

ACIP Rotavirus Vaccines Working Group: Overview

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Chair, ACIP Rotavirus Vaccines Working Group

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Members of ACIP Rotavirus Vaccines Working Group

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Rotavirus Vaccines 2006/7

Live, oral

- Attenuated monovalent human rotavirus vaccine: Rotarix® (GSK)
 - BLA submitted to FDA June 1, 2007
 - Studied as two-dose series at ages 2, 4 months
- Pentavalent human-bovine reassortant rotavirus vaccine: RotaTeq® (Merck)
 - Licensed Feb 2006
 - ACIP recommendations Feb 2006
 - Routine infant vaccination at ages 2, 4, 6 months

Rotavirus Vaccines

Presentations to ACIP

- October 2007
 - Rotarix: safety and efficacy data, by GSK
 - RotaTeq: safety update, coverage and age-adherence estimates
- February 2008
 - Draft of WG proposed recommendations
- June 2008
 - Possible ACIP vote on proposed recommendations (if Rotarix licensed)
 - New ACIP statement on Rotavirus Vaccines

Rotavirus Vaccines Working Group

Plans and progress

- Review data on Rotarix
- Draft proposed recommendations
 - Rotarix
 - Address issues with two products
- Continue to review post-marketing data on RotaTeq
 - ISO, FDA

Rotavirus Vaccines Working Group

Drafting proposed recommendations

- For Rotarix, and address issues with two products
 - Available data
 - Expectations and timeline for additional data
 - Opinion of working group members
 - Programmatic issues

Additional topics to be addressed by Working Group

- Develop proposed recommendations for Rotarix (and update for RotaTeq as indicated)
 - Special populations
 - Special circumstances
 - Contraindications
 - Precautions
- Review any additional information on safety and efficacy
- Review cost-effectiveness data for Rotarix

Presentation to ACIP on Rotavirus Vaccines

February 28, 2008

- Proposed recommendations from the Rotavirus Vaccines Working Group
 - Information, Discussion
- Survey results on physician attitudes regarding rotavirus vaccine (RotaTeq)
 - Information, Discussion

THANK YOU