



Complete Summary

GUIDELINE TITLE

Quadrivalent human papillomavirus vaccine: recommendations of the Advisory Committee on Immunization Practices (ACIP).

BIBLIOGRAPHIC SOURCE(S)

Markowitz LE, Dunne EF, Saraiya M, Lawson HW, Chesson H, Unger ER, Centers for Disease Control and Prevention (CDC). Quadrivalent human papillomavirus vaccine: recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR Recomm Rep* 2007 Mar 23;56(RR-2):1-24. [125 references]
[PubMed](#)

GUIDELINE STATUS

This is the current release of the guideline.

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SCOPE

DISEASE/CONDITION(S)

- Human papillomavirus (HPV) infection
- Sequelae to HPV infection, such as cervical cancer precursor lesions, vaginal and vulvar cancer precursor lesions, and genital warts

GUIDELINE CATEGORY

Prevention

CLINICAL SPECIALTY

Family Practice
Infectious Diseases
Obstetrics and Gynecology
Pediatrics
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Health Care Providers
Nurses
Physician Assistants
Physicians
Public Health Departments

GUIDELINE OBJECTIVE(S)

To present recommendations on the use of quadrivalent human papillomavirus (HPV) vaccine

TARGET POPULATION

Females aged 9 to 26 years in the United States

INTERVENTIONS AND PRACTICES CONSIDERED

Quadrivalent human papillomavirus (HPV) vaccine

MAJOR OUTCOMES CONSIDERED

- Efficacy of vaccine in preventing persistent human papillomavirus (HPV) infection, cervical cancer precursor lesions, vaginal and vulvar cancer precursor lesions, and genital warts caused by HPV
- Immunogenicity
- Safety and adverse effects
- Cost effectiveness

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases
Searches of Unpublished Data

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The Advisory Committee on Immunization Practices (ACIP) human papillomavirus (HPV) vaccine workgroup first met in February 2004 to begin reviewing data related to the quadrivalent HPV vaccine. The workgroup held monthly teleconferences and meetings three times a year to review published and unpublished data from the HPV vaccine clinical trials, including data on safety, immunogenicity, and efficacy. Data on epidemiology and natural history of HPV, vaccine acceptability, and sexual behavior in the United States also were reviewed. Several economic and cost effectiveness analyses were considered. Presentations on these topics were made to ACIP during meetings in June 2005, October 2005, and February 2006. Recommendation options were developed and discussed by the ACIP HPV vaccine workgroup. When evidence was lacking, the recommendations incorporated expert opinion of the workgroup members. Options being considered by the workgroup were presented to ACIP in February 2006. The final recommendations were presented to ACIP at the June 2006 ACIP meeting. After discussions, minor modifications were made and the recommendations were approved at the June 2006 meeting. Modifications were made to the ACIP statement during the subsequent review process at CDC to update and clarify wording in the document.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

Cost Effectiveness of HPV Vaccine

Since 2003, four studies have estimated the potential cost effectiveness of human papillomavirus (HPV) vaccination in the context of cervical cancer screening practices in the United States. Two of these studies applied Markov models to estimate the cost per quality-adjusted life year (QALY), focusing on the costs and impact of HPV vaccination for a given cohort, without considering the effect of vaccination on HPV transmission in the population (herd immunity). The other studies applied dynamic transmission models to incorporate the benefits of herd immunity in estimating the cost effectiveness of HPV vaccination.

The two studies based on Markov models of the natural history of HPV infection examined the cost effectiveness of vaccinating females aged 12 years. One study assumed 100% vaccine coverage, 90% vaccine efficacy against HPV 16/18, lifetime duration of protection, and a cost of \$377 per vaccine series. Under these assumptions, an estimated 58% reduction was achieved in the lifetime risk for cervical cancer for the vaccinated cohort at a cost of \$24,300 (2002 dollars) per QALY compared with no vaccination. A second study assumed 70% vaccine coverage, 75% efficacy against all high-risk HPV types, 10 years duration of protection plus 10 additional years of protection with a booster, and a cost of \$300 per vaccine series plus \$100 per booster. Under these assumptions, an estimated 20% reduction in cervical cancer incidence was achieved in the vaccinated cohort at a cost of \$22,800 per QALY (2001 dollars) compared with no vaccination.

The two cost effectiveness analyses based on dynamic transmission models examined the cost effectiveness of vaccinating females. One study assumed vaccination at age 12 years with 70% vaccine coverage. The vaccine cost \$300 per series plus \$100 per booster and targeted HPV 16/18 with 90% efficacy and 10-year duration of protection plus 10 additional years with a booster. Under these assumptions, the lifetime risk for cervical cancer among vaccinated females would be reduced by 62% at a cost per QALY of \$14,600 (2001 dollars) compared with no vaccination. A second study assumed vaccination at or before age 12 years with 70% vaccine coverage. The vaccine cost \$360 per series and targeted HPV types 6, 11, 16, and 18, with 90% efficacy against infection and 100% efficacy against HPV-related diseases attributable to these HPV types, with lifelong duration of protection. Under these assumptions, over the long term, a reduction of approximately 75% was achieved in the cervical cancer incidence rate attributable to HPV 16 and 18 at a cost of \$3,000 per QALY in 2005 dollars compared with no vaccination. This model also suggested that a catch-up program for females aged 12 to 24 years would cost \$4,700 per QALY compared with vaccination of females aged 12 years only.

The cost per QALY gained by routine vaccination of females at age 12 years in the published studies ranged from \$3,000 to \$24,300. The results summarized are calculated using base-case scenarios, which vary across studies. In the sensitivity analyses, when base-case assumptions were modified, the estimated cost effectiveness ratios changed substantially. For example, factors such as duration of vaccine-induced protection, duration of natural immunity, frequency of cervical cancer screening, vaccine coverage, and vaccine cost impacted the estimated cost effectiveness of HPV vaccination.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

After discussion, minor modifications were made and the recommendations were approved at the June 2006 Advisory Committee on Immunization Practices (ACIP) meeting. Modifications were made to the ACIP statement during the subsequent review process at the Centers for Disease Prevention and Control (CDC) to update and clarify wording in the document.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Recommendations for Use of Human Papillomavirus (HPV) Vaccine

Recommendations for Routine Use and Catch-Up

Routine Vaccination of Females Aged 11 to 12 Years

The Advisory Committee on Immunization Practices (ACIP) recommends routine vaccination of females aged 11--12 years with 3 doses of quadrivalent HPV vaccine. The vaccination series can be started as young as age 9 years.

Catch-Up Vaccination of Females Aged 13 to 26 Years

Vaccination also is recommended for females aged 13 to 26 years who have not been previously vaccinated or who have not completed the full series. Ideally, vaccine should be administered before potential exposure to HPV through sexual contact; however, females who might have already been exposed to HPV should be vaccinated. Sexually active females who have not been infected with any of the HPV vaccine types would receive full benefit from vaccination. Vaccination would provide less benefit to females if they have already been infected with one or more of the four vaccine HPV types. However, it is not possible for a clinician to assess the extent to which sexually active persons would benefit from vaccination, and the risk for HPV infection might continue as long as persons are sexually active. Pap testing and screening for HPV DNA or HPV antibody are not needed before vaccination at any age.

Dosage and Administration

The vaccine should be shaken well before administration. The dose of quadrivalent HPV vaccine is 0.5 mL, administered intramuscularly (IM), preferably in the deltoid muscle.

Recommended Schedule

Quadrivalent HPV vaccine is administered in a 3-dose schedule. The second and third doses should be administered 2 and 6 months after the first dose.

Minimum Dosing Intervals and Management of Persons Who Were Incorrectly Vaccinated

The minimum interval between the first and second doses of vaccine is 4 weeks. The minimum recommended interval between the second and third doses of vaccine is 12 weeks. Inadequate doses of quadrivalent HPV vaccine or vaccine doses received after a shorter-than-recommended dosing interval should be readministered.

Interrupted Vaccine Schedules

If the quadrivalent HPV vaccine schedule is interrupted, the vaccine series does not need to be restarted. If the series is interrupted after the first dose, the second dose should be administered as soon as possible, and the second and third doses should be separated by an interval of at least 12 weeks. If only the third dose is delayed, it should be administered as soon as possible.

Simultaneous Administration with Other Vaccines

Although no data exist on administration of quadrivalent HPV vaccine with vaccines other than hepatitis B vaccine, quadrivalent HPV vaccine is not a live vaccine and has no components that adversely impact safety or efficacy of other vaccinations. Quadrivalent HPV vaccine can be administered at the same visit as other age appropriate vaccines, such as the tetanus, diphtheria, and pertussis (Tdap) and quadrivalent meningococcal conjugate (MCV4) vaccines. Administering all indicated vaccines together at a single visit increases the likelihood that adolescents and young adults will receive each of the vaccines on schedule. Each vaccine should be administered using a separate syringe at a different anatomic site.

Cervical Cancer Screening Among Vaccinated Females

Cervical cancer screening recommendations have not changed for females who receive HPV vaccine (refer to Table 2 in the original guideline document). HPV types in the vaccine are responsible for approximately 70% of cervical cancers; females who are vaccinated could subsequently be infected with a carcinogenic HPV type for which the quadrivalent vaccine does not provide protection. Furthermore, those who were sexually active before vaccination could have been infected with a vaccine type HPV before vaccination. Health-care providers administering quadrivalent HPV vaccine should educate women about the importance of cervical cancer screening.

Groups for Which Vaccine is Not Licensed

Vaccination of Females Aged <9 Years and >26 Years

Quadrivalent HPV vaccine is not licensed for use among females aged <9 years or those aged >26 years. Studies are ongoing among females aged >26 years. No studies are under way among children aged <9 years.

Vaccination of Males

Quadrivalent HPV vaccine is not licensed for use among males. Although data on immunogenicity and safety are available for males aged 9 to 15 years, no data exist on efficacy in males at any age. Efficacy studies in males are under way.

Special Situations Among Females Aged 9 to 26 Years

Equivocal or Abnormal Pap Test or Known HPV Infection

Females who have an equivocal or abnormal Pap test could be infected with any of approximately 40 high-risk or low-risk genital HPV types. Such females are unlikely to be infected with all four HPV vaccine types, and they might not be infected with any HPV vaccine type. Vaccination would provide protection against infection with HPV vaccine types not already acquired. With increasing severity of Pap test findings, the likelihood of infection with HPV 16 or 18 increases and the benefit of vaccination would decrease. Women should be advised that results from clinical trials do not indicate the vaccine will have any therapeutic effect on existing HPV infection or cervical lesions.

Females who have a positive HC2 High-Risk test conducted in conjunction with a Pap test could have infection with any of 13 high-risk types. This assay does not identify specific HPV types, and testing for specific HPV types is not conducted routinely in clinical practice. Women with a positive HC2 High-Risk test might not have been infected with any of the four HPV vaccine types. Vaccination would provide protection against infection with HPV vaccine types not already acquired. However, women should be advised that results from clinical trials do not indicate the vaccine will have any therapeutic effect on existing HPV infection or cervical lesions.

Genital Warts

A history of genital warts or clinically evident genital warts indicates infection with HPV, most often type 6 or 11. However, these females might not have infection with both HPV 6 and 11 or infection with HPV 16 or 18. Vaccination would provide protection against infection with HPV vaccine types not already acquired. However, females should be advised that results from clinical trials do not indicate the vaccine will have any therapeutic effect on existing HPV infection or genital warts.

Lactating Women

Lactating women can receive HPV vaccine.

Immunocompromised Persons

Because quadrivalent HPV vaccine is a noninfectious vaccine, it can be administered to females who are immunosuppressed as a result of disease or medications. However, the immune response and vaccine efficacy might be less than that in persons who are immunocompetent.

Vaccination During Pregnancy

Quadrivalent HPV vaccine is not recommended for use in pregnancy. The vaccine has not been causally associated with adverse outcomes of pregnancy or adverse events in the developing fetus. However, data on vaccination during pregnancy are limited. Until additional information is available, initiation of the vaccine series should be delayed until after completion of the pregnancy. If a woman is found to be pregnant after initiating the vaccination series, the remainder of the 3-dose regimen should be delayed until after completion of the pregnancy. If a vaccine dose has been administered during pregnancy, no intervention is needed. A vaccine in pregnancy registry has been established; patients and health-care providers should report any exposure to quadrivalent HPV vaccine during pregnancy (telephone: 800-986-8999).

Precautions and Contraindications

Acute Illnesses

Quadrivalent HPV vaccine can be administered to persons with minor acute illnesses (e.g., diarrhea or mild upper respiratory tract infections with or without fever). Vaccination of persons with moderate or severe acute illnesses should be deferred until after the patient improves (Kroger et al., 2006).

Hypersensitivity or Allergy to Vaccine Components

Quadrivalent HPV vaccine is contraindicated for persons with a history of immediate hypersensitivity to yeast or to any vaccine component. Data from passive surveillance in Vaccine Adverse Event Reporting System (VAERS) indicates that recombinant yeast derived vaccines pose a minimal risk for anaphylactic reactions in persons with a history of allergic reactions to *Saccharomyces cerevisiae* (baker's yeast).

Preventing Syncope After Vaccination

Syncope (i.e., vasovagal or vasodepressor reaction) can occur after vaccination, most commonly among adolescents and young adults. Among reports to VAERS for any vaccine that were coded as syncope during 1990 to 2004, a total of 35% of these episodes were reported among persons aged 10 to 18 years. Through January 2007, the second most common report to VAERS following receipt of HPV vaccine was syncope. Vaccine providers should consider observing patients for 15 minutes after they receive HPV vaccine.

Reporting of Adverse Events After Vaccination

As with any newly licensed vaccine, surveillance for rare adverse events associated with administration of quadrivalent HPV vaccine is important for

assessing its safety in widespread use. All clinically significant adverse events should be reported to VAERS at <http://vaers.hhs.gov/>, even if causal relation to vaccination is not certain. VAERS reporting forms and information are available electronically at <http://www.vaers.hhs.gov/> or by telephone (800-822-7967). Web-based reporting is available and providers are encouraged to report electronically at <https://secure.vaers.org/VaersDataEntryintro.htm> to promote better timeliness and quality of safety data.

Safety surveillance for adolescent quadrivalent HPV vaccine, Tdap, MCV4, and other vaccines is being conducted on an ongoing basis in cooperation with the Food and Drug Administration (FDA). A vaccine in pregnancy registry has been established by Merck and Co., Inc.; patients and health-care providers should report any exposure to quadrivalent HPV vaccine during pregnancy (telephone: 800-986-8999).

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

REFERENCES SUPPORTING THE RECOMMENDATIONS

[References open in a new window](#)

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendations is not specifically stated.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Clinical trials indicate that the vaccine has high efficacy in preventing persistent human papillomavirus (HPV) infection, cervical cancer precursor lesions, vaginal and vulvar cancer precursor lesions, and genital warts caused by HPV types 6, 11, 16, or 18 among females who have not already been infected with the respective HPV type.

POTENTIAL HARMS

Adverse Events

Adverse events of human papillomavirus (HPV) vaccine

- Injection site adverse events, such as pain, swelling, or erythema
- Mild to moderate systemic adverse events (see Table 9 in the original guideline document)

- Serious adverse events, including bronchospasm, gastroenteritis, headache/hypertension, vaginal hemorrhage, and injection site pain/movement impairment) in less than 0.1% of persons in all safety studies

Precautions: Preventing Syncope After Vaccination

Syncope (i.e., vasovagal or vasodepressor reaction) can occur after vaccination, most commonly among adolescents and young adults). Among reports to Vaccine Adverse Event Reporting System (VAERS) for any vaccine that were coded as syncope during 1990 to 2004, a total of 35% of these episodes were reported among persons aged 10 to 18 years. Through January 2007, the second most common report to VAERS following receipt of HPV vaccine was syncope. Vaccine providers should consider observing patients for 15 minutes after they receive HPV vaccine.

CONTRAINDICATIONS

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Acute Illnesses

Quadrivalent human papillomavirus (HPV) vaccine can be administered to persons with minor acute illnesses (e.g., diarrhea or mild upper respiratory tract infections with or without fever). Vaccination of persons with moderate or severe acute illnesses should be deferred until after the patient improves.

Hypersensitivity or Allergy to Vaccine Components

Quadrivalent HPV vaccine is contraindicated for persons with a history of immediate hypersensitivity to yeast or to any vaccine component. Data from passive surveillance in Vaccine Adverse Event Reporting System (VAERS) indicates that recombinant yeast derived vaccines pose a minimal risk for anaphylactic reactions in persons with a history of allergic reactions to *Saccharomyces cerevisiae* (baker's yeast).

QUALIFYING STATEMENTS

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The quadrivalent human papillomavirus (HPV) vaccine is a new vaccine; additional data will be available in the near future from clinical trials. These data and any new information on epidemiology of HPV will be reviewed by the Advisory Committee on Immunization Practices (ACIP), and recommendations will be updated as needed.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Staff Training/Competency Material

For information about [availability](#), see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Markowitz LE, Dunne EF, Saraiya M, Lawson HW, Chesson H, Unger ER, Centers for Disease Control and Prevention (CDC). Quadrivalent human papillomavirus vaccine: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR Recomm Rep 2007 Mar 23;56(RR-2):1-24. [125 references]
[PubMed](#)

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2007 Mar 23

GUIDELINE DEVELOPER(S)

Centers for Disease Control and Prevention - Federal Government Agency [U.S.]

SOURCE(S) OF FUNDING

United States Government

GUIDELINE COMMITTEE

Advisory Committee on Immunization Practices

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Advisory Committee on Immunization Practices

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Centers for Disease Control and Prevention (CDC), our planners, and our content experts wish to disclose they have no financial interests or other relationships with the manufacturers of commercial products, suppliers of commercial services, or commercial supporters. On behalf of CDC, Dr. Elizabeth Unger is involved in a material transfer agreement with Merck Research Laboratories to implement the competitive Luminex assay for HPV 6, 11, 16, and 18 serology. Presentations will not include any discussion of the unlabeled use of a product or a product under investigational use.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available from the Centers for Disease Control and Prevention (CDC) Web site:

- [HTML Format](#)
- [Portable Document Format \(PDF\)](#)

Print copies: Available from the Centers for Disease Control and Prevention, MMWR, Atlanta, GA 30333. Additional copies can be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402-9325;(202) 783-3238.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Quadrivalent human papillomavirus vaccine. Recommendations of the Advisory Committee on Immunization Practices (ACIP). Continuing education activity. Available from the [Centers for Disease Control and Prevention \(CDC\) Web site](#).
- General information regarding human papillomavirus (HPV) infection is available from the [CDC Web site](#). See the Health Care Innovations Exchange Web site for QualityTools on [HPV and HPV Vaccine: Information for Healthcare Providers](#) and [Human Papillomavirus: HPV Information for Clinicians](#).

PATIENT RESOURCES

None available

NGC STATUS

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