

# ACIP Considerations

## Vaccination of women 27-45 years Quadrivalent HPV Vaccine

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CENTERS FOR DISEASE CONTROL AND PREVENTION



# Outline

- Background
- ACIP HPV Workgroup Considerations
  - Epidemiology/Burden of Disease
  - Efficacy/safety/immunogenicity HPV vaccine
  - Population Impact
  - Economic Models
  - Programmatic Issues
- Options Proposed

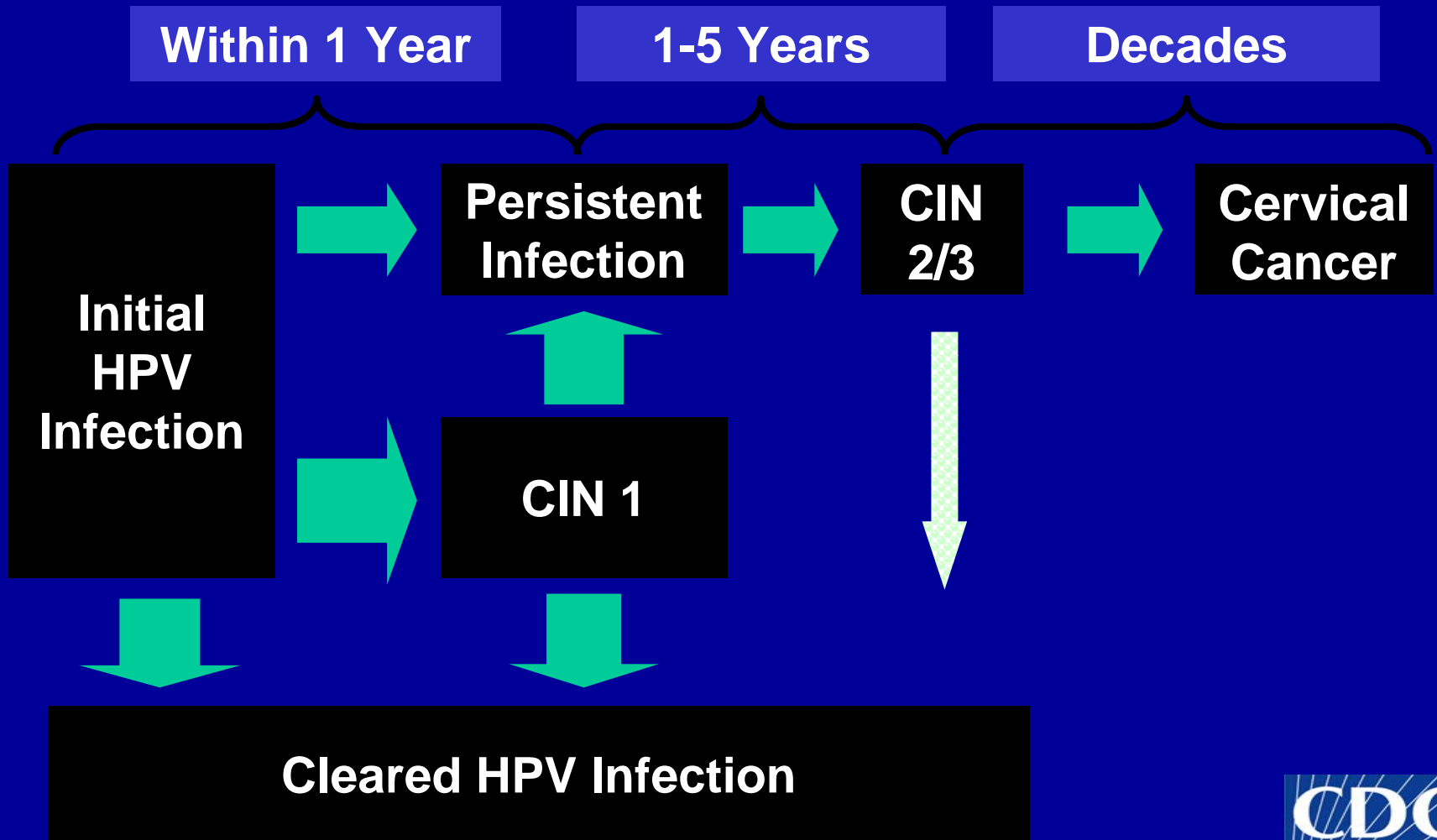
# Background

- June 2006, ACIP recommended routine vaccination of girls 11 and 12 years of age\*, catch-up in 13 through 26 year olds
- February 2008, presentation to ACIP on epidemiology of HPV infection, cost-effectiveness, and efficacy/safety of the HPV vaccine in women 24-45 years

\* Vaccine can also be given to 9 and 10 year olds



# Background: HPV natural history

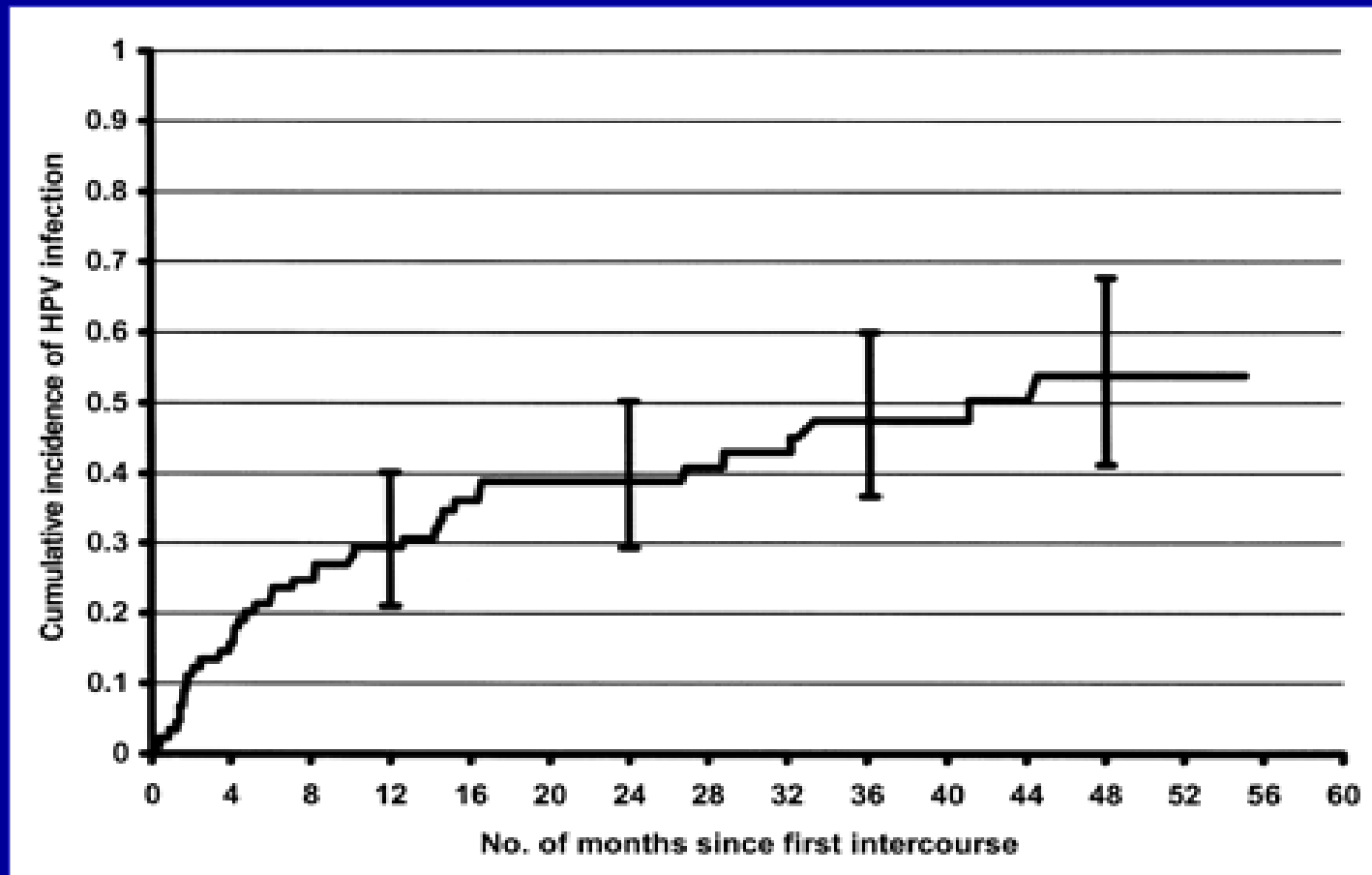


CIN= cervical intraepithelial neoplasia

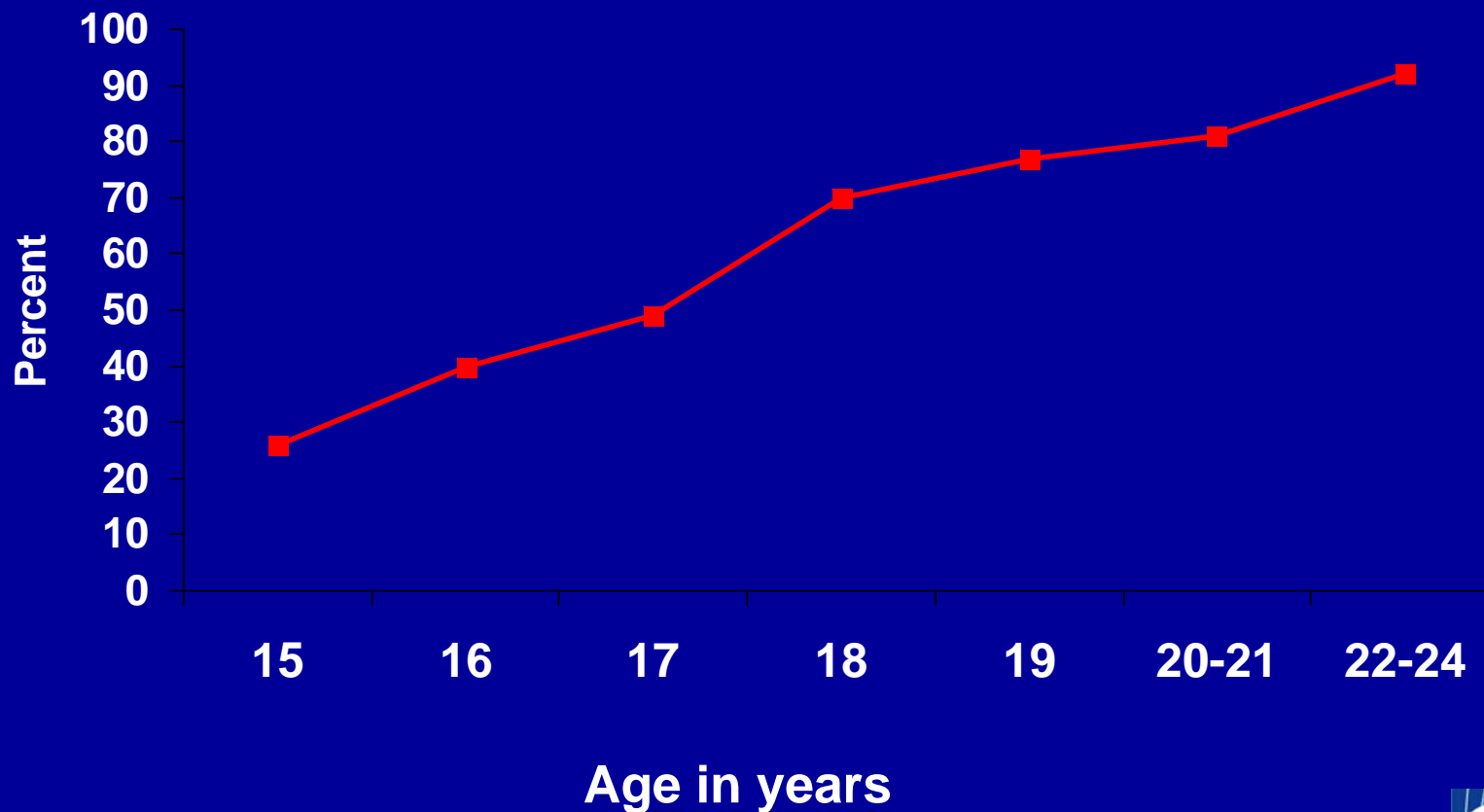


# Cumulative incidence of any HPV infection

## Months after sexual initiation, Women

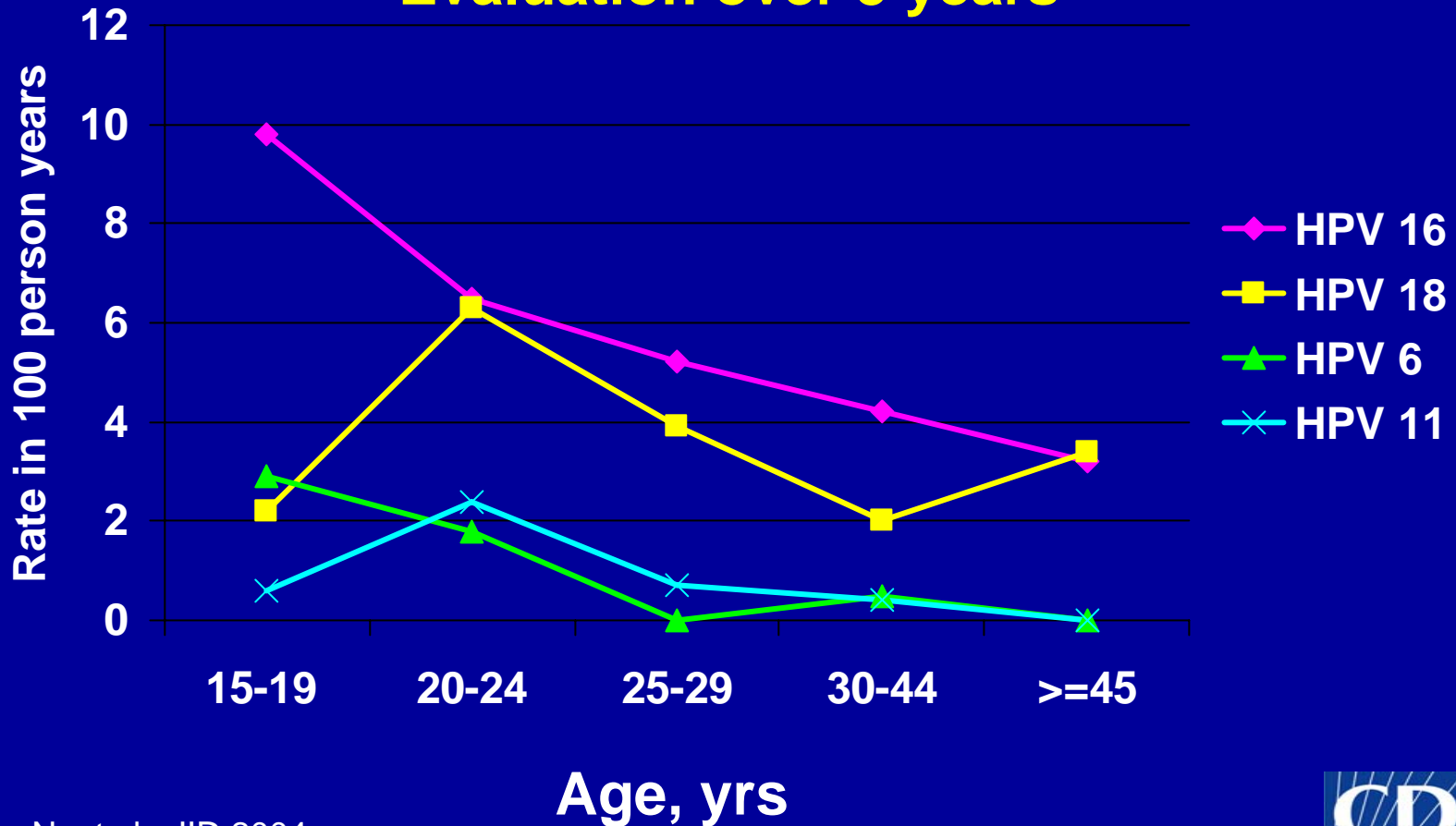


# Percentage of females who have had vaginal sex, by age, National Survey of Family Growth, 2002



# Incidence of HPV 16, 18, 6 or 11 among females, by age, Colombia

Evaluation over 5 years



# Quadrivalent HPV vaccine clinical trials

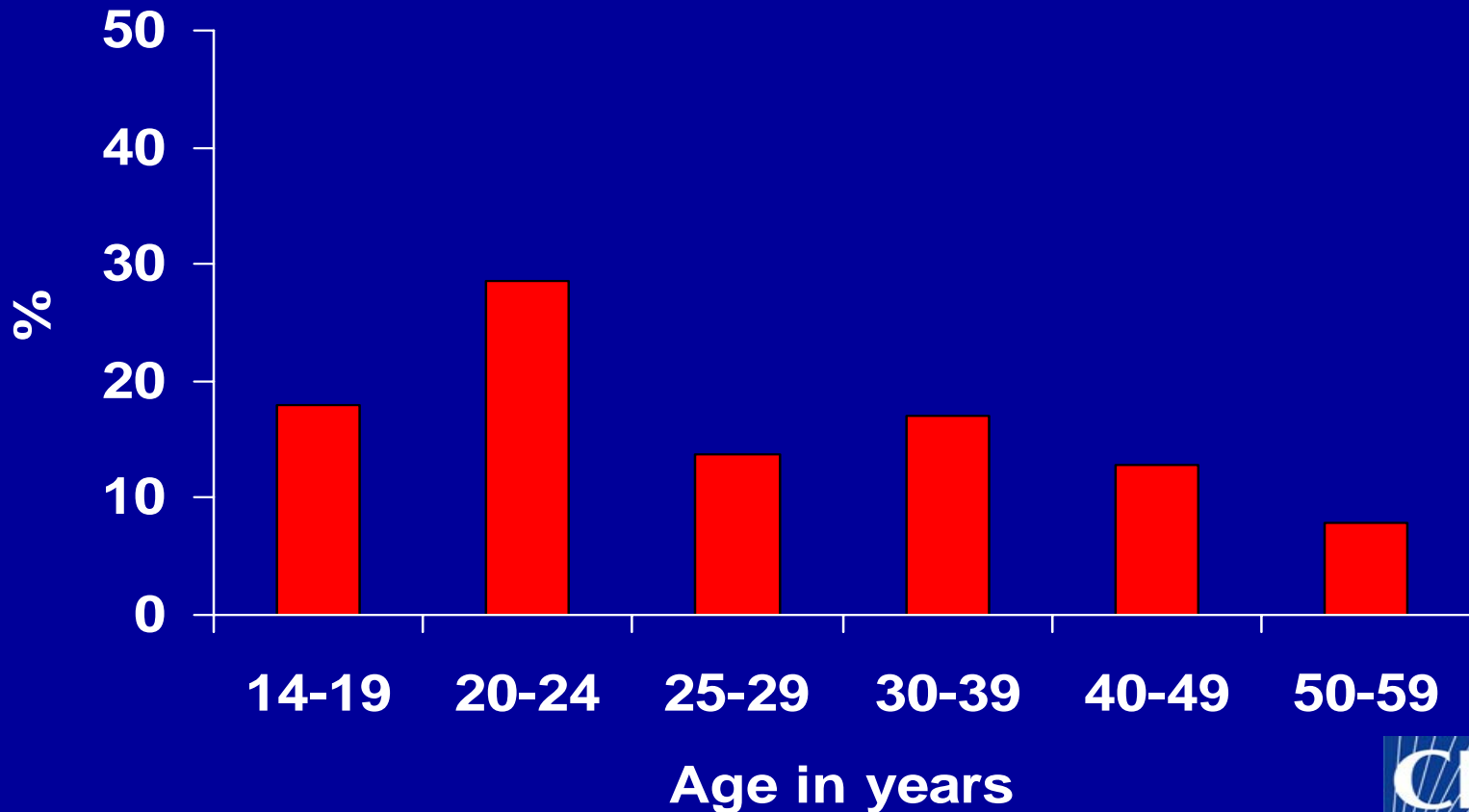
## Placebo Arm: Incidence of HPV 16, 18, 6 or 11 per 100 person years, by age

Age Group (years)	Incident Infection Rate (95% CI)
24-29	7.4 (5.90, 9.21)
30-34	3.6 (2.42, 5.05)
35-39	2.4 (1.50, 3.60)
40-45	1.9 (1.15, 2.95)



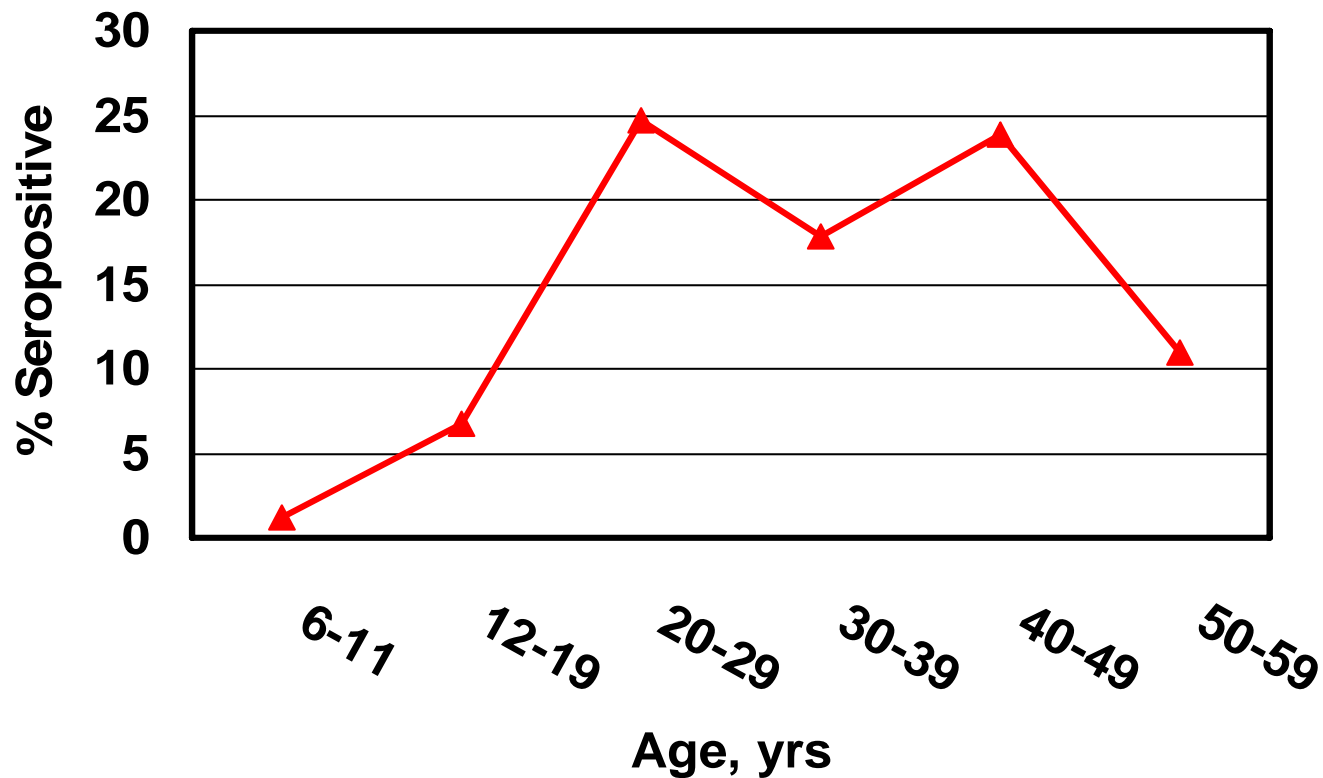


# High risk HPV prevalence among females by age, National Health and Nutrition Examination Survey (NHANES) 2003-2004 (N=1921)



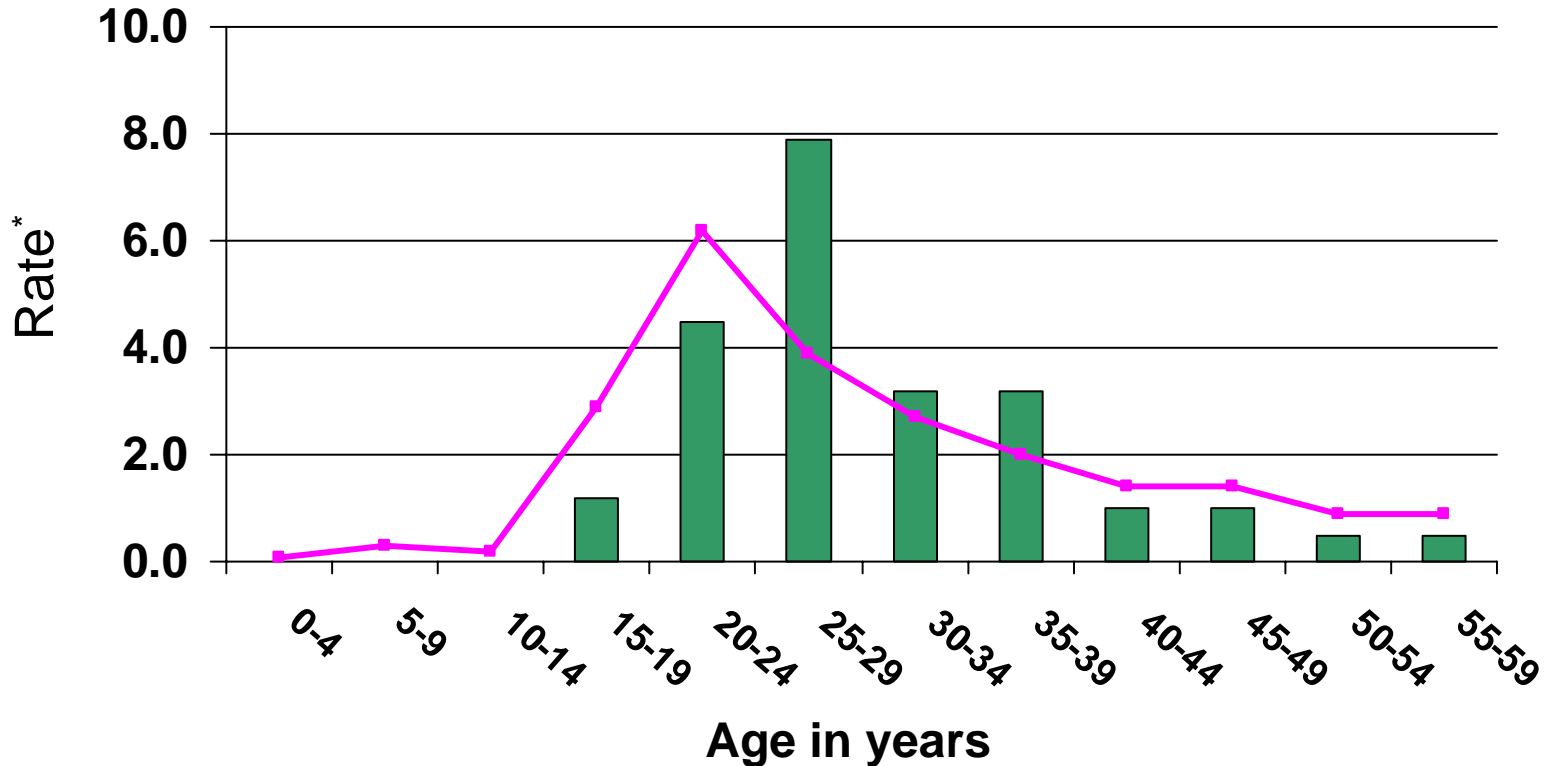
# HPV 16 seroprevalence

## National Health and Nutrition Examination Survey (NHANES), U.S. females



# Incident CIN 2/3 and genital wart diagnoses by age group, U.S. females

■ CIN 2/3    —●— Genital warts



\* CIN 2/3 yearly rate per 1000 enrollees, GW 1000 person-years

Insinga RP, CID 2003, Insinga RP, Am J Ob Gyn 2004



# Summary: Quadrivalent HPV vaccine efficacy (women 24-45 years)

- 3819 women were evaluated: 2.2 years follow-up
- Vaccine efficacy for HPV 6/11/16/18-related CIN or external genital lesions (EGL)
  - 92% (95% CI 50%, 100%)
- Few CIN 2/3 and adenocarcinoma in situ (AIS) (1 case in vaccine arm and 4 cases in placebo arm)
- Vaccine efficacy for CIN 2/3, AIS
  - 75.2% (95% CI = -150.6%, 99.5%)
- No intent to treat analysis as yet

# Population impact

- Decreasing incremental health impact as cut-off age for catch-up vaccination increases
  - More have already been exposed to HPV vaccine type infection
  - Incidence of HPV vaccine type infection decreases

# Two cost-effectiveness models

- Vaccination becomes less cost-effective as cut-off age for catch-up vaccination increases
- The age at which the cost-effectiveness estimates cross a certain threshold (e.g., \$100,00/QALY) differ

# ACIP HPV workgroup proposed options

- Most members of the workgroup did not support extending catch-up vaccination of women > 26 years
- One workgroup member supported extending catch-up vaccination of women through age 45 years
- Await further information provided from the vaccine trials, economic data, and FDA review

# Acknowledgments

Members of the ACIP HPV Workgroup

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