

# HPV Vaccines Work Group Plans

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## **Information presented today**

- **Background on 2-dose schedules for HPV vaccines**
- **New data from 2-dose immunogenicity trial of 9vHPV**
- **Current data on 2-dose studies of 2vHPV and 4vHPV**
- **Plans for additional data and issues**

## **Additional data for ACIP to consider**

- **GRADE for 2-dose schedules**
- **Post-licensure effectiveness data**
- **Modeling data and cost-effectiveness**
- **Programmatic considerations**
- **Additional follow-up data from 9vHPV trial**

## Issues for ACIP to consider

- **Should a 2-dose schedule be recommended?**
- **If so, would need to address:**
  - Target age or age range for 2-dose recommendation
  - Interval or range of intervals in 2-dose recommendation
  - 2 doses versus 2-or-3 doses
  - Special populations
    - Immunocompromised persons or others
  - Which HPV vaccines

## Issues for ACIP to consider

- All HPV vaccines are FDA-approved as a 3-dose series
- 9vHPV
  - 2-dose data will be reviewed by FDA
  - 2-dose schedule would be off-label unless label is changed
- 4vHPV
  - No plan to submit data to FDA
  - 2-dose schedule would be off-label
- 2vHPV
  - No plan to submit data to FDA
  - 2-dose schedule would be off-label

## Issues for ACIP to consider

- **Incomplete series**
  - About 20% of teens starting a 3-dose series did not complete\*
  - Recommendation could specify for each vaccine whether and when a 2<sup>nd</sup> dose or a 3<sup>rd</sup> dose should be given
- **Quadrivalent vaccine will be retired in the United States**
  - 2-dose recommendation might still apply to people who did not complete a 3-dose series

\* Reagan-Steiner S, et al. National, Regional, State, and Selected Local Area Vaccination Coverage Among Adolescents Aged 13-17 Years-- United States, 2014. *MMWR*. 2015 Jul 31;64(29):784-92.

# Plans

- **June 2016 ACIP meeting**
  - GRADE for 2-dose schedules
  - Modeling data for cost-effectiveness of 2-dose schedules
  - Programmatic considerations
  - Discussion of potential recommendations
  
- **Future ACIP meetings**
  - Additional follow-up data from 9vHPV trial, when available
  - FDA decisions, if any, changing indicated dosing of 9vHPV
  - Proposed recommendations and vote

# Acknowledgments

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