Vaccines for Children (VFC) Program
Rotarix - Rotavirus Vaccine Summary
August 29, 2008

Iowa Vaccines for Children (VFC) Program Implementation

Effective October 1, 2008, Rotarix vaccine will be available through the Iowa VFC Program.

Rotavirus (*Rotarix*) Vaccine Recommendations

Food and Drug Administration (FDA) - On April 3, 2008, the FDA approved Rotarix, a 2-dose vaccine that provides protection against rotavirus.

ACIP - On June 25, 2008, the ACIP provisionally recommended Rotarix vaccine for the prevention of rotavirus gastroenteritis in infants. (Provisional recommendations are provided by the ACIP but have not been approved by the CDC or the Department of Health and Human Services and have not yet been published in the Morbidity and Mortality Weekly Report (MMWR). Recommendations become official when they are published in the MMWR.)

VFC Resolution - On June 25, 2008, the ACIP workgroup approved Rotarix to be included in the VFC Program.

Recommended Schedule and Administration for Rotarix Vaccine

Two different rotavirus vaccines are licensed: RotaTeq (Merck & Co) (RV5) and ROTARIX (GSK) (RV1). They are considered equally safe and effective. The products differ in composition and schedule. The following is a harmonized schedule approved by the ACIP.

	RotaTeq (RV5 - Merck)	Rotarix (RV1 - 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	

- Administration/Route: Oral
- Presentation: 10 X 1 single dose oral applicator

Vaccine Storage and Handling

- Store refrigerated at 2° - 8° C, 35° - 46° F
- Do not freeze.
- Protect vaccine from light.

Interchangeability of Rotavirus Vaccine

ACIP recommends that the rotavirus vaccine series be completed with the same product whenever possible. However, vaccination should not be deferred if the product used for previous doses is not available or is unknown. In this situation, the provider should continue or complete the series with the product available. If any dose in the series was RotaTeq or the product is unknown, a total of three doses of rotavirus vaccine should be given.

IDPH/Immunization Program Recommendations

IDPH, Immunization Program routinely follows and promotes the Recommended Immunization Schedule. Therefore, the Immunization Program will implement the ROTARIX vaccine in accordance with the ACIP recommendations and the VFC resolution.

Vaccine Licensure / VFC Implementation

The Advisory Committee on Immunization Practices (ACIP) provides advice and guidance regarding the most appropriate application of vaccines for effective vaccine preventable disease control. The Food and Drug Administration (FDA) is responsible for the licensure of vaccines. Upon FDA approval the ACIP convenes and makes decisions on vaccine recommendations. A VFC resolution vote is required for the inclusion of new vaccines into the VFC Program or the modification of existing resolutions. The Centers for Disease Control and Prevention (CDC) then negotiates a contract for the purchase of vaccines. VFC vaccine must be administered according to the guidelines outlined by the ACIP recommendations and VFC resolutions.

CDC allocates individual state VFC funding based upon eligible populations, anticipated vaccine uptake, and negotiated federal contract amounts. CDC establishes monthly vaccine allocations for each vaccine. Additional 317 CDC discretionary funds are used to vaccinate underinsured individuals seen at Local Public Health Agencies (LPHAs) who are not eligible under VFC guidelines. Each state determines the vaccine implementation date based upon the above process which is generally four to six months following vaccine licensure.