

Human Papillomavirus Vaccines Session

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Chair, ACIP HPV Vaccines Work Group

Advisory Committee on Immunization Practices
October 19, 2016

Overview

- Since 2006, HPV vaccination has been recommended as a 3-dose series
- ACIP HPV Vaccines Work Group and ACIP have reviewed data on 2-dose schedules over the past year
- A vote is scheduled for this meeting

Information on 2-Dose Schedules Presented to ACIP in 2016

■ February 2016

- Background on 2-dose schedules
- 9vHPV 2-dose immunogenicity trial data
- 2vHPV and 4vHPV 2-dose data

■ June 2016

- HPV vaccine supply update
- Duration of protection after 3-dose series 2vHPV and 4vHPV
- Impact and cost-effectiveness modeling for 2-dose schedules
- Post-licensure vaccine effectiveness studies of 2vHPV and 4vHPV
- GRADE
- Recommendation considerations

9vHPV, 9-valent HPV vaccine; 2vHPV, bivalent HPV vaccine; 4vHPV, quadrivalent HPV vaccine

ACIP HPV Vaccines Work Group Activities Since June 2016

- **Held monthly conference calls**
- **Reviewed further data from 9vHPV 2-dose trial**
 - Follow-up data through month 12
 - Intervals between doses
- **Discussed policy options**
- **Drafted recommendations**

Approval of 9-valent HPV Vaccine 2-Dose Series

- FDA approved a 2-dose series for persons age 9–14 years, October 7, 2016
- Updated 9vHPV label includes:
 - Immunogenicity data from trial
 - Updated Dosage and Administration section

----- DOSAGE AND ADMINISTRATION -----		
For intramuscular administration only. (2)		
Each dose of GARDASIL 9 is 0.5-mL		
Administer GARDASIL 9 as follows: (2.1)		
Age	Regimen	Schedule
9 through 14 years	2-dose	0, 6 to 12 months*
	3-dose	0, 2, 6 months
15 through 26 years	3-dose	0, 2, 6 months
*If the second dose is administered earlier than 5 months after the first dose, administer a third dose at least 4 months after the second dose. (14.2 and 14.5)		

Potential Future Issues for HPV Vaccines Work Group

- Revisit wording for routine recommended age groups
- Revisit upper age recommendation for males

October 2016 ACIP HPV Vaccines Session

- **Review of evidence for 2-dose schedules**
 - Dr. Lauri Markowitz, CDC
- **Proposed recommendations for 2-dose HPV vaccination**
 - Dr. Elissa Meites, CDC
- **Public comment**
- **Vote**
 - Dr. Elissa Meites, CDC
- **VFC vote**
 - Dr. Jeanne Santoli, CDC

ACIP HPV Vaccines Work Group

ACIP Members

Allison Kempe (Chair)
Cynthia Pellegrini
Jose Romero

Ex Officio Members

Carolyn Deal (NIH)
Bruce Gellin (NVPO)
Jeff Roberts (FDA)
Joohee Lee (FDA)

CDC Lead

Lauri Markowitz

Liaison Representatives

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