Immunization Protocol

ORAL ROTAVIRUS (RotaTeq® and ROTARIX®) LIVE VIRUS VACCINES	
Last Reviewed	30 July 2021
Last Revised	30 July 2021
This order expires	31 July 2023

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1. What's new

No changes from the previous version.

2. Oregon immunization model standing order / pharmacy protocol

A. Check the ALERT Immunization Information System (IIS) to determine whether the patient needs this vaccine and any other vaccines.

B. Screen clients for contraindications and precautions.

C. Provide a current Vaccine Information Statement (VIS), answering any questions.

D. Record all required data elements in the client's permanent health record.

E. Rotavirus vaccines are for oral use only.

F. Both rotavirus vaccines can be administered simultaneously with other childhood vaccines indicated at the same visits, including Influenza, HIB, IPV, Hepatitis B, PCV, and DTaP vaccines.

Health Officer Signature Date

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3. Vaccine schedule for rotavirus vaccines[3]

Dose and Route: RotaTeq® — 2 mL, oral					
Dose	**Preferred age**	**Minimum acceptable age 1st dose**	**Maximum age 1st dose**	**Minimum acceptable spacing**	**Maximum acceptable age for last dose**
1	2 months	6 weeks	14 weeks, 6 days		
2	4 months			4 weeks	
3*	6 months			4 weeks	8 months, 0 days
Dose and Route: Rotarix® — 1 mL, oral					
Dose	**Preferred age**	**Minimum acceptable age**	**Maximum age 1st dose**	**Minimum acceptable spacing**	**Maximum acceptable age for last dose**
1	2 months	6 weeks	14 weeks, 6 days		
2	4 months			4 weeks	8 months, 0 days

*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.

4. Licensed rotavirus vaccines

Product Name	Vaccine Components	Acceptable Age Range	Thimerosal
RotaTeq (RV5)[2]	5 human–bovine reassortant virus strains: G1, G2, G3, G4 and P1A[8]	6–32 weeks*	No
ROTARIX (RV1)[1]	Human strain G1P[8]	6–24 weeks*	No

*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.[3]

5. Recommendations for use:

A. All infants should be immunized with a 2-dose series if using ROTARIX and a 3-dose series if using RotaTeq.

B. Premature Infants (i.e., those born at <37 weeks' gestation) can be immunized if they are:
   - at least 6 weeks of age,
   - being or have been discharged from the hospital nursery, and
   - clinically stable.[3]

C. Infants living in households with persons who have or are suspected of having an immunodeficiency disorder or impaired immune status may be vaccinated.

D. Infants living in households with pregnant women may be vaccinated.[3]

E. 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.[3]

F. 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.[3]

6. Contraindications:

A. History of severe allergic reaction (e.g., anaphylaxis) after a previous dose of rotavirus vaccine or to a vaccine component[3]

Vaccine	Vaccine Excipient Summary[7]
RotaTeq	sucrose, sodium citrate, sodium phosphate monobasic monohydrate, sodium hydroxide, polysorbate 80, cell culture media, fetal bovine serum. DNA from porcine circoviruses (PCV) 1 and 2 has been detected in RotaTeq. PCV-1 and PCV2 are not known to cause disease in humans.
ROTARIX	dextran, Dulbecco's Modified Eagle Medium (sodium chloride, potassium chloride, magnesium sulfate, ferric nitrate, sodium phosphate, sodium pyruvate, D-glucose, concentrated vitamin solution, L-cystine, L-tyrosine, amino acids, L-glutamine, calcium chloride, sodium hydrogenocarbonate, and phenol red), sorbitol, sucrose, calcium carbonate, sterile water, xanthan. Porcine circovirus type 1 (PCV1) is present in Rotarix. PCV-1 is not known to cause disease in humans.

B. Latex rubber is contained in the Rotarix® (RV1) oral applicator, so infants with a severe (anaphylactic) allergy to latex should not receive Rotarix®. (the RotaTeq® [RV5] dosing tube is latex-free).[3]

C. Infants with severe combined immunodeficiency disease (SCID)[4]

D. Previous history of intussusception[5]

7. Warnings and precautions:

A. Practitioners should consider the potential risks and benefits of administering rotavirus vaccine to infants with known or suspected altered immunocompetence; consultation with an immunologist or infectious diseases specialist is advised.[3]

B. Acute, moderate or severe gastroenteritis or other acute illness. However, infants with mild acute gastroenteritis can be vaccinated, particularly if the delay in vaccination might be substantial and might make the infant ineligible to receive vaccine (e.g., aged >15 weeks and 0 days before the vaccine series is started).[3]

8. Other considerations:

A. The practitioner should not readminister a dose of rotavirus vaccine to an infant who regurgitates, spits out, or vomits during or after administration of vaccine. The infant should receive the remaining recommended doses of rotavirus vaccine following the routine schedule (with a 4-week minimum interval between doses).[3]

B. 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.[3]

C. There is no evidence that breast feeding post vaccination reduces protection against rotavirus afforded by the vaccine. No restriction on an infant's liquid consumption before or after vaccination is recommended.[3]

D. Some experts prefer RotaTeq vaccine for infants with spina bifida or bladder exstrophy to minimize latex exposure in these children who are at increased risk of acquiring a latex allergy.[3]

9. Side effects and adverse reactions:

Adverse Reaction*	RotaTeq Frequency[2]	ROTARIX Frequency[1]
Fussiness/irritability	Up to 7.1%	Up to 52%
Cough/runny nose		Up to 28%
Fever	Up to 43%	Up to 25%
Loss of appetite		Up to 25%
Vomiting	Up to 15.2%	Up to 13%
Diarrhea	Up to 24.1%	Up to 4%
Otitis Media	Up to 14.5%	
Nasopharyngitis	Up to 6.9%	
Bronchospasm	Up to 1.1%	

*Within 1 week after first dose

10. Storage and handling:

All clinics and pharmacies enrolled with the Vaccines for Children (VFC) Program must immediately report any storage and handling deviations to the Oregon Immunization Program at 971-673-4VFC (4823).

Vaccine	Temp	Storage Issues	Notes
RotaTeq[2]	Store at 2°–8°C (36˚F–46˚F)	Administer as soon as possible after removing vaccine from refrigerator and protect from light.	No latex
ROTARIX[1]			Natural rubber latex in the tip caps
ROTARIX Diluent[1]	Store at 2°–8°C (36˚F–46˚F) **or** Room Temperature	Administer within 24 hours of reconstitution.	

11. Adverse events reporting:

Report suspected adverse events to the Vaccine Adverse Events Reporting System (VAERS) online at https://vaers.hhs.gov/reportevent.html. VAERS Reporting Table: https://vaers.hhs.gov/resources/infoproviders.html

Event and interval from vaccination
A. Intussusception (21 days)
B. Any acute complication or sequelae (including death) of above events (interval - not applicable)
C. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)

12. References

1. ROTARIX® package insert, available at: www.fda.gov/media/75726/download. Accessed 16 July 2021.
2. RotaTeq® (2017) package insert, available at: www.fda.gov/media/75718/download. Accessed 16 July 2021.
3. Cortese M, Parashar U. Prevention of rotavirus gastroenteritis among infants and children. Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2009; 58(2);1–25. Available at: www.cdc.gov/mmwr/PDF/rr/rr5802.pdf. Accessed 16 July 2021.
4. CDC. Addition of severe combined immunodeficiency as a contraindication for administration of rotavirus vaccine. MMWR 2010; 59(22):687–8. Available at: www.cdc.gov/mmwr/pdf/wk/mm5922.pdf. Accessed 16 July 2021.
5. CDC. Addition of history of Intussusception as a contraindication for rotavirus vaccination. MMWR 2011; 60(41):1427. Available at: www.cdc.gov/mmwr/pdf/wk/mm6041.pdf. Accessed 16 July 2021.
6. Kroger A, Bahta L, Hunter P. General Best Practice Guidelines for Immunization. Updated May 4, 2021. Available at: www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html. Accessed 16 July 2021.
7. CDC. Vaccine Excipient Table. February 2020. Available at: hwww.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf. Accessed 7 July 2021.

To request this material in an alternative format (e.g., Braille) or to clarify any part of the above order, contact the Oregon Health Authority Immunization Program at 971-673-0300 and 711 for TTY. For other questions, consult with the vaccine recipient's primary health care provider or a consulting physician.

Electronic copy of this standing order is available at: standing orders

13. Appendix A

Not applicable.