# Rotavirus Vaccine Update

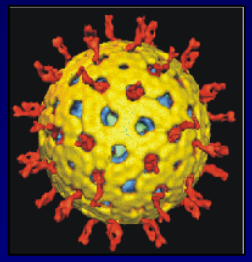
# *2006 -- Many Milestones for Rotavirus Vaccines*

1. US FDA licences RotaTeq
2. ACIP recommends RotaTeq for routine immunization of all American children
3. EMEA licences Rotarix
4. Rotarix introduced in immunization programs in Brazil, Panama, Venezuela, and El Salvador
5. GAVI approves purchase of rotavirus vaccines for Latin America and Eastern Europe

# Profiles of RotaTeq and Rotarix

# RotaTeq (Merck & Co.)

Bovine rotavirus with single human rotavirus gene substitution



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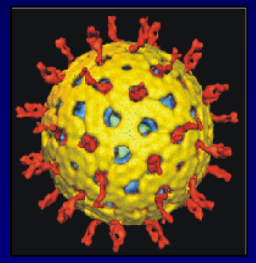

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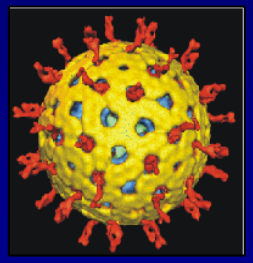

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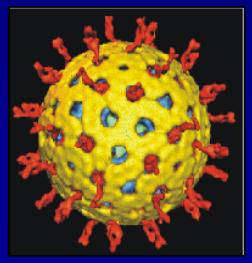

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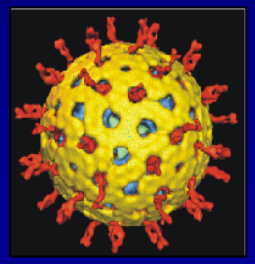

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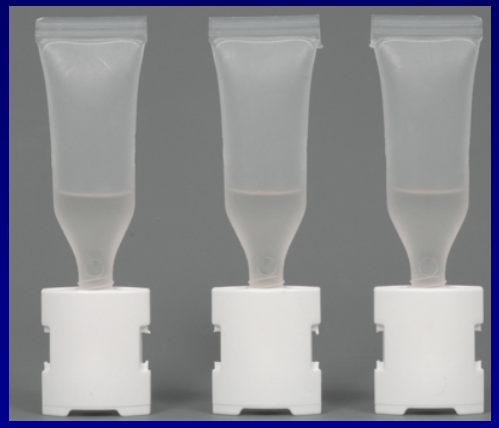


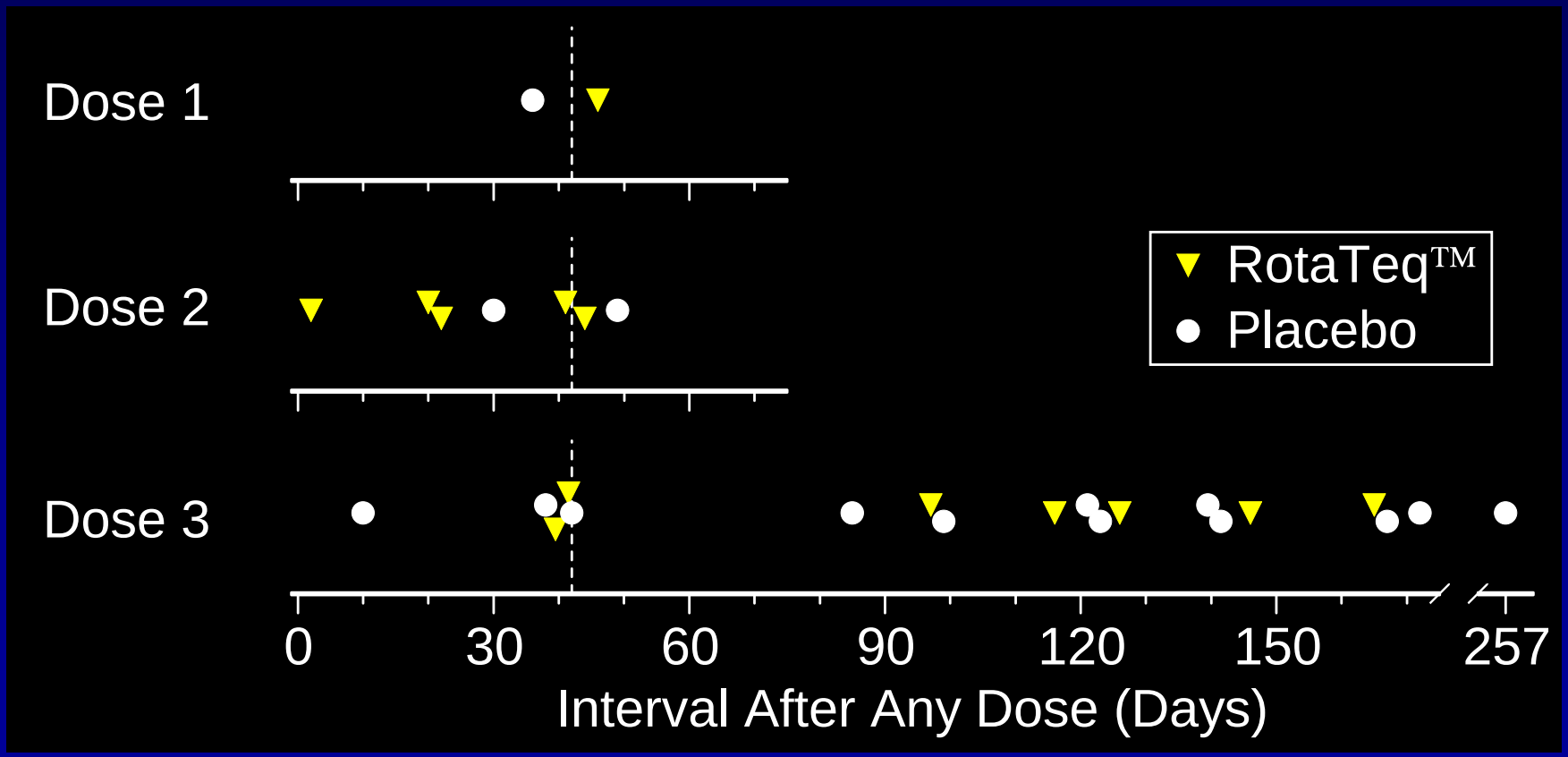
# Efficacy of RotaTeq™ to reduce healthcare utilization for RVGE*

| Type of Contact | Number of Cases | | % Rate Reduction | 95% CI |
|---|---|---|---|---|
| | Vaccine | Placebo | | |
| Hospitalizations† | 6 | 144 | 95.8 | 90.5, 98.2 |
| ED visits † | 15 | 232 | 93.5 | 88.6, 96.3 |
| Office visits†† | 14 | 100 | 85.2 | 73.1, 91.9 |

*Per protocol population (includes only cases that occurred at least 14 days after Dose 3)
† N=34,035 vaccine and 34,003 placebo recipients
†† N = 2,834 vaccine and 2839 placebo recipients

# RotaTeq intussusception (IS) data

42 days of Any Dose - 6V:5P
RR=1.2; 95% CI 0.3,5.0*



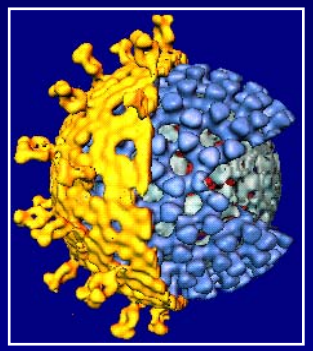

* Unadjusted for multiplicity.

# RotaTeq Status

- Recommended by ACIP for immunization of all US infants
- Licensed in several other countries (Europe, Australia, Canada, etc.)
- Demonstration project in Nicaragua – Vaccine donation for 3 years

# Rotarix (GSK)

Human rotavirus



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# Efficacy of Rotarix against RVGE

| Disease Severity | Number of Cases HRV (N=9009) | Placebo (N=8858) | % Efficacy | 95% CI |
|---|---|---|---|---|
| Severe | 12 | 77 | **84.7** | 71.7, 92.4 |
| Hospitalized | 9 | 59 | **85.0** | 69.6, 93.5 |

Ruiz-Palacios G. et al N. Engl. J. Med. 2006; 354: 11-22

# Rotarix intussusception (IS) data

**Number of IS Cases**

| | Vaccine group N=31,673 | Placebo group N=31,552 |
|---|---|---|
| *Total 0 → 31 days* | **6** | **7** |
| *0 → 31 days post dose 1* | **1** | **2** |
| *0 → 31 days post dose 2* | **5** | **5** |

Risk Difference = -0.32/10.000 vaccines (95% CI: -2.91 to 2.18)

**Relative Risk = 0.85 (95% CI: 0.30 to 2.42)**

Ruiz-Palacios G. *et al* N. Engl. J. Med. 2006; 354: 11-22

# Rotarix Status

- Licensed in >75 countries, including Europe
- Introduced in national programs in Brazil, Panama, Venezuela, and El Salvador
- Not yet submitted to FDA for US licensure

# Session Overview

- Ongoing active surveillance/vaccine effectiveness studies
- Post-marketing safety surveillance