

Human Papillomavirus Vaccines Session

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Chair, ACIP HPV Vaccines Work Group

Advisory Committee on Immunization Practices
February 24, 2016

ACIP HPV sessions over past year

❑ February 2015

- ACIP voted on 9-valent HPV vaccine recommendations

❑ June 2015

- Reviewed status of 9-valent vaccine introduction
- Reviewed data and discussed additional 9-valent HPV vaccination

❑ October 2015

- Reviewed HPV vaccination program
 - Coverage and implementation
 - Safety
 - Impact

9-valent HPV vaccine (9vHPV) licensure and recommendations

- ❑ **Licensed by FDA in December 2014**
- ❑ **Recommended by ACIP in February 2015**
 - MMWR Policy Note published in March 2015
 - 9vHPV as 1 of 3 HPV vaccines that can be used for females and 1 of 2 for males in the currently recommended age groups
- ❑ **Male age indications**
 - At time of first application to FDA, 9vHPV immunogenicity trials in males 16-26 yrs not completed; in December 2014 licensed for females 9-26 and males 9-15 yrs
 - December 14, 2015, FDA extended age indication to include males 16–26 yrs
<http://www.cdc.gov/hpv/downloads/9vhpv-fda.pdf>
- ❑ **Manufacturer plans**
 - Merck previously reported that they intended to maintain 4vHPV in the US market until 9vHPV approved by FDA for use in males 16-26 yrs (now approved)
 - Merck plans to retire 4vHPV by the end of 2016 in the US*

ACIP HPV Vaccines Workgroup activities since October 2015

- ❑ **Reviewed data on 2-dose schedules**
 - 9-valent HPV vaccine 2- vs 3- dose immunogenicity trial
 - 2-dose trials for other HPV vaccines
 - Modeling and cost effectiveness

- ❑ **Discussed policy considerations related to 2-dose schedules**
 - Additional data needed
 - Timeline and decisions

HPV session today

- The HPV session will provide data on 2-dose HPV vaccination schedules**
- Presentations will include information and background needed for discussion and decisions about HPV vaccine policy options that ACIP will address over the next few meetings**

February 2016 HPV session

- ❑ **Introduction**
 - Dr. Allison Kempe, Chair

- ❑ **Background on 2-dose schedules**
 - Dr. Lauri Markowitz, CDC

- ❑ **9-valent HPV vaccine 2- vs 3-dose trial data**
 - Dr. Alain Luxembourg, Merck

- ❑ **Review of data on 2 doses of bivalent and quadrivalent HPV vaccines**
 - Dr. Lauri Markowitz, CDC

- ❑ **HPV Vaccines Workgroup plans**
 - Dr. Elissa Meites, CDC

ACIP HPV Vaccines Work Group members

ACIP Members

Allison Kempe (Chair)
Cynthia Pellegrini
Laura Riley
Jose Romero

Ex Officio Members

Carolyn Deal (NIH)
Bruce Gellin (NVPO)
Jeff Roberts (FDA)
Sixun Yang (FDA)

CDC Lead

Lauri Markowitz

Liaison Representatives

Shelley Deeks (NACCI)
Linda Eckert (ACOG)
Sandra Fryhofer (ACP)
Amy Middleman (SAHM)
Chris Nyquist (AAP)
Margo Savoy (AAFP)
Patricia Whitley-Williams (NMA)
Jane Zucker (AIM)

Consultants

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