

Quadrivalent HPV Vaccine For Males Future Considerations

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Quadrivalent HPV Vaccine in Males

- October 2009
 - FDA licensure of vaccine for males 9 through 26 yrs for prevention of HPV types 6/11-related genital warts*
 - ACIP made a permissive recommendation for use in males
- Data now available on prevention of anal intraepithelial neoplasia (AIN) in males

*<http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm094042.htm>

Projected Timeline for Review of New Data

- Submission of AIN sBLA by Merck to FDA expected in 2010
- FDA review 6-10 months

Status of Recommendations and Availability of Quadrivalent HPV Vaccine for Males

- Permissive ACIP recommendation
- Included in Vaccines for Children (VFC)
- Included in Merck Patient Assistance Program

October 2009 - ACIP Recommendation and VFC Resolution

ACIP Recommendation:

The 3-dose series of quadrivalent HPV vaccine may be given to males aged 9 through 26 years to reduce their likelihood of acquiring genital warts. Ideally, vaccine should be administered before potential exposure to HPV through sexual contact.

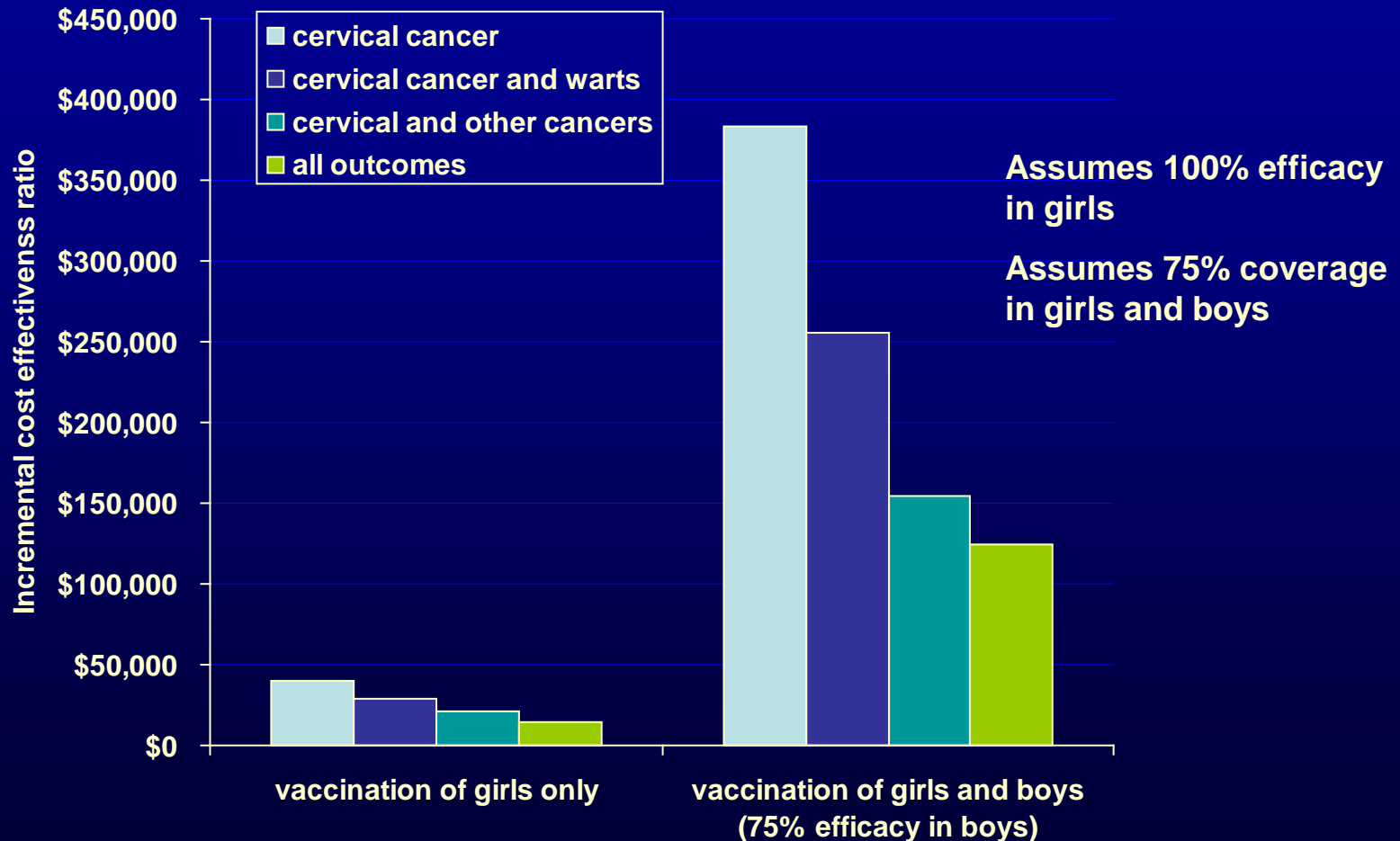
Vaccines for Children (VFC):

Quadrivalent HPV vaccine for males approved to be included in VFC enabling VFC providers to provide VFC HPV vaccine to eligible males, age 9 through 18 years.

Considerations for Recommendations in Males

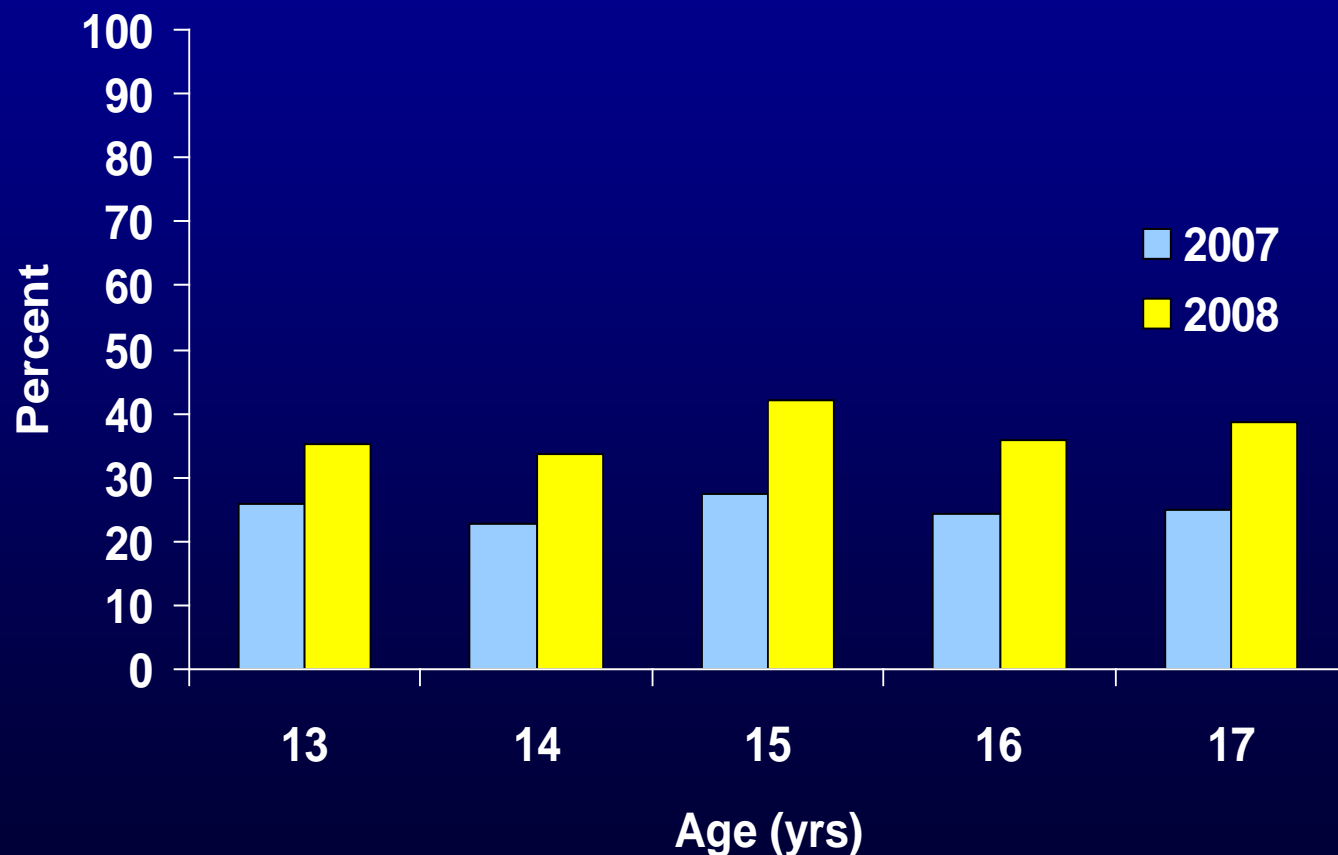
- Vaccine efficacy
- Epidemiology and burden of disease
- Programmatic issues
- Cost effectiveness
 - Depends on assumptions in models
 - Male vaccination is most cost effective when
 - Coverage among females is low
 - All potential health outcomes included
 - Vaccine efficacy is high in males

Cost Effectiveness Ratios for Male HPV Vaccination in the US, Impact of Disease Outcomes



Estimated 1+ Dose HPV Vaccination Coverage, Females 13-17 Years

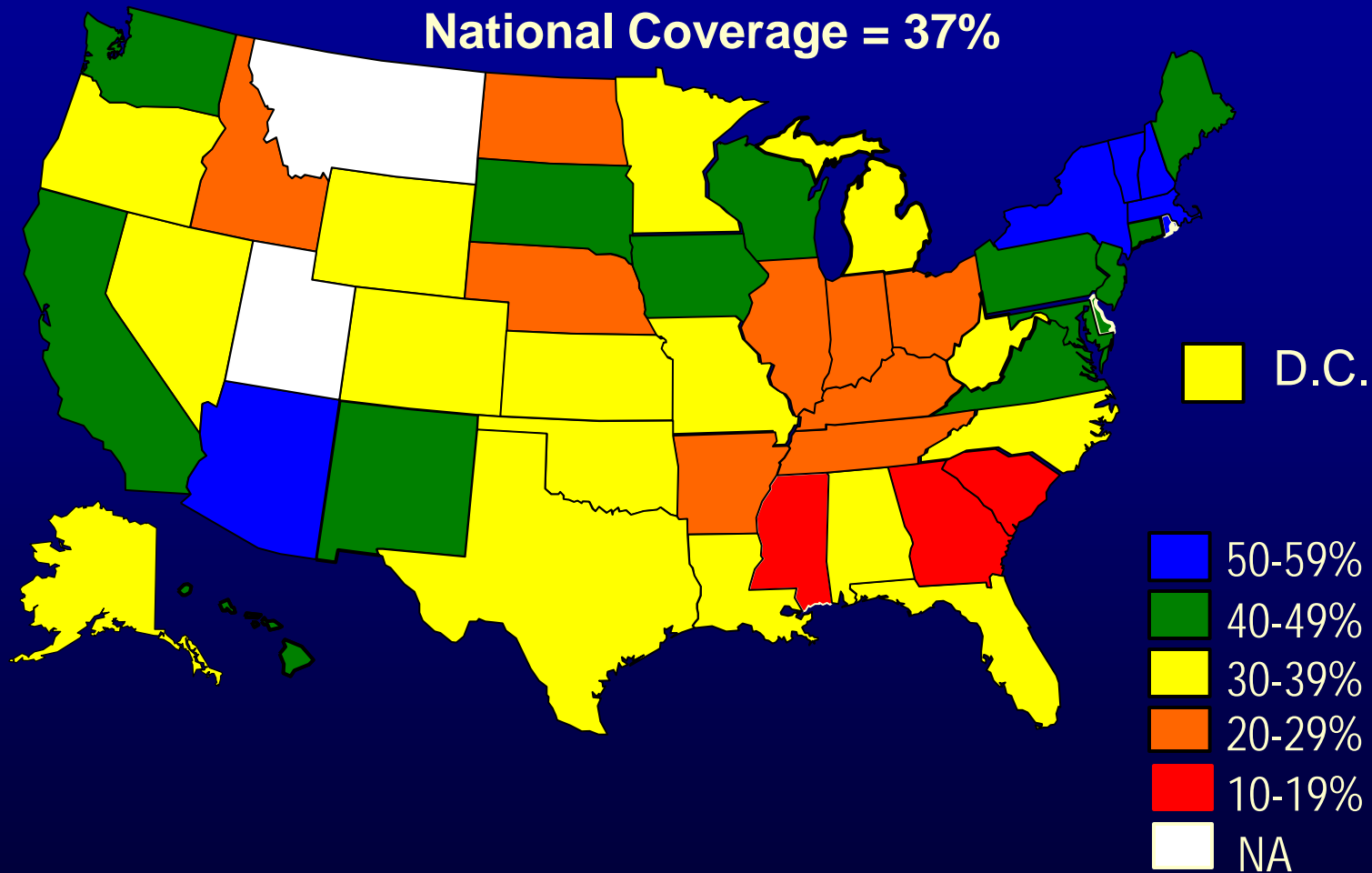
National Immunization Survey, 2007 and 2008



Estimated 1+ Dose HPV Vaccination Coverage, Females 13-17 Years

National Immunization Survey, 2008

National Coverage = 37%



Source: CDC. National, state, and local area vaccination coverage among adolescents aged 13-17 years---United States, 2008.

ACIP HPV Vaccine WG Plans

- Vaccine trial data in males
- Cost effectiveness analyses with vaccine trial data and different coverage assumptions
- Epidemiology and cost effectiveness of HPV vaccine in men who have sex with men (MSM)
- Feasibility of reaching MSM when they would most benefit from vaccination
- Further consideration of recommendations for males at June 2010 and subsequent ACIP meetings