

Standing Orders for Administering Rotavirus (ROTARIX®) Vaccine to Infants

Purpose: To reduce morbidity and mortality from rotavirus (RV) gastroenteritis disease by vaccinating all infants who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP), the Food and Drug Administration (FDA) product labeling, and the Department of Defense (DoD).

Policy: Under these standing orders, eligible nurses and other healthcare professionals working within their scope of practice may vaccinate infants who meet the criteria below.

Procedure

1. Identify infants ages 6 weeks through 24 weeks of age who have not completed a rotavirus (RV) vaccination series.

Note: ACIP recommendations allow for the final dose in the series of the rotavirus vaccine schedule as late as 8 months and zero days old. However, dosing ROTARIX after 24 weeks of age is **considered off-label** and would not be covered under this standing order. Please obtain an order from the patient's primary care manager if indicated.

2. Screen all patients for contraindications and precautions to rotavirus vaccine:

Contraindications:

- history of a serious allergic reaction (e.g., anaphylaxis) after a previous dose of RV vaccine or to an RV vaccine component. For information on vaccine components, refer to the [manufacturers' package insert](#) or go to <http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/b/excipient-table-2.pdf>
- diagnosis of severe combined immunodeficiency (SCID)
- history of intussusception
- history of an uncorrected congenital malformation of the gastrointestinal tract such as Meckel's diverticulum

Precautions:

- altered immunocompetence
- chronic gastrointestinal disease
- spina bifida or bladder exstrophy
- moderate or severe acute illness with or without fever
- use caution when vaccinating latex-sensitive individuals since the tip caps of the oral applicator of diluent may contain natural latex rubber that may cause allergic reactions in latex-sensitive individuals.
- ROTARIX should be delayed in infants suffering from acute diarrhea or vomiting
- For questions or concerns, consider consulting the DHA Immunization Healthcare Branch at 877-438-8222, Option 1.
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3. Provide all patients (or their parent/legal representative) with a copy of the most current federal [Vaccine Information Statement \(VIS\)](#). You must document, in the patient's medical record, the publication date of the VIS and the date it was given to the patient (parent/legal representative). Provide non-English speaking patients with a copy of the VIS in their native language, if available and preferred; these can be found at www.immunize.org/vis.

4. Provide routine vaccination with ROTARIX as a 2-dose series at ages 2 and 4 months. Administer the full dose (1 mL for ROTARIX) of vaccine by administering the entire contents of the dosing applicator of the liquid vaccine into the infant's mouth toward the inner cheek until empty. Note that ROTARIX needs to be reconstituted before administration.
5. For infants who have not received RV vaccine by age 2 months, give the first dose at the earliest opportunity but no later than age 14 weeks 6 days. Then schedule subsequent doses by observing minimum intervals of 4 weeks between the remaining dose such that the final dose can be administered by age 24 weeks. Do not administer ROTARIX vaccine beyond the age of 24 weeks.

Note: ACIP recommendations allow RV vaccine initiation as late as 15 weeks with a maximum age for the final dose in the series to be 8 months and zero days.

6. Documentation
 - Document all immunizations administered in the electronic health record. Include date, immunization given, dose, anatomical location of administration, lot number, manufacturer, Vaccine Information Sheet (VIS) date, and the identification of the person administering the vaccine. If vaccine was not given, record the reason for non-receipt.
7. Be prepared to manage a medical emergency related to the administration of vaccines by having a written emergency medical protocol available, as well as equipment and medications.
8. Adverse Events occurring after administration of any vaccine should be reported to the Vaccine Adverse Event Reporting System (VAERS). Reports can be submitted to VAERS online, by fax, or by mail. Additional information about VAERS is available by telephone (1-800-822-7967) or online at <https://vaers.hhs.gov>.
9. This policy and procedure shall remain in effect for all patients of the _____ until rescinded and/or upon a change in the Medical Director, whichever is earlier.

Medical Director's Signature

Date