

HPV Vaccine Session

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Overview of Upcoming Issues for ACIP Consideration

- Recommendations for bivalent HPV vaccine
- Recommendation issues related to two licensed HPV vaccines
- Additional data from quadrivalent and bivalent HPV vaccine that may impact recommendations
- Considerations not included in first ACIP statement

Bivalent HPV vaccine

- BLA submitted to FDA in March 2007
 - Data included on females 10 - 55 yrs
 - Efficacy data in females 15-25 yrs
 - Immunobridging data in younger and older females
 - Timeline for FDA decision
 - 10 month review → ~January 2008

ACIP HPV Vaccine Workgroup

Recent Activities

- ~Monthly conference calls to review data:
 - Bivalent HPV vaccine efficacy, immunogenicity, and safety
 - Quadrivalent HPV vaccine cross protection
 - VAERS data and vaccine safety
 - Recurrent respiratory papillomatosis and genital warts
 - Cost effectiveness of bivalent & quadrivalent vaccines
 - Vaccination of HIV-infected adults
 - HPV in 'older women'
- Discussion of recommendation options

Outline of Session

- Summary of HPV vaccine trial data
- Quadrivalent vaccine – cross protection
- Bivalent vaccine
 - ASO4 adjuvant and vaccine safety overview
- Burden of disease due to HPV 6/11
 - Genital warts and RRP
- Considerations for ACIP