OREGON HEALTH AUTHORITY
IMMUNIZATION PROGRAM

I. OREGON IMMUNIZATION MODEL STANDING ORDER:

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

2. Screen clients for contraindications.

3. Provide a current Vaccine Information Statement (VIS), and answer any questions.

4. Record all required data elements in the client’s permanent health record.

5. Rotavirus vaccines are for oral use only: See Appendices A and B, for assembly directions.

<table>
<thead>
<tr>
<th>Dose</th>
<th>Recommended age</th>
<th>Minimum Age 1st dose</th>
<th>Maximum age 1st dose</th>
<th>Minimal Acceptable Spacing</th>
<th>Maximum age for last dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2 mo</td>
<td>2 mo</td>
<td>6 weeks</td>
<td>14 weeks 6 days‡</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>4 mo</td>
<td>4 mo</td>
<td></td>
<td>≥4 weeks◊</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>6 mo</td>
<td></td>
<td></td>
<td></td>
<td>8 mo 0 days</td>
</tr>
</tbody>
</table>

See section II for footnotes

6. 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.
INSTRUCTIONS FOR ORAL ADMINISTRATION OF VACCINES

A) RotaTeq® (RV5)\(^1\) (Images in Appendix A)

- 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 RotaTeq® 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)\(^2\) (Images in Appendix B)

- 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 (lyophilized vaccine).
- Shake oral applicator containing liquid diluent vigorously. The suspension will appear as a turbid liquid with a slow settling white deposit.
- Connect oral applicator to transfer adapter.
- Push plunger of oral applicator to 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.
II. RECOMMENDED VACCINE SCHEDULE\textsuperscript{1, 2, 3}

* If any dose in the series was RotaTeq\textsuperscript{®} or the product is unknown for any dose in the series, a total of three doses of rotavirus vaccine should be given \textsuperscript{4}

◊ For retrospective checking, doses that violate the minimum spacing or age by 4 or fewer days do not need to be repeated \textsuperscript{4}

§ Premature Infants (i.e., those born at <37 weeks’ gestation) can be immunized if they
   a) are at least 6 weeks of age, and younger than 14 weeks and 6 days for dose 1.\textsuperscript{5}
   b) are being or have been discharged from the hospital nursery, and are clinically stable.
   c) are clinically stable. \textsuperscript{4}

‡ Vaccination should not be initiated for infants ≥15 weeks of age. However, for infants in whom the 1\textsuperscript{st} 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.\textsuperscript{6}

III. LICENSED LIVE ROTAVIRUS ORAL VACCINES\textsuperscript{1, 2}

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Vaccine Components</th>
<th>Acceptable Age Range</th>
<th>Dose and Route</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rota Teq\textsuperscript{®} (RV5)</td>
<td>5 human–bovine reassortant virus strains: G1, G2, G3, G4 and P1A[8]</td>
<td>6–32 weeks\textsuperscript{§}</td>
<td>2mL Orally</td>
</tr>
<tr>
<td>Rotarix\textsuperscript{®} (RV1)</td>
<td>Human strain G1P[8]</td>
<td>6–24 weeks\textsuperscript{§}</td>
<td>1mL orally</td>
</tr>
</tbody>
</table>

* Live virus vaccines that replicate in the small intestine and induce immunity.
◊ Store and transport refrigerated at 2–8°C (36–46°F) and protect from light.
§ 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).\textsuperscript{3, 4}
IV. RECOMMENDATIONS FOR USE

A. 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. 3, 4

B. Special Situations
Premature Infants (i.e., those born at <37 weeks’ gestation) can be immunized if they:
- are at least 6 weeks of age,
- are being or have been discharged from the hospital nursery, and
- are clinically stable. 3, 4

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.4

C. 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.4

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

V. CONTRAINDICATIONS

A. The tip caps of the Rotarix® prefilled oral applicators of diluent may contain natural rubber latex which may cause allergic reactions in latex-sensitive individuals.2

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

C. Since latex rubber is contained in the Rotarix® oral applicator, infants with a severe anaphylactic latex allergy should not receive Rotarix®. (RotaTeq® is latex free).3

D. RotaTeq® and Rotarix®: history of severe combined immunodeficiency disease (SCID)*3, 6

E. Previous history of intussusception◊ 3, 5
* SCID is a severe defect in both the T- & B-lymphocyte systems. This usually results in the onset of one or more serious infections within the first few months of life.\(^3,5\)

◊ Infants with a history of intussusception are at a higher risk for a repeat episode. \(^3,5\)

VI. PRECAUTIONS AND WARNINGS

A. Altered immunocompetence
   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.\(^5\)

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).\(^5\)
### VII. A. SIDE EFFECTS AND ADVERSE EVENTS

Solicited adverse events within 8 days following dose 1 of Rotarix®1 or Placebo (Total vaccinated cohort)

<table>
<thead>
<tr>
<th>Number followed for Safety</th>
<th><strong>Rotarix®</strong> Study Number N =3,284</th>
<th><strong>Placebo</strong> Study Number N=2,013</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adverse Reaction %</td>
<td>Dose 1 Infants</td>
<td>Dose 1 infants</td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Systemic Complaints</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diarrhea</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>Vomiting</td>
<td>13</td>
<td>11</td>
</tr>
<tr>
<td>Loss of appetite</td>
<td>25</td>
<td>25</td>
</tr>
<tr>
<td>Fever ≥100.4°F (≥38.0°C) rectally or ≥99.5°F (≥37.5°C) orally</td>
<td>25</td>
<td>33</td>
</tr>
<tr>
<td>Cough/ runny nose</td>
<td>28</td>
<td>30</td>
</tr>
<tr>
<td>Fussiness/irritability</td>
<td>52</td>
<td>52</td>
</tr>
</tbody>
</table>

Table 1, page 6 package insert¹
VII. B. SIDE EFFECTS AND ADVERSE EVENTS

Adverse events that occurred at a statistically higher incidence within 42 days of any dose among recipients of RotaTeq® as compared with placebo recipients

<table>
<thead>
<tr>
<th>Number followed for Safety</th>
<th>Rota Teq®</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Study Number</td>
<td>Study Number</td>
</tr>
<tr>
<td></td>
<td>N =6,138</td>
<td>N=5,573</td>
</tr>
<tr>
<td>Adverse Reaction %</td>
<td>Dose 1</td>
<td>Adverse Reaction %</td>
</tr>
<tr>
<td>Infants</td>
<td></td>
<td>Dose 1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>infants</td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Systemic Complaints</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diarrhea</td>
<td>24.1</td>
<td>21.3</td>
</tr>
<tr>
<td>Vomiting</td>
<td>15.2</td>
<td>13.6</td>
</tr>
<tr>
<td>Otitis Media</td>
<td>14.5</td>
<td>13.0</td>
</tr>
<tr>
<td>Nasopharyngitis</td>
<td>6.9</td>
<td>5.8</td>
</tr>
<tr>
<td>Bronchospasm</td>
<td>1.1</td>
<td>0.7</td>
</tr>
<tr>
<td>Fever*</td>
<td>42.6</td>
<td>42.8</td>
</tr>
</tbody>
</table>

Table 5, page 6 package insert²

*Temperature ≥100.5°F [38.1°C] rectal equivalent obtained by adding 1 degree F to otic and oral temperatures and 2 degrees F to axillary temperatures.²
VIII. OTHER CONSIDERATIONS

1. **Adverse Events**: epinephrine hydrochloride solution (1:1,000) and other appropriate agents and equipment must be available for immediate use in case of anaphylactic or acute hypersensitivity reaction. ⁴

2. **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. ³

3. **Immunosuppressive therapies** including irradiation, antimetabolites, alkylating agents, cytotoxic drugs and corticosteroids may reduce the immune response to vaccine. ²

4. **Infant Feeding**: breast feeding OK; no evidence that breast feeding reduced the protection against rotavirus afforded by Rotarix®. No restriction on infant’s liquid consumption before or after vaccination. ³

5. **Regurgitation of Vaccine**: 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. No data exist on the benefits or risks associated with readministering a dose. The infant should receive the remaining recommended doses of rotavirus vaccine following the routine schedule (with a 4-week minimum interval between doses). ⁵
## IX. 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).

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Temp</th>
<th>Storage Issues</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rota Teq®️₁</td>
<td>Store at 2°–8°C (36°F–46°F)</td>
<td>Administer as soon as possible after removing vaccine from refrigerator and protect from light.</td>
<td>No latex.</td>
</tr>
<tr>
<td>Rotarix®️₂</td>
<td>Reconstitute only with accompanying diluent.</td>
<td>Natural rubber latex in the tip caps.</td>
<td></td>
</tr>
<tr>
<td>Rotarix®️₂ Diluent</td>
<td>Store at 2°–8°C (36°F–46°F) or Room Temperature</td>
<td>Administer within 24 hours of reconstitution.</td>
<td></td>
</tr>
</tbody>
</table>
X. ADVERSE EVENTS REPORTING
Public providers are to complete the Vaccine Adverse Events Reporting System (VAERS) report online at https://vaers.hhs.gov/reportevent.html

1. Save a copy of the report number for your records
2. Send copies of the report and VAERS ID number to the Oregon Immunization Program Vaccine Safety Coordinator via confidential email at ORVAERS.Reports@state.or.us or fax (971-673-0278).

Private providers are to report events directly to VAERS and can read about options on how to do so at https://vaers.hhs.gov/reportevent.html.

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: http://1.usa.gov/OregonStandingOrders

VAERS Reporting Table *:
https://vaers.hhs.gov/docs/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf

<table>
<thead>
<tr>
<th>Event and interval from vaccination</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Intussusception (21 days)</td>
</tr>
<tr>
<td>B. Any acute complication or sequelae (including death) of above events (interval - not applicable)</td>
</tr>
<tr>
<td>C. Events described in manufacturer’s package insert as contraindications to additional doses of vaccine (interval - see package insert)</td>
</tr>
</tbody>
</table>

Effective date: March 21, 2017. The Reportable Events Table (RET) reflects what is reportable by law (42 USC 300aa-25) to the Vaccine Adverse Event Reporting System (VAERS) including conditions found in the manufacturer package insert. In addition, healthcare professionals are encouraged to report any clinically significant or unexpected events (even if not certain the vaccine caused the event) for any vaccine, whether or not it is listed on the RET.
Reconstitution Instructions for Oral Administration of Rotarix®

Remove vial cap and push transfer adapter onto vial (lyophilized vaccine)

Shake diluent in oral applicator (white, turbid suspension). Connect oral applicator to transfer adapter.

Push plunger of oral applicator to transfer diluent into vial. Suspension will appear white and turbid.

Withdraw vaccine into oral applicator.

Twist and remove the oral applicator.
Ready for oral administration

Do not use a needle with ROTARIX®.
APPENDIX B

Instructions for RotaTeq® for oral administration.

Tear open the pouch and remove the dosing tube.

Clear the fluid from the dispensing tip by holding tube vertically and tapping cap.

Open the dosing tube in 2 easy motions:

1. Puncture the dispensing tip by screwing cap clockwise until it becomes tight.

2. Remove cap by turning it counterclockwise.

Administer dose by gently squeezing liquid into infant's mouth toward the inner cheek until dosing tube is empty. (A residual drop may remain in the tip of the tube.)

Not for Injection
REFERENCES

1. Rotarix® (nd) package insert, available at: 

2. RotaTeq® (2017) package insert, available at: 


   https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html
   Accessed 01 June 2018.

5. CDC. Prevention of rotavirus gastroenteritis among infants and children. 