

HPV Vaccines Issues for ACIP Consideration

Advisory Committee on Immunization Practices
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Overview of Upcoming Issues for ACIP Consideration

- Bivalent HPV vaccine
- Two licensed HPV vaccines
- Considerations not included in first statement

ACIP Meeting HPV Sessions

June 2007

- Bivalent HPV vaccine Phase III data
- Upcoming considerations for ACIP recommendations

October 2007

- Over view of data from vaccine clinical trials
- Cross protection data – quadrivalent HPV vaccine
- Adjuvant – bivalent HPV vaccine
- Epidemiology HPV 6,11-related outcomes
- Discussion of potential recommendations

February 2008 (proposed)

- Review of vaccine data
- Other data
- Cost effectiveness data
- Potential vote on bivalent HPV vaccine

Quadrivalent HPV Vaccine

Routine & Catch-up Vaccination

- ACIP recommends routine vaccination of females 11-12 years of age with three doses of quadrivalent HPV vaccine
 - The vaccination series can be started as young as 9 years of age
- Vaccination is recommended for females 13-26 years of age who have not been previously vaccinated or completed the full series

Quadrivalent HPV Vaccine

Special Situations

- Equivocal or abnormal Pap test, positive HPV test, genital warts
 - Vaccination would provide protection against vaccine types not already acquired. Vaccine will not have any therapeutic effect on existing HPV infection or disease
- Immunocompromised
 - Can be administered although immune response and vaccine efficacy might be less than in persons who are immunocompetent

Quadrivalent HPV Vaccine Simultaneous Administration

- Quadrivalent HPV vaccine can be administered at the same visit as other age appropriate vaccines, such Tdap and MCV4
 - Although no data exist on administration of quadrivalent vaccine with vaccines other than hepatitis B vaccine, HPV vaccine is not a live vaccine and has no components that adversely impact safety or efficacy of other vaccinations

Quadrivalent HPV Vaccine Pregnancy

- Quadrivalent HPV vaccine is not recommended for use in pregnancy

Issues for ACIP Consideration

- Bivalent HPV vaccine
- Two licensed HPV vaccines

Bivalent HPV Vaccine Questions

- What recommendations should be made for bivalent vaccine use in 10-25 year-old females?
- If licensed for use in older females, what recommendations should be made?

Bivalent HPV Vaccine

Possible ACIP Recommendations for 10-25 year-old Females

Age at vaccination 11-12 yrs, can be given as young as 10 yrs
13-25 yrs - catch up

Special situations Same as quadrivalent HPV vaccine

Pregnancy Same as quadrivalent HPV vaccine

Bivalent HPV Vaccine

ACIP Recommendation Options for 10-25 year-old Females

Simultaneous Administration

Issues

- No data on simultaneous administration
- Studies ongoing with MCV4, Tdap, DTaP/IPV
- New adjuvant
- Not live vaccine

Recommendation options

- No simultaneous administration until further data
- Can be administered simultaneously

Bivalent HPV Vaccine

ACIP Recommendation Options for >25 year-old Females

- If indication for use in older females, what recommendations should be made?

Recommendation options

- Permissive
- Specific age groups
- No recommendation
- Other

Overview of Issues for ACIP Consideration

- Bivalent HPV vaccine
- Two licensed HPV vaccines

Two licensed HPV Vaccines

Questions

- Should a preference be stated for one vaccine?
 - Are there differences related to protection against
 - HPV 16/18
 - Other oncogenic types
 - HPV 6/11
 - Are there differences in cost effectiveness?
- Can the vaccines be used interchangeably in the vaccination series (for protection against HPV 16/18)?

Comparison of HPV Vaccines

Attribute	Quadrivalent	Bivalent
Protection against HPV 16/18 related CIN/AIS*	Similar	Similar
Protection against HPV 6/11 related genital lesions	Yes	No
Cross-protection against high risk types other than HPV 16,18	? Similar	? Similar
Duration of protection	?	?
Cost of vaccine series	\$360	?

* Quadrivalent vaccine - also demonstrated protection against VIN and VaIN

Possible ACIP Recommendation for 10-25 year-old Females

- State differences in data available for the two vaccines
 - Specifically, differences with regard to protection against HPV 6/11
 - Quadrivalent vaccine provides protection against genital warts
- Encourage providers to understand differences between the two vaccines
- For protection against HPV 6/11/16/18 related outcomes, quadrivalent vaccine is recommended
- For protection against HPV 16/18 related outcomes, quadrivalent or bivalent vaccine is recommended

Two Licensed HPV Vaccines

- ACIP HPV vaccine workgroup has discussed issues related to preferential recommendations

Two Licensed HPV Vaccines

Possible ACIP Recommendation

Interchangeability of doses

Whenever feasible, the same brand of HPV vaccine should be used for all doses of the vaccination series. If vaccination providers do not know or have available the type of HPV vaccine previously administered to a female, any vaccine should be used to continue or complete the series to provide protection against types 16/18.

Ongoing Workgroup Activities

HPV vaccine workgroup is continuing to:

- Review data and discuss issues related to recommendations for the bivalent vaccine and two licensed HPV vaccines
- Review new data on the quadrivalent vaccine
- Prepare for a possible vote on the bivalent HPV vaccine in February 2008