

Human Papillomavirus (HPV) Vaccine Session

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Advisory Committee on Immunization Practices
Atlanta, GA
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Today's HPV session

- **Review of investigational 9-valent HPV vaccine and related background**
 - HPV 6/11/16/18/31/33/45/52/58

- **Review and approval of updated HPV vaccine ACIP statement**
 - Includes recommendations for:
 - bivalent (HPV 16/18) and quadrivalent (HPV 6/11/16/18) vaccines
 - females and males

October 2013 ACIP meeting HPV session

- ❑ Update on HPV vaccination coverage in the United States
- ❑ 9-valent HPV vaccine development program
- ❑ Overview of draft updated ACIP statement (bivalent and quadrivalent HPV vaccines, males and females)

ACIP HPV Vaccine Work Group: Conference calls

- ❑ Reviewed data from 9-valent HPV vaccine clinical trials
- ❑ Reviewed data on HPV type attribution in HPV-associated disease
- ❑ Initiated discussions for GRADE consideration

Proposed ACIP timeline for consideration of 9-valent HPV vaccine

ACIP Date	Topic
Oct 2013	Overview of 9-valent vaccine clinical program
Feb 2014	Attribution of types in HPV-associated disease Clinical trial data
June 2014	Clinical trial data Health economics
Oct 2014	GRADE Recommendation options and discussion
Feb 2015	Recommendations Vote and VFC

Outline of HPV ACIP session

- ❑ HPV type attribution in cervical precancers
 - Dr. Susan Hariri, NCHHSTP, CDC
- ❑ HPV type attribution in HPV-associated cancers
 - Dr. Mona Saraiya, NCCDPHP, CDC
- ❑ 9-valent HPV vaccine clinical trial data
 - Dr. Alain Luxembourg, Merck
- ❑ Summary and next steps
 - Dr. Lauri Markowitz, NCHHSTP, CDC
- ❑ Updated ACIP statement - bivalent and quadrivalent vaccines

Burden of disease attributable to HPV types

- ❑ Understanding HPV-associated disease attributable to HPV types is important to assessing potential impact and cost effectiveness of HPV vaccines
- ❑ Detecting HPV in a cancer tissue does not necessarily indicate a causal relationship. The International Agency for Research on Cancer defined some cancers to have strong evidence for causal etiology*
- ❑ HPV-associated cancers include: cervical, vaginal, vulvar, anal, penile and oropharyngeal cancers
 - Therefore, detecting HPV in these tissues is a good indication of causality
- ❑ Determining types responsible for HPV-associated disease depends on a variety of factors including quality of specimen, assay used to detect HPV, algorithm to assign type attributable (if multiple types), and can vary by the population sampled

ACIP HPV Vaccine Workgroup members

ACIP Members

Joseph Bocchini (WG chair)
Tamera Coyne-Beasley
Renee Jenkins
Allison Kempe

Ex Officio Members

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

CDC Lead

Lauri Markowitz

Liasion Representatives

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

Consultants

Janet Englund
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