HPV Vaccine Session

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Advisory Committee on Immunization Practices
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DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION

ACIP HPV Vaccine Workgroup Activities

- Manufacturer submitted a supplemental BLA for use of the quadrivalent HPV vaccine in women over 26 years of age in January 2008
- ACIP HPV Vaccine WG has been preparing possible recommendation options for use of the vaccine in this age group
- FDA recently requested additional data; ACIP vote may occur in October 2008 or later if FDA approval

ACIP HPV Vaccine Workgroup Activities
Recommendations for women >26 years

- Conference calls to review data
  - Quadrivalent HPV vaccine in adult women – Haupt (Merck)
  - Epidemiology of HPV in ‘older women’ – Winer (U Wash)
  - Sexual behavior in the US – Leichliter (CDC)
  - Cost effectiveness – Goldie (Harvard)
  - Natural Hx of HPV – Schiffman and Rodriguez (NCI)

ACIP HPV Vaccine Workgroup Activities

Recommendations for women >26 years

- February 2008 ACIP meeting
  - Adult women trial data
  - Overview of epidemiology and cost effectiveness
  - Recommendation options
- Further consideration of cost effectiveness data
- Discussion of recommendation options

Quadrivalent HPV Vaccine Efficacy Study in Adult Women

- **24- to 45-Year-Old Women (N=3819)**
- **Multi-Center, International Study**
  - 27% US/EU; 42% Latin America; 31% Asia
- **Key Exclusion Criteria**
  - No history of LEEP or hysterectomy, genital warts
  - No history of cervical biopsy in past 5 years
  - No limitation of lifetime sex partners

Efficacy Study in Adult Women

HPV 6,11,16,18-Related Persistent Infection, CIN or EGL

Per-Protocol Efficacy Population; Mean Follow-Up 2.2 Years

Endpoint	Vaccine (N=1910)	Placebo (N=1907)	Efficacy %	Efficacy (95% CI)
HPV 6/11/16/18-Related Persistent Infection, CIN or EGL	4*	41	91	(74, 98)
HPV 16/18-Related Persistent Infection, CIN or EGL	4	23	83	(51, 96)
HPV 6/11-Related Persistent Infection, CIN or EGL	0	19	100	(79, 100)

*All cases were due to Type 16; 3 were persistent infection, 1 was a CIN 2 co-infection with Type 52
EGL – external genital lesion, CIN – cervical intraepithelial neoplasia

Haupt, presented at Feb 2008 ACIP meeting

Efficacy Study in Adult Women

HPV 6/11/16/18-Related Disease Endpoints

Per Protocol Efficacy Population, Mean Follow-Up 2.2 Years

Endpoint	Vaccine	Placebo	Efficacy %	Efficacy (95% CI)
HPV 6/11/16/18-Related CIN or EGL	**1**	**13**	**92**	**(50, 100)**
HPV 16/18-Related CIN or EGL	1	8	88	(9, 100)
HPV 6/11-Related CIN or EGL	0	6	100	(16, 100)

EGL – external genital lesion, CIN – cervical intraepithelial neoplasia

Haupt, presented at Feb 2008 ACIP meeting

Efficacy Study in Adult Women

Safety Profile

	Vaccine (N= 1899)		Placebo (N=1886)	
	n	(%)	n	(%)
SAEs				
Overall	3	(0.2)	7	(0.4)
VR-SAEs	0	(0.0)	0	(0.0)
Injection Site AEs	1443	(76)	1210	(64)
Erythema*	273	(15)	200	(11)
Pain*	1423	(75)	1170	(62)
Pruritus	31	(2)	25	(1)
Swelling*	353	(19)	214	(11)

*p<.001

Haupt, presented at Feb 2008 ACIP meeting

Outline of HPV Session

- Cost effectiveness of HPV vaccination in the US
  - Dr. Jane Kim
- Review of economic analyses
  - Dr. Harrell Chesson
- Issues and options for recommendations: women 27 through 45 years
  - Dr. Eileen Dunne

Outline of HPV Session

- Quadrivalent HPV vaccine intervals - VFC vote
  - Dr. Greg Wallace

Projected Dates for ACIP Votes

Possible Date	Decision
Oct 2008 or later	Quadrivalent vaccine in females 27-45 yrs
2009 or later	Bivalent vaccine in females
2009 or later	Quadrivalent vaccine in males