OREGON STATE PUBLIC HEALTH DIVISION, DHS
IMMUNIZATION PROGRAM

ROTAVIRUS VACCINES
Live Virus Vaccine

Revisions as of 8/08:

- The newly licensed Rotarix® (RV1) is being added to this order.
- A new ACIP-recommended vaccine schedule in Section V, p 4 blends the manufacturers' recommended maximum ages for the first and last dose of Rotarix® and RotaTeq® vaccine series.
- Interchangeability recommendations for the two Rotavirus vaccines are given in Section IV, p 3.

I. <u>ORDER</u>:

1. Screen for contraindications.
2. Provide the current Vaccine Information Statement (VIS), answering any questions.
3. Obtain a signed Vaccine Administration Record (VAR).
4. Rotavirus vaccines are for oral use only.
    - o RotaTeq® (RV5) is administered orally in a 3-dose series.
    - o Rotarix® (RV1) is administered orally in a 2-dose series.
5. Both rotavirus vaccines can be administered simultaneously with other childhood vaccines indicated at the same visits, including HIB, IPV, Hepatitis B, PCV, and DTaP vaccines.

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Signature Health Officer or Medical Provider Date

II. INSTRUCTIONS FOR ORAL ADMINISTRATION OF VACCINES

A) RotaTeq® (RV5)

- Administer as soon as possible after removing vaccine from refrigerator and protect from light.
- Tear open the pouch and remove dosing tube
- Clear fluid from dispensing tip by taping cap
- Puncture dispensing tip by screwing cap clockwise
- Remove cap by turning it counterclockwise
- Administer the 2 ml suspension of oral rotavirus vaccine into the patient's mouth by gently squeezing the liquid toward the inner cheek until dosing tube is empty. (A residual drop may remain in the tip of the tube).
- Discard the empty tube and cap in approved biological waste containers
- If an infant regurgitates, spits out, or vomits during or after administration of vaccine, re-administration is **not** recommended.
- There are no restrictions on the infant's consumption of food or liquid, including breast milk, either before or after vaccination with PRV.

B) Rotarix® (RV1)

- **Reconstitute only with accompanying diluent**.(which can be refrigerated or stored at room temperature)
- **Administer within 24 hours of reconstitution.**
- Remove vial cap and push transfer adapter onto the vial.
- Connect oral applicator to transfer adapter.
- Shake oral applicator containing liquid diluent vigorously. The suspension will appear as a turbid liquid with a slow settling white deposit.
- Transfer diluent into vial.
- Withdraw reconstituted vaccine into the oral applicator.
- Twist and remove oral applicator.
- With the infant seated in reclining position administer the 1 ml. dose orally inside the cheek.
- Dispose of applicator and vaccine vial in biohazard waste container.
- If an infant regurgitates, spits out, or vomits during or after administration of vaccine, re-administration is **not** necessary**.**

III. LICENSED LIVE ROTAVIRUS VACCINES

Product Name	Vaccine components	Acceptable Age Range	Thimerosal
RotaTeq®[1,2] (Merck)	5 human-bovine reassortant virus strains: G1, G2, G3, G4, and P1[8]	6–32 weeks[3]	none
Rotarix®[1,2] (GSK)	Human strain G1P[8]	6–24 weeks[3]	none

[1] Live virus vaccines that replicate in the small intestine and induce immunity.
[2] Store and transport refrigerated at 2–8°C (36–46°F) and protect from light.
[3] Although these are the FDA-approved age ranges found in the package inserts, ACIP has recommended a 6-weeks-to-8-months range for both vaccines (Section V p. 4).

IV. RECOMMENDATIONS FOR USE

Infants

- All infants should be immunized with a 2-dose series if using Rotarix® and a 3-dose series if using RotaTeq®. The series should start no earlier than 6 weeks of age and finish no later than 8 months 0 days of age. The first dose should not be given ≥15 weeks of age.

Special Situations

- Premature Infants (i.e., those born at <37 weeks' gestation) can be immunized if they:
    1. are at least 6 weeks of age,
    2. are being or have been discharged from the hospital nursery, and
    3. are clinically stable.
- Infants living in households with persons who have or are suspected of having an immunodeficiency disorder or impaired immune status may be vaccinated.
- Infants living in households with pregnant women may be vaccinated.

Interchangeability of Rotavirus Vaccines

- ACIP recommends that the rotavirus vaccine series be completed with the same product whenever possible. However, the vaccine provider should continue or complete the series with the product available.
- If any dose in the series was RotaTeq® or the product is unknown for any dose in the series, a total of three doses of rotavirus vaccine should be given.

V. RECOMMENDED ROTAVIRUS VACCINE SCHEDULE[1]

Dose	RotaTeq® Age	Rotarix® Age
1	2 months	2 months
2	4 months	4 months
3	6 months	----------

Dosage Intervals and Ages for Rotavirus Vaccines[1]

	RV5 (RotaTeq®)	RV1 (Rotarix®)
Number of doses in series	3	2
Minimum age for 1st dose[2,3]	6 weeks	
Maximum age for 1st dose	14 weeks 6 days[4]	
Interval between doses[2]	≥4 weeks	
Maximum age for last dose	8 months 0 days	

[1]If any dose in the series was RotaTeq® or the product is unknown for any dose in the series, a total of three doses of rotavirus vaccine should be given

[2]For retrospective checking, doses that violate the minimum spacing or age by 4 or fewer days do not need to be repeated

[3]Premature Infants (i.e., those born at <37 weeks' gestation) can be immunized if they

a) are 6 weeks of age,
b) are being or have been discharged from the hospital nursery, and are clinically stable.
c) are clinically stable.

[4]Vaccination should not be initiated for infants ≥15 weeks of age. However, for infants in whom the 1st dose of a rotavirus vaccine is inadvertently administered off label at age ≥15 weeks, the rest of the vaccination series can be continued and completed per the schedule as long as the infant is ≤8 months of age.

VI. CONTRAINDICATIONS

A. History of severe allergic reaction(e.g., anaphylaxis) after a previous dose of rotavirus vaccine or to a vaccine component

B. Since latex rubber is contained in the Rotarix® oral applicator, infants with a severe (anaphylactic) latex allergy should not receive Rotarix®.

VII. PRECAUTIONS

A. Altered immunocompetence[1]
   - o Infants with blood dyscrasias, leukemia, lymphomas of any type, or other malignant neoplasms affecting the bone marrow or lymphatic system
   - o Infants on immunosuppressive therapy (including high-dose systemic corticosteroids)
   - o Infants with primary and acquired immunodeficiency states, including HIV/AIDS or other clinical manifestations of infection with human immunodeficiency viruses; cellular immune deficiencies; and hypogammaglobulinemic and dysgammaglobulinemic states.
   - o Infants with indeterminate HIV status who are born to mothers with HIV/AIDS
   - o Infants who have received a blood transfusion or blood products, including immunoglobulins, within 42 days

B. Moderate or severe illness, including acute gastroenteritis

C. Preexisting chronic gastrointestinal disease[2]

D. Previous history of intussusception[3]

[1]Consultation with an immunologist or ID specialist is advised when considering the risks and benefits of giving rotavirus vaccine to infants with known or suspected altered immune states since no safety or efficacy data are available for rotavirus vaccine in this population.

[2] Infants with congenital malabsorption syndromes, Hirschsprung's disease, or short-gut syndrome who are not undergoing immunosuppressive therapy should benefit from rotavirus vaccine, and ACIP considers the benefits to outweigh the theoretical risks.

[3]Compared to infants who have never had intussusception, infants with a history of intussusception are at higher risk for a repeat episode of intussusception.

VIII. ROTAVIRUS VACCINE ADVERSE REACTIONS

RotaTeq®(RV5) Adverse Reactions in first 7 days of any dose[1]

	Vaccine Recipients	Placebo Recipients
Vomiting	15%	14%
Diarrhea	24%	21%
Nasopharyngitis	7%	6%
Fever	43%	43%

[1]No serious adverse reactions were reported

MMWR 2006; 55(RR-12)1–13

RotaTeq® (RV5) Vaccine and Intussusception

	Vaccine Recipients N = 34,035	Placebo Recipients N = 34,003
Within 42 days of Vaccination	6 cases	5 cases
Within 1 year of Vaccination	12 cases	15 cases

New Eng J Med 2006; 354: 23–33

Rotarix® Adverse Reactions within 8 days of Dose 1 and Dose 2

Adverse Reactions	Dose 1		Dose 2	
	Rotarix %	Placebo%	Rotarix%	Placebo%
Fussiness/irritability	52	52	42	42
Cough/runny nose	28	30	31	33
Fever ≥100.4ºF rectally or ≥99.5ºF oral	25	33	28	34
Loss of appetite	25	25	21	21
Vomiting	13	11	8	8
Diarrhea	4	3	3	3

2008 Rotarix® package insert p. 6

Rotarix® (RV1) Vaccine and Intussusception

	Vaccine Recipients N = 31,673	Placebo Recipients N = 31,552
Within 100 days of Dose #1	9 cases	16 cases

2008 Rotarix® package insert p.7

IX. OTHER CONSIDERATIONS

A Hospitalization after Vaccination: If a recently vaccinated child is hospitalized for any reason, no precautions beyond the routine universal precautions need be taken to prevent the spread of vaccine virus in the hospital setting.

B Immunosuppressive therapies including irradiation, antimetabolites, alkylating agents, cytotoxic drugs and corticosteroids may reduce the immune response to vaccine.

X. ADVERSE EVENT REPORTING

Adverse events following immunization should be reported by public providers to the State Public Health Immunization Program, DHS, using a Vaccine Adverse Events Reporting System form (VAERS), according to state guidelines. Private providers should report all adverse events directly to VAERS.

VAERS phone number: 800-822-7967, and the website address is http://vaers.hhs.gov.

XI. REFERENCES

1. CDC. ACIP. provisional recommendations for the prevention of rotavirus gastroenteritis among infants and children. Available at www.cdc.gov/vaccines/recs/provisional/downloads/roto-7-1-08-508.pdf .
2. RotaTeq® package insert. Available at: www.merck.com/product/usa/pi_circulars/r/rotateq/rotateq_pi.pdf.
3. Rotarix® 2008 package insert. Available at: www.fda.gov/Cber/label/rotarixLB.pdf
4. ACIP. VFC Resolution No. 6/08-1; Vaccines To Prevent Rotavirus Gastroenteritis. Available at: www.cdc.gov/vaccines/programs/vfc/downloads/resolutions/0608rotavirus.pdf
5. CDC. Prevention of rotavirus gastroenteritis among infants and children: recommendations of the Advisory committee on Immunization Practices (ACIP). MMWR 2006; 55(RR-12).
6. Ruiz-Palacios GM, Pérez-Schael I, Velázquez FR, et al. Safety and efficacy of an attenuated vaccine against severe rotavirus gastroenteritis. N Engl J Med 2006; 354:11–22.
7. Vesikari T, Matson DO, Dennehy P, et al. Safety and efficacy of a pentavalent human-bovine (WC3) reassortant rotavirus vaccine. N Engl J Med 2006; 354:23–33.

For more information or to clarify any part of the above order, consult with your health officer or call the Oregon State Public Health Division Immunization Program

at 971-673-0300.

To download a copy visit our website at
http://oregon.gov/DHS/ph/imm/provider/stdgordr.shtml.
To request this material in an alternate format (e.g., Braille),
please call 971-673-0300.