

Human Papillomavirus (HPV) Vaccine Session

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Advisory Committee on Immunization Practices
Atlanta, GA
October 30, 2014

ACIP HPV vaccine workgroup activities

- Preparing for licensure of 9-valent HPV vaccine
 - Potential licensure late 2014
- Continuing to review data on 2-dose schedules
 - ACIP presentation (June 2014)

Investigational 9-valent HPV vaccine

- ❑ L1 VLP vaccine, similar to quadrivalent HPV vaccine
- ❑ Targets 5 additional high risk types
 - 6,11,16,18, **31, 33, 45, 52, 58**
- ❑ BLA submitted to FDA in December 2013
 - Females 9-26 yrs, males 9-15 yrs
 - Trials conducted with 3-dose schedule
- ❑ Males 16-26 yrs - not part BLA submitted in 2013
 - Presentation for ACIP today
- ❑ ACIP WG reviewing data and considering policy options for presentation to ACIP

Investigational 9-valent HPV vaccine past presentations to ACIP

❑ **October 2013**

- Overview of investigational 9-valent program

❑ **February 2014**

- Burden of cancers and cervical precancers due to HPV types in the United States
- 9-valent HPV vaccine: pivotal efficacy and immunobridging trials

❑ **June 2014**

- 9-valent HPV vaccine: concomitant use trials, safety data, revaccination study
- Policy questions

2-dose schedules

- Comprehensive review of data for ACIP, June 2014
 - Bivalent and quadrivalent HPV vaccines
- Intersection with consideration of 9-valent HPV vaccine
 - No data available for 9-valent HPV vaccine 2-dose schedules but trial ongoing

Outline of HPV ACIP session

- Summary of 9-valent HPV vaccine program and new data in males 16-26 years
 - Dr. Alain Luxembourg, Merck
- 9-valent HPV vaccine impact and cost effectiveness in the U.S.
 - Dr. Marc Brisson, Laval University
- GRADE for 9-valent vaccine
 - Dr. Emiko Petrosky, NCHHSTP, CDC
- Policy considerations and options
 - Dr. Lauri Markowitz, NCHHSTP, 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)