



Memorandum

TO: Regional Directors, Health Service Regions  
 Regionallmmunization Program Managers, Health Service Regions  
 Health Department Directors, Local Health Departments  
 Immunization Program Managers, Local Health Departments

FROM: Karen Hess, Manager  
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THRU: Jack C. Sims, Manager  
 Immunization Branch *Jack C. Sims*

DATE: September 17, 2009

SUBJECTS: Texas Vaccines for Children Program: Rotarix® and Hiberix® Implementation

The purpose of this memo is to inform providers that two vaccines, Rotarix® [Rotavirus Vaccine, live, oral] and Hiberix® [Haentophilllsb Conjugate Vaccine (Tetanus Toxoid Conjugate)], will become available through the Texas Vaccines for Children Program (TVFC) beginning October 1, 2009.

**ROTARIX®**

Rotarix®, manufactured by GlaxoSmithKline (GSK), protects against rotavirus gastroenteritis in infants, and is licensed to complete the rotavirus immunization series by four months of age with two doses. Rotarix® is the second rotavirus vaccine available through the TVFC. Rotatcqaq, manufactured by Merck, is currently available through the TVFC and provides similar protection against rotavirus in a three dose series.

The Centers for Disease Control and Prevention (CDC) indicates no preference between these products and recommends that they be given at 2 and 4 months of age, and that the third dose of RotaTeq® be given at 6 months. The chart below shows the CDC recommended dosing intervals and ages for the two vaccines

	RVS (RotaTeq®; Merck)	RVI (Rotarix®; GSK)
Number of doses in series	3	2
Recommended ages for doses	2, 4, and 6 months	2 and 4 months
Minimum age for first dose	6 weeks	
Maximum age for first dose	14 weeks 6 days	
Interval between doses	4 weeks or more	
Maximum age for last dose	8 months 0 days	

Although using the same rotavirus vaccine product to complete the series is preferred, RotaTeq® and Rotarix® may be used interchangeably. However, if RotaTeq® is used for any dose in the series, the child must receive a total of three doses of rotavirus vaccine. Only if Rotarix® is used for Dose 1 and Dose 2 will the series be complete with only two doses.

Rotarix® is supplied in boxes containing 10 each of vials of lyophilized vaccine, transfer adapters, and prefilled oral applicators with diluent. Rotarix® must be reconstituted prior to administration. A video on reconstitution and oral application is available at <http://www.rotarix.com/oral-administration-video.html>. Complete prescribing information is available on the package insert or at [http://us.gsk.com/products/assets/us\\_rotarix.pdf](http://us.gsk.com/products/assets/us_rotarix.pdf)

### **HIBERIX®**

Hiberix® is indicated as a booster dose for the prevention of invasive disease caused by *Haemophilus influenzae* type b (Hib). Hiberix® is approved for use in children 15 months through 4 years of age.

Hiberix® is supplied in vials containing a sterile, lyophilized powder. The vials will be packaged separately from the prefilled diluent syringes used to reconstitute the vaccine. A video on reconstitution is available at <http://www.hiberix.com/packaging-dosing-dose-administration.html>. For documentation purposes, providers should record the lot number from the vial containing the vaccine (not the diluent). Complete prescribing information for Hiberix® is available at [http://us.gsk.com/products/assets/us\\_hiberix.pdf](http://us.gsk.com/products/assets/us_hiberix.pdf)

Inventory and usage of Rotarix® and Hiberix® should be submitted monthly along with other vaccines using the Monthly Biological Report (EC-33). Rotarix® should be recorded as rotavirus and Hiberix® as **Hib** on the existing EC-33. A maximum stock level (MSL) will be determined after usage stabilizes (about three months). Until then, providers should order based on the projected need of the 15 month to 4 year-old age populations.

Please direct questions regarding the ordering or implementation of Rotarix® and Hiberix® to health service regions, local health departments, or TVFC consultants.