

Human Papillomavirus Vaccines Session

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Advisory Committee on Immunization Practices
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Current recommendations for HPV vaccination

- **Routine vaccination**
 - Age 11 or 12 years
 - Vaccination can be started at age 9 years
- **Catch-up vaccination**
 - Females through age 26 years
 - Males through age 21 years
 - Certain populations through age 26 years*
- **Males aged 22 through 26 years may be vaccinated**

*Men who have sex with men, transgender persons, and persons with certain immunocompromising conditions
MMWR 2014;63 (RR05) MMWR 2015;64:300-4 MMWR 2016; 65:2105-8

HPV vaccination policy issues for consideration today

- Harmonization of catch-up vaccination through age 26 years: Should catch-up HPV vaccination be recommended for primary prevention of HPV infection and HPV-related disease for all persons through age 26 years?
- Vaccination of adults older than age 26 years: Should catch-up HPV vaccination be recommended for primary prevention of HPV infection and HPV-related disease for all persons aged 27 through 45 years?

HPV vaccination policy issues for consideration today

- **Harmonization of catch-up vaccination through age 26 years: Should catch-up HPV vaccination be recommended for primary prevention of HPV infection and HPV-related disease for all persons through age 26 years?**
 - Work Group had discussions in 2017 and 2018 related to simplification of the vaccination schedule; background provided in next talk.
- **Vaccination of adults older than age 26 years: Should catch-up HPV vaccination be recommended for primary prevention of HPV infection and HPV-related disease for all persons aged 27 through 45 years?**
 - Manufacturer filed an application in April 2018 to expand the age indication for 9-valent HPV vaccine (9vHPV) from age 9–26 years to age 9–45 years
 - Approved by FDA in October 2018

Past ACIP HPV vaccine sessions related to the expanded age indication

June 2018

- Overview and history of application for licensure in mid-adults
- HPV epidemiology, natural history and burden of disease
- Clinical trial data in sBLA for 9-valent vaccine in adults aged 27-45 years

October 2018

- Regulatory basis for licensure
- U.S. vaccination program: vaccination coverage, impact
- HPV epidemiology and sexual behavior, post-licensure effectiveness studies
- Global HPV vaccination & vaccine supply
- GRADE: Efficacy, immunogenicity, safety
- Preliminary health economic analyses
- Policy considerations

Past ACIP HPV vaccine sessions related to the expanded age indication

February 2019

- Overview and background on natural history considerations
- Impact and cost effectiveness of mid-adult HPV vaccination; HPV ADVISE model
- Overview of health economic results from 5 models
- Patient values and acceptability
- Program and vaccine provider surveys
- Work Group considerations and policy options

ACIP HPV Vaccines Work Group – topics reviewed since February 2019

- Impact modeling and health economic modeling results
- Vaccine supply and shortage (industry presentation)
- Preliminary review of two topics
 - HPV vaccine in HIV-infected adults
 - Vaccination post treatment for anogenital disease
- 9vHPV immunogenicity and safety trial in mid-adult women
- Evidence to Recommendations documents
- Recommendation options for consideration

Work Group considerations for vaccination of adults older than age 26 years

- **At February 2019 ACIP meeting**
 - Options presented:
 - Clinical decision making, or
 - Not making a recommendation
- **After February 2019 ACIP meeting and further discussions**
 - Options being proposed today:
 - Shared clinical decision making, or
 - Do not recommend the intervention

HPV vaccine policy issues for consideration today

- **Harmonization of catch-up vaccination through age 26 years:** Should catch-up HPV vaccination be recommended for primary prevention of HPV infection and HPV-related disease for all persons through age 26 years?
 - Work Group reached consensus
- **Vaccination of adults older than age 26 years:** Should catch-up HPV vaccination be recommended for primary prevention of HPV infection and HPV-related disease for all persons aged 27 through 45 years?
 - Two options proposed (majority opinion and minority opinion)

Today's Session

- Background
Dr. Lauri Markowitz, CDC/NCIRD
- 9vHPV Immunogenicity and Safety Trial in Women Age 27–45 Years
Dr. Alain Luxembourg, Merck
- Overview of Health Economic Models for HPV Vaccination of Mid-Adults
Dr. Harrell Chesson, CDC/NCHHSTP
- Evidence to Recommendations
Dr. Elissa Meites, CDC/NCIRD
- Work Group Considerations
Dr. Lauri Markowitz, CDC/NCIRD

ACIP HPV Vaccines Work Group

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