Human Papillomavirus Vaccines Session

Peter Szilagyi, MD, MPH
ACIP HPV Vaccines Work Group Chair

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?
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

sBLA, Supplemental Biologics License Application; Grade: Grading of Recommendations, Assessment, Development and Evaluation
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

ACIP Members
Peter Szilagyi (Chair)
Jose Romero
Kevin Ault

Ex Officio Members
Jeff Roberts (FDA)
Joohee Lee (FDA)

CDC Lead
Lauri Markowitz

Liaison Representatives
Shelley Deeks (NACCI)
Linda Eckert (ACOG)
Sandra Fryhofer (ACP)
Amy Middleman (SAHM)
Chris Nyquist (AAP)
Sean O’Leary (PIDS)
Robin O’Meara (AAFP)
Patricia Whitley-Williams (NMA)
Jane Zucker (AIM)

Consultants
Joseph Bocchini
Tamera Coyne-Beasley
John Douglas
Allison Kempe
Aimee Kreimer (NCI)
Debbie Saslow (ACS)
Rodney Willoughby
Rachel Winer

CDC Contributors
Harrell Chesson
Julianne Gee
Elissa Meites
Jeanne Santoli
Mona Saraiya
John Su
Shannon Stokley
Lakshmi Panagiotakopoulos
Elizabeth Unger
Charnetta Williams