



North Carolina Department of Health and Human Services
Division of Public Health – Women’s & Children’s Health Section

1917 Mail Service Center • Raleigh, North Carolina 27699-1917

Tel 919-707-5550 • Fax 919-870-4824

Michael F. Easley, Governor

Dempsey Benton, Secretary

December 1, 2008

MEMORANDUM

TO: Universal Childhood Vaccine Distribution Program (UCVDP) Participants

FROM: Beth Rowe-West, R.N., B.S.N., Head,
Immunization Branch

SUBJECT: Availability of Additional Rotavirus Vaccine Product

The purpose of this memo is to announce the availability of the rotavirus vaccine, Rotarix®, as an alternative to the currently available rotavirus vaccine, RotaTeq®. Effective **December 1, 2008**, the Universal Childhood Vaccine Distribution Program (UCVDP) will provide Rotarix® in addition to RotaTeq® for children who are eligible under the Vaccines for Children (VFC) program. Manufactured by GlaxoSmithKline, Rotarix®, CPT® 90681, is a monovalent rotavirus vaccine licensed for a two-dose series. RotaTeq®, manufactured by Merck, is a pentavalent rotavirus vaccine licensed for a three-dose series, CPT® 90680.

Below are questions and answers regarding the eligibility, ordering, storage, and accountability protocols associated with the administration of Rotarix® for UCVDP providers choosing to use this vaccine.

Which children are eligible for Rotarix® and RotaTeq®?

Both vaccines are available for administration to children from 2 months through 7 months of age for the rotavirus vaccination series who meet one or more of the following VFC criteria:

- Medicaid eligible
- Uninsured
- American Indian or Alaskan Native or
- Underinsured (that is, children whose health insurance benefit plan does not cover the full cost of vaccinations, regardless of where they receive immunizations).

When may our practice begin ordering state-supplied Rotarix®?

You may begin ordering on **Monday, December 1, 2008**. Please allow one to two weeks for delivery. For those providers not using the North Carolina Immunization Registry (NCIR), an order form is attached.

Are we required to use this vaccine?

No. Although UCVDP does require providers to carry and provide all vaccines recommended by the Advisory Committee on Immunization Practices (ACIP), in this case there are two rotavirus vaccines available. **Providers have a choice** of using either Rotarix® or RotaTeq® to meet the rotavirus vaccine recommendation for VFC-eligible infants presenting in your practice.

If our practice chooses to use Rotarix®, what should we do with our current inventory of RotaTeq® vaccine?

It is imperative that you continue to use your current supplies of RotaTeq® vaccine and not allow it to expire. If state-supplied RotaTeq® vaccine expires due to your decision to use Rotarix®, this will be considered a failure to properly rotate vaccine, and you will be subject to the Financial Restitution Policy. Do not destroy viable RotaTeq®, nor attempt to return it to the UCVDP, nor allow it to expire.

How much should our practice order?

Because Rotarix® vaccine is a two-dose series and RotaTeq® vaccine is a three-dose series, if your practice decides to switch to Rotarix®, your three-month's supply of Rotarix® will be determined by multiplying your last month's usage of RotaTeq® by two.

Patients who have begun their rotavirus series with RotaTeq® should complete that three-dose series with RotaTeq®. Even if providers plan to use only Rotarix®, a minimal amount of RotaTeq® should be kept on hand until all patients who began their rotavirus series with RotaTeq® have received all three doses in the series.

Is there new Vaccine Information Statements (VIS) for the two-dose vaccine?

Yes, the CDC released a new VIS for use whether you are using RotaTeq® or Rotarix®. That VIS is available on-line at: <http://www.cdc.gov/vaccines/pubs/vis/downloads/vis-rotavirus.pdf>

How do I record and report administration of a dose of these vaccines?

For those providers on North Carolina Immunization Registry (NCIR), Rotarix® is currently available for ordering online, placing in inventory, and administering to patients. For those providers not using the NCIR, rotavirus should be reported on the Vaccines Administered Log (VAL).

If a child spits out some of the Rotarix® vaccine, do we need to administer another dose of vaccine?

No, ACIP is not recommending re-dosing due to a patient's spitting out the vaccine.

For additional information on the use of Rotarix®, please see:

- **PROVISIONAL Rotavirus Recommendations by ACIP:**
<http://www.cdc.gov/vaccines/recs/provisional/downloads/roto-7-1-08-508.pdf>
- **Rotarix® Package Insert:**
http://us.gsk.com/products/assets/us_rotarix.pdf

If you have clinical questions not answered in this memo nor in the resources mentioned above, please call your Regional Immunization Nurse Consultant.

If you have questions about your current supply of vaccines, ordering state-supplied Rotarix®, or the vaccine order form, please call the Immunization Branch Help Desk at 1-877-873-6247.

CC:	SMT	NC Immunization Branch	NCIB Field Services	Steve Shore
	Joy Reed	Ann Nance	Vaccine Manufacturers	Maclyn Powell

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