

Quadrivalent HPV vaccine Recommendation Options for Adult Women 27-45 Years

ACIP HPV Vaccine Workgroup

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



Quadrivalent HPV vaccine

Recommendation Options Considered for Adult Women 27-45 Years

- Permissive recommendation
- Targeted catch-up recommendation
 - Risk-based
- Extend catch-up recommendation
 - All or part of this age group

Key Points

- HPV vaccine is prophylactic; vaccine will have greatest impact and is most cost effective when administered before exposure to HPV
- Infections occur in females >26 years, but incidence decreases with increasing age
- Difficult to target by risk factors
 - Risk factors for prevalent infection and past exposure are similar to those associated with incident infection
- Models show decreasing cost effectiveness with age at vaccination for adult women
 - Age at which vaccine not 'cost effective' differs by model, within models

Other Issues

- If licensed for use in women > 26 years, what will the indications be?
 - Few CIN2/3 cases in trial
 - No cases of VIN / VaIN2/3

CIN, cervical intraepithelial neoplasia; VIN, vulvar intraepithelial neoplasia;
VaIN, vaginal intraepithelial neoplasia

Primary Efficacy Results

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

Per Protocol Efficacy Population

Endpoints	Gardasil (N=1910)	Placebo (N=1907)	Observed Efficacy (%)	95% CI
	# of Cases	# of Cases		
Persistent Infection, CIN, or EGL	10	86	88.7	78, 95
Persistent Infection	9	85	89.6	79, 95
CIN (any grade)	1	17	94.1	63, 100
CIN 2/3 or worse	1	6	83.3	-38, 100
EGL	0	7	100	31, 100
Condyloma	0	7	100	31, 100
VIN 2/3 or VaIN 2/3	0	0	NA	NA

CIN – cervical intraepithelial neoplasia; EGL – external genital lesions; VIN – vaginal intraepithelial neoplasia; VaIN – vaginal intraepithelial neoplasia

Quadrivalent HPV vaccine

Recommendation to be proposed by
ACIP HPV Workgroup for women 27-45 years

- Permissive recommendation
- Rationale:
 - Relatively small impact of vaccination in adult women
 - Models show potential for high cost per QALY in this age range
 - Main focus of vaccination program should be adolescents

ACIP HPV Vaccine WG Plans

- Further review of data on adult women
- Prepare for vote at June 2010 ACIP meeting
- Draft “Policy Note” for MMWR (publication pending ACIP vote)
 - State efficacy observed in this age group
 - Vaccine may be given to women age 27-45 years, no extension of catch-up recommendation
 - Cervical cancer screening should be main focus of cervical cancer prevention in this age group