

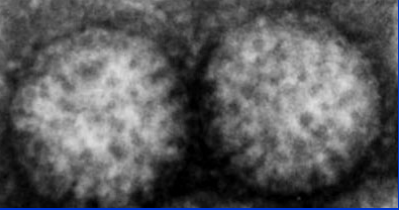
# Rotavirus Vaccine – Introduction to the Discussion

Lance Chilton, MD, FAAP  
Chair, Rotavirus Work Group  
ACIP Meeting, Atlanta, June 25, 2008



DEPARTMENT OF HEALTH AND HUMAN SERVICES



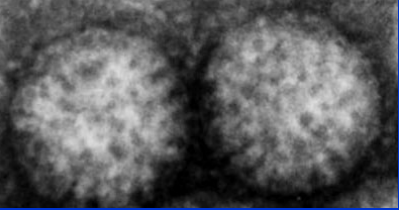


# Members of ACIP Rotavirus Vaccines Working Group

Bill Atkinson  
James Baggs  
Angela Calugar  
Lance Chilton  
Margaret Cortese  
Penny Dennehy  
Geoff Evans  
Paul Gargiullo  
Roger Glass  
Stanley Grogg  
Penina Haber  
Sam Katz  
Paul Kitsutani

Thomas Koinis  
Susan Lett  
Ed Marcuse  
John Modlin  
Julie Morita  
Trudy Murphy  
Umesh Parashar  
Manish Patel  
Jane Seward  
Greg Wallace  
Marc-Alain Widdows

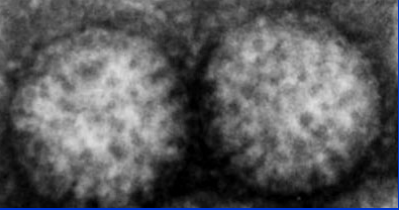




# RV Work Group Meetings July 2007-June 19, 2008

- Evaluate available data
  - Independent studies
  - Proprietary studies
  - Economic analysis
- Gather expert opinion
  - Committee members
  - FDA action
  - European Society for Paediatric Infectious Diseases/European Society for Paediatric Gastroenterology, Hepatology, and Nutrition
  - World Health Organization
  - Australian recommendations

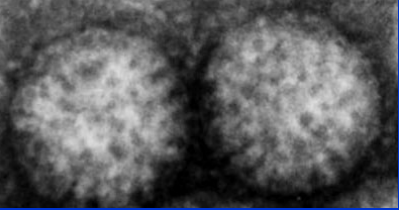




# RV Work Group Meetings July 2007-June 19, 2008

- Stress safety first, efficacy next
- Write clear, unambiguous recommendations
- Recommendations should stand on their own, without references to background necessary
- Make recommendations as user-friendly as possible





# Stress safety first, efficacy next

- Evaluate safety data, especially regarding intussusception
- Give rotavirus vaccine to as many infants as possible, consistent with safety
  - Consider vaccine economics for practitioners
- Plan for continued post-marketing evaluation





# Make recommendations as user-friendly as possible

Example 1: Make age recommendations the same for both vaccines.

Example 2:

- Today is June 25, 2008. My colleague is considering giving the third dose of rotavirus vaccine to an infant born on November 6, 2007. Should he do so?
  - Current recommendations: not after 32 weeks. Current age  $(24+31+31+29+31+30+31+25)/7 = 232/7 = 33 \frac{1}{7}$  weeks = NO
  - Recommended new recommendation: not after 8 months 0 days. Current age (June 25 – Nov 6 = <8 months) = YES

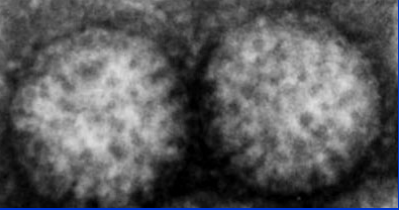




# Recommendations: Issues Especially Carefully Considered

- Preference for one vaccine over another in certain circumstances?
- Age maximums for first dose and last dose?
- Mixed series (RotaTeq® + Rotarix®)
- Special populations
  - Premature infants
  - Blood product recipients
  - Immunocompromised infants
  - Infants with immunocompromised household members
  - Infants with GI tract disease





# Rotavirus Vaccines – Discussion and Action

- Rotavirus Vaccines Workgroup: update: Dr. Lance Chilton (ACIP, WG Chair)
- Update on safety monitoring of RotaTeq®: Ms. Penina Haber and Dr. James Baggs (CDC/OCSO/ISO)
- Update on 2007/08 rotavirus season: Ms. Cathy Panozzo (CDC/CCID/NCIRD/DVD)
- Rotarix® vaccine: summary of efficacy and safety data, and GSK post-licensure monitoring plans: Dr. Leonard Friedland (GSK)
- Update on cost-effectiveness of rotavirus vaccination: Dr. Marc-Alain Widdowson (CDC/CCID/NCIRD/DVD)
- Plans for post-marketing safety monitoring of Rotarix®: Ms. Penina Haber (CDC/OCSO/ISO)
- Proposed Rotarix® vaccine recommendations and updated RotaTeq® vaccine recommendations: Dr. Margaret Cortese (CDC/CCID/NCIRD/DVD)

- **VOTE**

- WFC vote: Dr. Greg Wallace (CDC/CCID/NCIRD/ISD)



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