gov/std/HPV/STDFact-HPV.htm>. Retrieved November 4, 2013.
- 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.
- GlaxoSmithKline Biologicals. Cervarix: highlights of prescribing information. Research Triangle Park (NC): GSK; 2012. Available at: http://us.gsk.com/products/assets/us_cervarix.pdf. Retrieved November 4, 2013.
- 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.
- Palefsky JM, Giuliano AR, Goldstone S, Moreira ED Jr, Aranda C, Jessen H, et al. HPV vaccine against anal HPV infection and anal intraepithelial neoplasia. *N Engl J Med* 2011;365:1576–85.
- 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.
- 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.
- De Vincenzo R, Ricci C, Conte C, Scambia G. HPV vaccine cross-protection: Highlights on additional clinical benefit. *Gynecol Oncol* 2013;130:642–51.
- Leval A, Herweijer E, Ploner A, Eloranta S, Fridman Simard J, Dillner J, et al. Quadrivalent human papillomavirus vaccine effectiveness: a Swedish national cohort study. *J Natl Cancer Inst* 2013;105:469–74.
- Dobson SR, McNeil S, Dionne M, Dawar M, Ogilvie G, Krajden M, et al. Immunogenicity of 2 doses of HPV vaccine in younger adolescents vs 3 doses in young women: a randomized clinical trial. *JAMA* 2013;309:1793–802.
- Schwarz TF, Huang LM, Medina DM, Valencia A, Lin TY, Behre U, et al. Four-year follow-up of the immunogenicity and safety of the HPV-16/18 AS04-adjuvanted vaccine when administered to adolescent girls aged 10–14 years. *J Adolesc Health* 2012;50:187–94.
- Markowitz LE, Hariri S, Lin C, Dunne EF, Steinau M, McQuillan G, et al. Reduction in human papillomavirus (HPV) prevalence among young women following HPV vaccine introduction in the United States, National Health and Nutrition Examination Surveys, 2003–2010. *J Infect Dis* 2013;208:385–93.
- Human papillomavirus vaccination coverage among adolescent girls, 2007–2012, and postlicensure vaccine safety monitoring, 2006–2013 - United States. Centers for Disease Control and Prevention (CDC). *MMWR Morb Mortal Wkly Rep* 2013;62:591–5.
- Centers for Disease Control and Prevention. Vaccine safety: human papillomavirus (HPV) vaccine. Available at: <http://www.cdc.gov/vaccinesafety/vaccines/HPV/index.html>. Retrieved November 4, 2013.
- Gee J, Naleway A, Shui I, Baggs J, Yin R, Li R, et al. Monitoring the safety of quadrivalent human papillomavirus vaccine: findings from the Vaccine Safety Datalink. *Vaccine* 2011;29:8279–84.
- Guttmacher Institute. An overview of minors' consent law. State Policies in Brief. New York (NY): GI; 2013. Available at: http://www.guttmacher.org/statecenter/spibs/spib_OMCL.pdf. Retrieved November 4, 2013.
- Cervical cancer in adolescents: screening, evaluation, and management. Committee Opinion No. 463. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2010;116:469–72.
- Management of abnormal cervical cytology and histology. Practice Bulletin No. 140. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2013;122:1338–67.

25. Garland SM, Ault KA, Gall SA, Paavonen J, Sings HL, Ciperro KL, et al. Pregnancy and infant outcomes in the clinical trials of a human papillomavirus type 6/11/16/18 vaccine: a combined analysis of five randomized controlled trials. Quadrivalent Human Papillomavirus Vaccine Phase III Investigators. *Obstet Gynecol* 2009;114:1179–88.
26. Roteli-Martins CM, Naud P, De Borba P, Teixeira JC, De Carvalho NS, Zahaf T, et al. Sustained immunogenicity and efficacy of the HPV-16/18 AS04-adjuvanted vaccine: up to 8.4 years of follow-up. *Hum Vaccin Immunother* 2012;8:390–7.
27. Merck & Company, Inc. Gardasil: highlights of prescribing information. Whitehouse Station (NJ): Merck; 2013. Available at: http://www.merck.com/product/usa/pi_circulars/g/gardasil/gardasil_pi.pdf. Retrieved November 4, 2013.
28. Atkinson WL, Pickering LK, Schwartz B, Weniger BG, Iskander JK, Watson JC. General recommendations on immunization. Recommendations of the Advisory Committee on Immunization Practices (ACIP) and the American Academy of Family Physicians (AAFP). Centers for Disease Control and Prevention. *MMWR Recomm Rep* 2002;51:1–35.
29. Levin MJ, Moscicki AB, Song LY, Fenton T, Meyer WA 3rd, Read JS, et al. Safety and immunogenicity of a quadrivalent human papillomavirus (types 6, 11, 16, and 18) vaccine in HIV-infected children 7 to 12 years old. IMPAACT P1047 Protocol Team. *J Acquir Immune Defic Syndr* 2010; 55:197–204.
30. Zimet GD, Mays RM, Winston Y, Kee R, Dickes J, Su L. Acceptability of human papillomavirus immunization. *J Womens Health Gend Based Med* 2000;9:47–50.
31. Darden PM, Thompson DM, Roberts JR, Hale JJ, Pope C, Naifeh M, et al. Reasons for not vaccinating adolescents: National Immunization Survey of Teens, 2008–2010. *Pediatrics* 2013;131:645–51.
32. Bednarczyk RA, Davis R, Ault K, Orenstein W, Omer SB. Sexual activity-related outcomes after human papillomavirus vaccination of 11- to 12-year-olds. *Pediatrics* 2012; 130:798–805.

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The HPV VACCINE is a LIFESAVER



THE HPV VACCINE COULD PREVENT ABOUT 21,000 HPV-RELATED CANCERS EACH YEAR

CANCER PREVENTION

HPV vaccine protects against HPV types that cause

70%

of cervical cancers



EFFECTIVE AGAINST OTHER CANCERS

The HPV vaccine can also protect against cancers of the vagina, vulva, penis and anus



The HPV VACCINE is...

PROTECTIVE

Make sure everyone in your family who needs the HPV vaccine gets it!

11 or 12 years (Target Age)

Most effective for girls and boys before sexual activity begins



Under 27 years (Catch-up Age)

Provides protection for women and men even if sexual activity has begun



SAFE

Millions of people have received the HPV vaccine without serious side effects



GET THE FACTS

- HPV IS THE MOST COMMON SEXUALLY TRANSMITTED INFECTION, AND 79 MILLION AMERICANS ARE CURRENTLY INFECTED
- HPV VACCINATION IS NOT LINKED TO MORE OR EARLIER SEXUAL ACTIVITY
- THE HPV VACCINE IS GIVEN IN A SERIES OF 3 SHOTS OVER 6 MONTHS, WHICH ARE ALL NEEDED FOR BEST PROTECTION
- IT'S STILL IMPORTANT TO GET A PAPER TEST TO SCREEN FOR CERVICAL CANCER

MORE INFORMATION?

ASK YOUR OB-GYN, VISIT WWW.IMMUNIZATIONFORWOMEN.ORG/HPV OR SCAN THIS QR CODE:



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

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Immunization for Women Web Site

With sections for health care providers and patients, the American College of Obstetricians and Gynecologists' immunization web site, Immunization for Women, is an excellent resource with up-to-date information about immunizations and vaccine-preventable diseases. On the site you can find information on the following:

- ◆ Tool Kit resources, including physician scripts, coding information, and frequently asked questions for patients
- ◆ Updated immunization recommendations for adult and adolescent females
- ◆ Specific immunizations for pregnant women and breastfeeding women
- ◆ Details on proper immunization coding and reimbursement
- ◆ Information on how to set up and expand an office-based immunization program

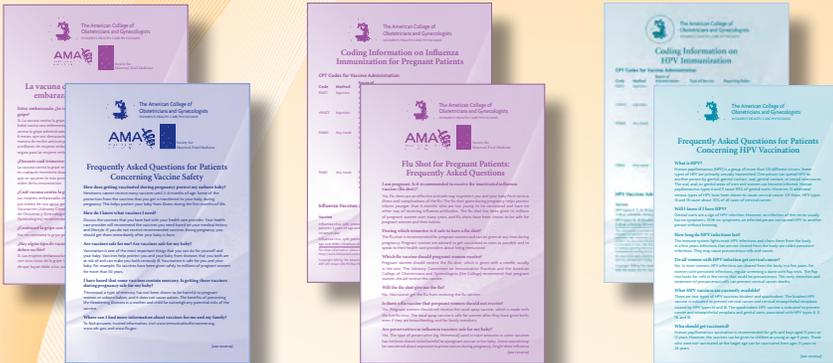
www.immunizationforwomen.org

The screenshot displays the homepage of the Immunization for Women website. At the top, there is a navigation bar with the site's logo and title, "Immunization for Women: Immunization Information for Ob-Gyns and Their Patients". Below this is a search bar and a main menu with categories like "ABOUT US", "IMMUNIZATION FACTS", "PRACTICE MANAGEMENT", "VACCINE SAFETY", "NEWS & MEDIA", "RESOURCES", and "FAQS". The main content area features a "What's New on Immunizing Women" section with a sub-section for "Latest Immunization News & Updates" and a "Toolkits" section with links for "HPV", "FLU", "TDAP", and "BOOKSTORE". There are three main content boxes: "Seasonal Influenza (Flu)", "Pregnancy", and "Adults & Adolescents", each with "OB-GYNS" and "PATIENTS" tabs and relevant text. At the bottom, there are sections for "E-Mail Updates & Alert Sign-up" and "Help Spread the Word". The footer contains a navigation menu, a disclaimer, and copyright information for 2012.

Immunization Resources

The American College of Obstetricians and Gynecologists (the College) has the following immunization resources for patients and health care providers. You can access all of this and more on the College's Immunization for Women web site:

www.immunizationforwomen.org



FAQ Tear Pads for Patients (English and Spanish)

- ◆ Flu Shot for Pregnant Patients: Frequently Asked Questions
- ◆ Frequently Asked Questions for Patients Concerning Tdap Vaccination
- ◆ Frequently Asked Questions for Patients Concerning HPV Vaccination
- ◆ Frequently Asked Questions for Patients Concerning Vaccine Safety

Laminated Physician Scripts and Coding Information

- ◆ Physician Script on Influenza Immunization During Pregnancy and Coding Information for Pregnant Patients
- ◆ Physician Script Concerning Tdap Vaccination and Coding Information on Tdap Immunization for Patients
- ◆ Physician Script Concerning HPV Vaccination and Coding Information on HPV Immunization

Committee Opinions

Human Papillomavirus Vaccination (Committee Opinion No. 588) March 2014

Update on Immunization and Pregnancy: Tetanus, Diphtheria, and Pertussis Vaccination (Committee Opinion No. 566) June 2013

Integrating Immunizations Into Practice (Committee Opinion No. 558) April 2013

Influenza Vaccination During Pregnancy (Committee Opinion No. 468) October 2010

Vaccine Information Statements

Visit www.immunize.org/vis for a comprehensive list of vaccine information statements in multiple languages.

Additional Resources

Immunizations and Routine Obstetric—Gynecologic Care: A Guide for Providers and Patients

Immunization Coding for Obstetrician—Gynecologists 2013 and corresponding quick-glance laminated card
Adult Immunization Record Card



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

Questions? Contact Us: immunization@acog.org

Give a strong recommendation for HPV vaccine to increase uptake!

Dear Colleague:

The American Academy of Family Physicians (AAFP), American Academy of Pediatrics (AAP), American College of Obstetricians and Gynecologists (ACOG), American College of Physicians (ACP), the Centers for Disease Control and Prevention (CDC), and the Immunization Action Coalition (IAC) are asking you to urge your patients to get vaccinated against human papilloma-virus (HPV).

HPV vaccine is cancer prevention. However, HPV vaccine is underutilized in our country, despite the overwhelming evidence of its safety and effectiveness. While vaccination rates continue to improve for the other adolescent vaccines, HPV vaccination rates have not. Missed opportunities data suggest that providers are not giving strong recommendations for HPV vaccine when patients are 11 or 12 years old. The healthcare provider recommendation is the single best predictor of vaccination. Recent studies show that a patient who receives a provider recommendation is 4–5 times more likely to receive the HPV vaccine.^{1,2}

What you say, and how you say it, matters. A half-hearted recommendation to a patient may not only result in the patient leaving your practice unvaccinated, but may lead the patient to believe that HPV vaccine is not as important as the other adolescent vaccines. The undersigned organizations hope that this letter, which provides key facts about HPV vaccine safety and effectiveness, will lead you to recommend HPV vaccination – firmly and strongly – to your patients. Your recommendation will reflect your commitment to prevent HPV-associated cancers and disease in the United States.

HPV-associated disease³

- Approximately 79 million persons in the United States are infected with HPV, and approximately 14 million people in the United States will become newly infected with HPV each year.
 - Each year, an estimated 26,000 cancers are attributable to HPV; about 17,000 in women and 9,000 in men.
 - Cervical cancer is the most common HPV-associated cancer among women, and oropharyngeal cancers are the most common among men.
- *Despite these statistics, the use of HPV vaccination to prevent HPV infection is limited and immunization rates remain low.*

Prevention of HPV-associated disease by vaccination

- Two vaccines (bivalent/HPV2 and quadrivalent/HPV4) are available to protect against HPV 16 and 18, the types that cause most cervical and other anogenital cancers, as well as some oropharyngeal cancers.

- The Advisory Committee on Immunization Practices (ACIP) recommends routine vaccination of girls age 11 or 12 years with the 3-dose series of either HPV vaccine and routine vaccination of boys age 11 or 12 years with the 3-dose series of HPV4.
 - Vaccination is recommended for females through age 26 years and for males through age 21 years who were not vaccinated when they were younger.
- ▶ *In 2012, only 33% of teenage girls ages 13–17 years had received 3 doses of HPV vaccine.⁴ This was the first year in which HPV vaccination coverage rates did not increase from the prior year.*

Safety of HPV vaccine

- More than 175 million doses of HPV vaccine have been distributed worldwide and 57 million doses have been distributed in the United States.
 - More than 7 years of post-licensure vaccine safety monitoring in the United States provide continued evidence of the safety of HPV4. Data on safety are also available from post-licensure monitoring in other countries for both vaccines and provide continued evidence of the safety of HPV2 and HPV4.
 - Syncope can occur among adolescents who receive any vaccines, including HPV vaccine. ACIP recommends that clinicians consider observing patients for 15 minutes after vaccination.
- ▶ *Regardless of a safety profile that is similar to the other adolescent vaccines, parents cite safety concerns as one of the top five reasons they do not intend to vaccinate daughters against HPV.*

Efficacy of HPV vaccines

- Among women who have not been previously infected with a targeted HPV type, both vaccines have over 95% efficacy in preventing cervical precancers caused by HPV 16 or 18.
 - HPV4 also demonstrated nearly 100% vaccine efficacy in preventing vulvar and vaginal precancers, and genital warts in women caused by the vaccine types.
 - In males, HPV4 demonstrated 90% vaccine efficacy in preventing genital warts and 75% vaccine efficacy in preventing anal precancers caused by vaccine types.
- ▶ *Since the vaccine does not protect against all HPV types, it does not replace other prevention strategies, such as regular cervical cancer screening.*

What you say matters; how you say it matters even more.

Based on research conducted with parents and physicians, CDC suggests recommending the HPV vaccine series the same way you recommend the other adolescent vaccines.

Parents may be interested in vaccinating, yet still have questions. Taking the time to listen to parents' questions helps you save time and give an effective response. CDC has created an excellent tip

sheet to assist you in answering questions parents may have about HPV vaccines. This tip sheet and many other tools on the HPV vaccine are available at www.cdc.gov/vaccines/youarethekey.

As a healthcare provider, we urge you to improve the strength and consistency of your recommendation for HPV vaccination to your patients. Your recommendation is the number one reason why someone will get the HPV vaccine and be protected from HPV-associated cancers and disease.

Signed:



REID B. BLACKWELDER, MD

President

American Academy of Family Physicians



THOMAS K. MCINERNEY, MD

President

American Academy of Pediatrics



JEANNE CONRY, MD

President

American College of Obstetricians
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MOLLY COOKE, MD

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THOMAS FRIEDEN, MD

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DEBORAH WEXLER, MD

Executive Director

Immunization Action Coalition

REFERENCES

1. Health care provider recommendation, human papillomavirus vaccination, and race/ethnicity in the U.S. National Immunization Survey. *American Journal of Public Health*. 2013. 103(1):164–169.
2. Factors associated with human papillomavirus vaccine-series initiation and healthcare provider recommendation in U.S. adolescent females: 2007 National Survey of Children's Health. *Vaccine*. 2012. 30(20):3112–3118.
3. Human papillomavirus-associated cancers – United States, 2004–2008. *MMWR*. 2012. 61(15): 258–261.
4. Human papillomavirus vaccination coverage among adolescent girls, 2007–2012, and Postlicensure Vaccine Safety Monitoring, 2006–2013 – United States. *MMWR*. 2013. 62(29): 591–595.

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.

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 HPV vaccine [HPV 4: Gardasil, Merck] or latex for bivalent HPV vaccine [HPV2: Cervarix, GSK]). For information on vaccine components, refer to the manufacturers’ package insert (www.immunize.org/packageinserts) or go to 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.
4. Provide 1) either HPV2 or HPV4 to women or 2) HPV4 to men. Provide either vaccine in a 3-dose schedule at 0, 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 5/8" 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 27th 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 22nd 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. 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 to HPV vaccine to the federal Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov or by calling (800) 822-7967. VAERS report forms are available at 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

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

Hojas de Información Sobre Vacunas están disponibles en Español y en muchos otros idiomas. Visite 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, 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.

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
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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[®] (Human Papillomavirus)

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

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

5/3/2011

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Tips and Time-savers for Talking with Parents about HPV Vaccine

Recommend the HPV vaccine series the same way you recommend the other adolescent vaccines. For example, you can say “Your child needs these shots today,” and name all of the vaccines recommended for the child’s age.

Parents may be interested in vaccinating, yet still have questions. Taking the time to listen to parents’ questions helps you save time and give an effective response. CDC research shows these straightforward messages work with parents when discussing HPV vaccine—and are easy for you or your staff to deliver.



- CDC RESEARCH SHOWS:** The “HPV vaccine is cancer prevention” message resonates strongly with parents. In addition, studies show that a strong recommendation from you is the single best predictor of vaccination.
- TRY SAYING:** HPV vaccine is very important because it prevents cancer. I want your child to be protected from cancer. That’s why I’m recommending that your daughter/son receive the first dose of HPV vaccine today.
- CDC RESEARCH SHOWS:** Disease prevalence is not understood, and parents are unclear about what the vaccine actually protects against.
- TRY SAYING:** HPV can cause cancers of the cervix, vagina, and vulva in women, cancer of the penis in men, and cancers of the anus and the mouth or throat in both women and men. There are about 26,000 of these cancers each year—and most could be prevented with HPV vaccine. There are also many more precancerous conditions requiring treatment that can have lasting effects.
- CDC RESEARCH SHOWS:** Parents want a concrete reason to understand the recommendation that 11–12 year olds receive HPV vaccine.
- TRY SAYING:** We’re vaccinating today so your child will have the best protection possible long before the start of any kind of sexual activity. We vaccinate people well before they are exposed to an infection, as is the case with measles and the other recommended childhood vaccines. Similarly, we want to vaccinate children well before they get exposed to HPV.
- CDC RESEARCH SHOWS:** Parents may be concerned that vaccinating may be perceived by the child as permission to have sex.
- TRY SAYING:** Research has shown that getting the HPV vaccine does not make kids more likely to be sexually active or start having sex at a younger age.
- CDC RESEARCH SHOWS:** Parents might believe their child won’t be exposed to HPV because they aren’t sexually active or may not be for a long time.
- TRY SAYING:** HPV is so common that almost everyone will be infected at some point. It is estimated that 79 million Americans are currently infected with 14 million new HPV infections each year. Most people infected will never know. So even if your son/daughter waits until marriage to have sex, or only has one partner in the future, he/she could still be exposed if their partner has been exposed.
- CDC RESEARCH SHOWS:** Emphasizing your personal belief in the importance of HPV vaccine helps parents feel secure in their decision.
- TRY SAYING:** I strongly believe in the importance of this cancer-preventing vaccine, and I have given HPV vaccine to my son/daughter/grandchild/niece/nephew/friend’s children. Experts (like the American Academy of Pediatrics, cancer doctors, and the CDC) also agree that this vaccine is very important for your child.
- CDC RESEARCH SHOWS:** Understanding that the side effects are minor and emphasizing the extensive research that vaccines must undergo can help parents feel reassured.
- TRY SAYING:** HPV vaccine has been carefully studied by medical and scientific experts. HPV vaccine has been shown to be very effective and very safe. Like other shots, most side effects are mild, primarily pain or redness in the arm. This should go away quickly, and HPV vaccine has not been associated with any long-term side effects. Since 2006, about 57 million doses of HPV vaccine have been distributed in the U.S., and in the years of HPV vaccine safety studies and monitoring, no serious safety concerns have been identified.
- CDC RESEARCH SHOWS:** Parents want to know that HPV vaccine is effective.
- TRY SAYING:** In clinical trials of boys and girls, the vaccine was shown to be extremely effective. In addition, studies in the U.S. and other countries that have introduced HPV vaccine have shown a significant reduction in infections caused by the HPV types targeted by the vaccine.
- CDC RESEARCH SHOWS:** Many parents do not know that the full vaccine series requires 3 shots. Your reminder will help them to complete the series.
- TRY SAYING:** I want to make sure that your son/daughter receives all 3 shots of HPV vaccine to give them the best possible protection from cancer caused by HPV. Please make sure to make appointments on the way out, and put those appointments on your calendar before you leave the office today!



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www.cdc.gov/vaccines/teens | PreteenVaccines@cdc.gov