

HPV Vaccine Updated ACIP Statement

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Published ACIP recommendations for HPV vaccines

❑ 2007 ACIP Statement

- Recommendation for routine vaccination of females at age 11 or 12 years with quadrivalent HPV vaccine

❑ 2010 Policy Note

- Recommendation for routine vaccination of females with bivalent or quadrivalent HPV vaccine

❑ 2010 Policy Note

- Quadrivalent HPV vaccine may be given to males 9 through 26 years

❑ 2011 Policy Note

- Recommendation for routine vaccination of males at age 11 or 12 years with quadrivalent HPV vaccine
- GRADE used for this recommendation

Updated HPV Vaccine ACIP Statement

Objectives:

- ❑ Consolidate recommendations for females and males
- ❑ Consolidate information and recommendations for bivalent and quadrivalent vaccines
- ❑ Harmonize wording that differed in policy notes/statement
- ❑ Update background information, and data regarding efficacy, safety, immunogenicity, impact monitoring, etc.

Note:

- ❑ Work on the updated statement will overlap with consideration of the 9-valent vaccine
- ❑ Updated ACIP statement will facilitate efforts to develop future policy

Updated HPV Vaccine ACIP Statement: Background Sections

- ❑ **Biology, immunology, epidemiology and natural history**
- ❑ **Clinical sequelae**
 - Cancers
 - Anogenital warts
 - Recurrent respiratory papillomatosis (RRP)
- ❑ **Prevention, treatment and cervical cancer screening**
 - Prevention of sexual transmission of HPV
 - Treatment of HPV related disease
 - Cervical cancer screening
 - Selected health care and research laboratory workers
 - Discussed at June 2013 ACIP meeting

Background Section

Selected Health Care and Research Laboratory Workers

- ❑ Health care workers performing laser or electrosurgical procedures
 - Appropriately ventilated room using standard precautions* and local exhaust ventilation (e.g., smoke evacuator)⁺
 - Use of N-95 respirator to be discussed at upcoming HICPAC meeting
 - Final wording will be consistent with CDC guidelines

- ❑ Research HPV laboratory workers working with wild type virus or “quasi virions”
 - Proper infection control; at minimum biosafety level 2 (BSL2)

HIPAC, Healthcare Infection Control Practices Advisory Committee

*Siegel JD, Rhinehart E, Jackson M, Chiarello L. 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Health Care Settings. Am J Infect Control 2007;35:S65-164

⁺<http://www.cdc.gov/niosh/docs/hazardcontrol/hc11.html>

Updated HPV Vaccine ACIP Statement: Vaccine Sections

- ❑ **HPV vaccines and evaluations**
- ❑ **HPV vaccines: quadrivalent and bivalent vaccines**
 - **Efficacy**
 - Updated data from pivotal efficacy trials
 - Duration of protection
 - Evaluation of cross protection
 - **Immunogenicity**
 - Immunobridging
 - Spacing of vaccine doses, concomitant administration
 - Persons with HIV infection
 - **Safety**
 - Data from clinical trials
 - Post-licensure evaluations

Updated HPV Vaccine ACIP Statement

- ❑ **Economic burden of HPV disease and cost-effectiveness of vaccination**
- ❑ **HPV vaccination program in the United States**
- ❑ **Summary of rationale for HPV vaccination recommendations**

Updated ACIP Statement: Recommendation sections

- ❑ Recommendations for females**
- ❑ Recommendations for males**
- ❑ Administration, intervals, concomitant administration, interchangeability**
- ❑ Special situations**
- ❑ Precautions and contraindications**

Recommendations for females

ACIP recommends routine vaccination of females aged 11 or 12 years with either HPV2 or HPV4 administered as a 3-dose series. The vaccine series can be started beginning at age 9 years.

HPV4 and HPV2 protect against HPV 16 and 18, types that cause cervical cancer and other HPV-associated cancers. HPV4 also protects against HPV 6 and 11, types that cause genital warts.

Vaccination also is recommended for females aged 13 through 26 years who have not been previously vaccinated or who have not completed the 3-dose series.

If a female reaches 27 years of age before the vaccination series is complete, the second or third doses of vaccine can be administered after age 26 years to complete the vaccination series.

Prevaccination assessments (e.g., Pap testing or screening for high-risk HPV DNA, type-specific HPV tests, or HPV antibody) to establish the appropriateness of HPV vaccination are not recommended.

Recommendations for males

ACIP recommends routine vaccination of males aged 11 or 12 years with HPV4 administered as a 3-dose series (*GRADE recommendation category: A, evidence type: 2**). The vaccination series can be started beginning at age 9 years.

Vaccination with HPV4 is recommended for males aged 13 through 21 years who have not been vaccinated previously or who have not completed the 3-dose series. Males aged 22 through 26 years may be vaccinated.

If a male reaches 27 years of age before the vaccination series is complete, the second or third doses of vaccine can be administered after age 26 years to complete the vaccination series.

*Recommendation category A: recommendation that applies to all persons in an age or risk-based group. Evidence type 2: randomized controlled trials with important limitations or exceptionally strong evidence from observational studies.

Alternative recommendation wording

ACIP recommends routine vaccination of children aged 11 or 12 years with either HPV2 (girls) or HPV4 (boys* and girls) administered as a 3-dose series. The vaccine series can be started beginning at age 9 years.

Vaccination also is recommended for girls and women aged 13 through 26 years and for boys and men aged 13 through 21 years, who have not been previously vaccinated or who have not completed the 3-dose series. Men aged 22 through 26 years may be vaccinated.

If woman or man reaches age 27 years before the vaccination series is complete, the second or third doses of vaccine can be administered after age 26 to complete the vaccination series.

**GRADE used for recommendation: Recommendation category A: recommendation that applies to all persons in an age or risk-based group. Evidence type 2: randomized controlled trials with important limitations or exceptionally strong evidence from observational studies.*

Addressing use of GRADE for male recommendation

- ❑ In *Methods* at beginning of document:

“Grading of Recommendations Assessment, Development and Evaluation (GRADE) was adopted by ACIP in 2011 and recommendations for males were considered using GRADE. Factors considered in determining the recommendation included benefits and harms, evidence type, values and preferences, and health economic analysis.”
- ❑ In *Recommendations*:
 - Grading category and evidence type noted within the recommendation statement
 - Link to GRADE evidence tables online

Updated HPV Vaccine ACIP Statement: Recommendation Sections

■ **Special situations**

- Persons with abnormal Pap, genital warts, etc.
- Immunocompromised persons
- Men who have sex with men (MSM)
- Children with history of sexual abuse or assault

Updated HPV Vaccine ACIP Statement: Recommendation Sections

❑ **Special situations**

■ **Immunocompromised persons including HIV infection**

- Harmonization of wording in male and female recommendations
- 2011 Male Policy Note: "For immunocompromised males, ACIP recommends routine vaccination with HPV4...and vaccination through age 26 years for those who have not been vaccinated previously...."
- 2010 Female Policy Note: "HPV2 and HPV4 are not live vaccines, and can be administered to females who are immunosuppressed..."
- Updated draft: "ACIP recommends routine vaccination with HPV4 or HPV2 for females and with HPV4 for males. Vaccination is recommended through age 26 for those who have not been vaccinated previously or who have not completed the 3-dose series."

Updated HPV Vaccine ACIP Statement: Recommendation Sections

- ❑ **Special situations**

- **Children with history of sexual abuse or assault**

- Recommendation to start vaccination at age 9 years
 - Vaccine will not protect against progression of infection to disease or promote clearance of infection, but will protect against vaccine types not yet acquired

Updated HPV Vaccine ACIP Statement: Recommendations

❑ **Precautions and contraindications**

- Hypersensitivity or allergy
- Acute illness
- Preventing syncope
- Pregnancy

Updated HPV Vaccine ACIP Statement: Recommendations

❑ Precautions and contraindications

■ Pregnancy

- No change in recommendation – not recommended
- Removal of mention of quadrivalent vaccine in pregnancy registry reporting; continue to report to manufacturer and VAERS
- Placement in the *Precautions and Contraindications* section, per guidance developed by ACIP in 2008*
 - In 2007 ACIP Statement, *Pregnancy* was in separate section
 - In 2010 Policy Note, included in *Precautions and Contraindications*
 - Listed as a “precaution” in ACIP General Recommendations⁺ and in the adult schedule

*<http://www.cdc.gov/vaccines/acip/committee/downloads/preg-principles-2008.pdf>

⁺MMWR Recomm Rep 2011 / 60(RR02);1-60

Pregnancy wording

HPV vaccines are not recommended for use in pregnant women. The vaccines have not been causally associated with adverse outcomes of pregnancy or adverse events in the developing fetus. However, if a woman is found to be pregnant after initiating the vaccination series, the remainder of the 3-dose series should be delayed until completion of pregnancy. Pregnancy testing is not needed before vaccination. If a vaccine dose has been administered during pregnancy, no intervention is needed.

Comments to date:

- ❑ **Include more post-licensure safety data**
- ❑ **Reorganize wording of routine recommendations**
 - In current draft worded separately for females and males
 - Alternative wording is to state recommendations for 11 or 12 year olds and then discuss different vaccines, and age range for females and males

Next steps

- ❑ Incorporate comments from Work Group and ACIP members
- ❑ Although no new recommendations, ACIP will vote on updated statement
 - Vote will occur at next meeting

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Questions

- ❑ Wording of vaccination recommendations for females and males
 - Separate or combined?
- ❑ Placement of *Pregnancy* section

Future plans

- ❑ Complete updated statement**
- ❑ Review data for 9-valent vaccine**
 - Data from clinical trials
 - Burden of disease due to additional types
 - Cost effectiveness considerations

Thank you

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