

Human Papillomavirus (HPV) Vaccine Session

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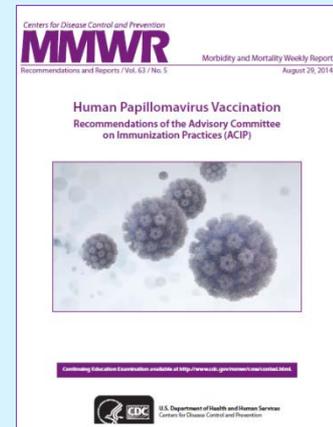
Advisory Committee on Immunization Practices
Atlanta, GA
February 26, 2015

9-Valent HPV vaccine (9vHPV)

- ❑ Licensed by FDA December 10, 2014
 - Females 9-26 yrs, males 9-15 yrs
 - Trials conducted with 3-dose schedule
- ❑ L1 VLP vaccine, similar to quadrivalent HPV vaccine
- ❑ Targets 5 additional high risk types
 - 6,11,16,18, **31,33,45,52,58**
- ❑ Males 16-26 yrs - not part BLA submitted in 2013
 - Data presented to ACIP October 2014
 - sBLA submitted to FDA

Current recommendations for HPV vaccination in the United States

- ❑ Routine vaccination at age 11 or 12 years*
- ❑ Vaccination recommended through age 26 for females and through age 21 for males not previously vaccinated
- ❑ Vaccination recommended for immunocompromised persons (including persons HIV-infected) and for men who have sex with men through age 26
- ❑ 3-dose schedule (0,1-2 and 6 months)



*The vaccination series can be started at age 9 years

Available HPV vaccines

	Bivalent (Cervarix)	Quadrivalent (Gardasil)	9-valent (Gardasil 9)
Manufacturer	GlaxoSmithKline	Merck	Merck
L1 VLP types	16, 18	6, 11, 16, 18	6, 11, 16, 18, 31, 33, 45, 52, 58
Adjuvant	AS04: 500 µg aluminum hydroxide 50 µg 3- <i>O</i> -desacyl-4'- monophosphoryl lipid A	AAHS: 225 µg amorphous aluminum hydroxyphosphate sulfate	AAHS: 500 µg amorphous aluminum hydroxyphosphate sulfate
Licensed	Females 9-25 years	Females 9-26 years Males 9-26 years	Females 9-26 years Males 9-15 years

Preparation for 9vHPV – ACIP presentations

- ❑ Epidemiology and burden of disease due to HPV types
 - February 2014
- ❑ Clinical trial data
 - February 2014, June 2014, October 2014
- ❑ GRADE for 9vHPV
 - October 2014
- ❑ Health economic analysis
 - October 2014
- ❑ Discussion of policy options
 - October 2014

Outline of February 2015 HPV session

- ❑ Summary of 9vHPV clinical trial data
 - Dr. Emiko Petrosky, NCHHSTP, CDC
- ❑ Vaccine impact and cost effectiveness
 - Dr. Harrell Chesson, NCHHSTP, CDC
- ❑ Considerations for recommendations
 - Dr. Lauri Markowitz, NCHHSTP, CDC
- ❑ ACIP discussion, Vote
- ❑ VFC resolution
 - Dr. Jeanne Santoli, NCIRD, CDC

ACIP HPV Vaccine Workgroup members

ACIP Members

Joseph Bocchini (WG chair)
Allison Kempe
Jose Romero
Laura Riley

Ex Officio Members

Carolyn Deal (NIH)
Bruce Gellin (NVPO)
Nancy Miller (FDA)
Jeff Roberts (FDA)

CDC Lead

Lauri Markowitz

Liaison Representatives

Sandra Fryhofer (ACP)
Amy Middleman (SAM)
James Turner (ACHA)
Patricia Whitley-Williams (NMA)
Rodney Willoughby (AAP)
Jane Zucker (AIM)
Margo Savoy (AAFP)
Linda Eckert (AGOG)
Shelley Deeks (NACCI)

Consultants

Tamera Coyne-Beasley
John Douglas
Janet Englund
Sam Katz
Debbie Saslow (ACS)
Aimee Kreimer (NCI)