STANDING ORDERS FOR
Administering Rotavirus Vaccine to Infants

Purpose

To reduce morbidity and mortality from rotavirus disease by vaccinating all infants who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Policy

Where allowed by state law, standing orders enable eligible nurses, pharmacists, and other healthcare professionals to assess the need for and vaccinate children and teens who meet any of the criteria below.

Procedure

1 Assess Infants in Need of Vaccination against rotavirus disease based on the following criteria:

Routine rotavirus vaccination

- Age 6 weeks through 14 weeks, 6 days who have not initiated a series of rotavirus vaccine
- Age 8 months, 0 days or younger who have not completed a series of rotavirus vaccine

2 Screen for Contraindications and Precautions

Contraindications

- Do not give rotavirus vaccine (Rotarix [RV1] by GSK or RotaTeq [RV5] by Merck) to a child who has experienced a serious reaction (e.g., anaphylaxis) to a prior dose of the vaccine or to any of its components. For information on vaccine components, refer to the manufacturers' package insert (www.immunize.org/official-guidance/fda/pkg-inserts/) or go to www.fda.gov/vaccines-blood-biologics/vaccines/vaccines-licensed-use-united-states. If child has allergy to latex, use RV5.
- Do not give rotavirus vaccine to an infant who has had a diagnosis of severe combined immunodeficiency (SCID).
- Do not give rotavirus vaccine to an infant who has a history of intussusception.

Precautions (required evaluation before vaccination)

- Moderate or severe acute illness, with or without fever
- Altered immunocompetence other than SCID
- Chronic gastrointestinal disease
- For RV1 only, spina bifida or bladder exstrophy

3 Provide Vaccine Information Statements

Provide all patients (or, in the case of minors, their parent, or legal representative) with a copy of the most current federal Vaccine Information Statement (VIS). Provide non-English speaking patients with a copy of the VIS in their native language, if one is available and desired; these can be found at www.immunize.org/vaccines/vis/rotavirus/. For information about how to document that the VIS was given, see section 6 titled "Document Vaccination."

4 Prepare to Administer Vaccine

Both rotavirus vaccines (RV1 and RV5) are given by mouth. Never inject these vaccines.

Note: RV1 (Rotarix) may be packaged as either (a) an oral dosing applicator only (does not need reconstitution or dilution before use), or (b) a lyophilized vaccine powder with an oral dosing applicator containing diluent (requires reconstitution not more than 24 hours before use).

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The schedule for administering each vaccine is as follows:

VACCINE PRODUCT	SCHEDULE
Rotarix (RV1)	Ages 2m[1], 4m[2,3]
RotaTeq (RV5)	Ages 2m[1], 4m[2], 6m[2,3]

1 May give dose #1 as early as age 6 weeks, but not exceeding age 14 weeks, 6 days.

2 Intervals between doses may be as short as 4 weeks.

3 Give final dose no later than age 8 months, 0 days.

Note: If prior vaccination included use of a different or unknown brand(s), a total of 3 doses should be given.

5 Administer Rotavirus Vaccine (RV1 or RV5) to all healthy children via the oral route according to the guidance on page 4 "How to Administer Intranasal and Oral Vaccinations."

6 Document Vaccination

Document each patient's vaccine administration information and update the following:

- Medical record: Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and address and, if appropriate, the title of the person administering the vaccine. You must also document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. Note that medical records/charts should be documented and retained in accordance with applicable state laws and regulations. If vaccine was not administered, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal); plan to discuss the need for vaccine with the patient's parent or legal representative at the next visit.
- Personal immunization record card: Record the date of vaccination and the name/location of the administering clinic.
- Immunization Information System (IIS) or "registry": Report the vaccination to the appropriate state or local IIS, if available.

7 Be Prepared to Manage Medical Emergencies

Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications. For Immunize.org's "Medical Management of Vaccine Reactions in Children and Teens in a Community Setting," go to www.immunize.org/catg.d/p3082a.pdf. For "Medical Management of Vaccine Reactions in Adult Patients in a Community Setting," go to www.immunize.org/catg.d/p3082.pdf.

8 Report Adverse Events to VAERS

Report all adverse events following the administration of rotavirus vaccine to the federal Vaccine Adverse Event Reporting System (VAERS). To submit a VAERS report online (preferred) or to download a writable PDF form, go to https://www.vaers.hhs.gov/reportevent.html. Further assistance is available at (800) 822-7967.

Standing Orders Authorization

This policy and procedure shall remain in effect for all patients of the _____ (NAME OF PRACTICE OR CLINIC)

effective _____ (DATE) until rescinded or until _____ (DATE) .

Medical Director _____ (PRINT NAME) / _____ (SIGNATURE) _____ (DATE)

How to Administer Intranasal and Oral Vaccinations

While most vaccines are administered by either intramuscular or subcutaneous injection, there are several vaccines that are administered through other means. These include the intradermal route, the intranasal route, and the oral route. Here are some simple instructions to use as a guide. Complete information is available in the package inserts and can also be obtained at www.immunize.org/fda.

Nasal spray: Influenza vaccine

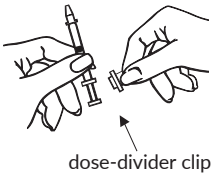
■ *FluMist by AstraZeneca, Live Attenuated Influenza Vaccine (LAIV)*

Instructions for administration by a healthcare provider in a healthcare setting:

1 FluMist (LAIV) is for intranasal administration only. Do not inject FluMist.

2 Remove the rubber tip protector. Do not remove the dose-divider clip at the other end of the sprayer.

3 With the patient in an upright position, place the tip just inside the nostril to ensure LAIV is delivered into the nose. The patient should breathe normally.



4 With a single motion, depress the plunger as rapidly as possible until the dose-divider clip prevents you from going further.

5 Pinch and remove the dose-divider clip from the plunger.

6 Place the tip just inside the other nostril, and with a single motion, depress plunger as rapidly as possible to deliver the remaining vaccine.

7 Dispose of the sprayer according to the standard procedures for medical waste (such as in a sharps container or biohazard container).

Oral drops: Rotavirus vaccines

■ *Rotarix by GSK – available in two presentations: (a) a vial and oral dosing applicator (requires reconstitution) and (b) a fully liquid oral dosing applicator only.*

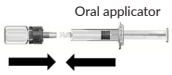
If using the fully liquid presentation,

1 Remove the cap from the oral dosing applicator.

2 Follow steps 6 and 7 below.

If using vial and oral dosing applicator (requires reconstitution),

1 Remove the cap of the vial and push the transfer adapter onto the vial (lyophilized vaccine).



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

3 Push the plunger of the oral applicator to transfer the diluent into the vial. The suspension will appear white and cloudy.

4 Withdraw the vaccine into the oral applicator.

5 Twist and remove the oral applicator from the vial.

6 Administer the dose by gently placing the applicator plunger into the infant's mouth toward the inner cheek and gently expelling the contents until the applicator is empty.

7 Discard the empty vial (if lyophilized vaccine was used), cap, and oral applicator in an approved biological waste container according to local regulations.

■ *Rotateq by Merck*

1 Tear open the pouch and remove the dosing tube. Clear the fluid from the dispensing tip by holding the tube vertically and tapping the cap.

2 Open the dosing tube in two easy motions:

a) Puncture the dispensing tip by screwing cap **clockwise** until it becomes tight.

b) Remove the cap by turning it **counter-clockwise**.

3 Administer the 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.)

4 Discard the empty tube and cap in an approved biological waste container according to local regulations.

Note: If, for any reason, an incomplete dose is administered (e.g., infant spits or regurgitates the vaccine), a replacement dose is not recommended.