

TEMPORARY ROTARIX VACCINE SUSPENSION

Dear Care1st Practitioners and Staff:

The FDA is recommending the temporary suspension of Rotarix vaccine (GlaxoSmithKline) for rotavirus immunization in the US while the agency learns more about components of an extraneous virus detected in the vaccine. Further recommendations are expected in 4-6 weeks. **There is no evidence at this time that this finding poses a safety risk. Rotarix efficacy is unaffected by this finding.**

The FDA recently became aware that a research team, using a novel technique, found DNA from porcine circovirus type 1 (PCV1) in Rotarix. It is not yet known if the PCV1 DNA is only a fragment, if it is the entire virus, or if it is able to replicate. PCV1 is not known to cause illness in humans or other animals. Therefore, it would not be expected to cause illness in children even though it was found in the vaccine. Rotarix has been studied extensively and found to have an excellent safety record. However, the cautious approach is to not give Rotarix until more information can be obtained.

Preliminary testing of RotaTeq (Merck) has not detected components of PCV1. Further doses of rotavirus vaccine should be given using RotaTeq.

ADHS Recommendations:

1. Please stop use of Rotarix at this time.
2. Continue to store Rotarix and hold it to maintain vaccine viability.
3. For now please use only RotaTeq for rotavirus vaccination.
4. If a child has received just one dose of Rotarix, then the child will need two doses of RotaTeq. If a child has received two doses of Rotarix, s/he is fully immunized and does not need any additional doses.
5. What we know now is reassuring because PCV1 is not known to cause human disease. There are no symptoms to expect, there is no clinical intervention that is needed, and there is no testing that is needed on those who received Rotarix.
6. Even if patients were to ask for testing, there is no commercially available serologic test to evaluate for antibodies to PCV1.
7. More information will be available in the upcoming days and weeks and can be found at <http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm205539.htm> and <http://www.cdc.gov/vaccines>

ASIIS and Rotarix:

For providers or patients who want to identify which vaccine a child has received, the provider may use Arizona State Immunization Information System (ASIIS) <https://www.asiis.state.az.us/asiisweb/> to track whether a patient received RotaTeq or Rotarix.

If you have any questions regarding this change, please contact Provider Network Operations at the numbers listed below.

Thank you!