

Study supports AAP recommendation on rotavirus vaccines

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Using two different rotavirus vaccines for the same child is safe and effective, a new study found.

The findings are significant as it is not always possible to use the same formula for all doses, researchers said in “Safety and Immunogenicity of Sequential Rotavirus Vaccine Schedules” (Libster R, et al. *Pediatrics*. Jan. 28, 2016, www.pediatrics.org/cgi/doi/10.1542/peds.2015-2603).

Two vaccines protect against rotavirus: RotaTeq (RV5; Merck and Co. Inc.), a three-dose live oral vaccine with five human/bovine reassortant rotaviruses, and Rotarix (RV1; GlaxoSmithKline), a two-dose, live-attenuated vaccine made from one human strain. Using two different rotavirus vaccines for the same child is safe and effective, a new study found. AAP News photo by Jeff Knox

The Academy and the Centers for Disease Control and Prevention’s Advisory Committee on Immunization Practices recommend vaccinating children at ages 2, 4 and 6 months for the three-dose series and 2 and 4 months for the two-dose series. While the same vaccine should be used each time if possible, both say immunization should not be deferred if that product is not available.



Researchers tested the effectiveness of mixing vaccine types in a randomized non-blinded study with 1,393 infants ages 6-14 weeks, each assigned to one of five groups. Two of the groups used the same vaccine while the other three used a combination.

One month after vaccination, researchers found 77% to 96% of the children were seropositive against at least one antigen.

“All the sequential mixed vaccine schedules were shown to be non-inferior when compared with two single vaccine reference groups,” according to the study.

In addition, the vaccines were well-tolerated, with irritability being the most frequent adverse event. One hospitalization was associated with a vaccine. That infant was diagnosed with gastroenteritis as well as a

urinary tract infection.

In a related [commentary](#) “Rotavirus Vaccines – OK to Mix and Match,” AAP Committee on Infectious Diseases Chair Carrie L. Byington, M.D., FAAP, and Vice Chair Yvonne A. Maldonado, M.D., FAAP, said the study supports the Academy’s recommendation not to delay vaccination when the same product isn’t available.

“The publication by Libster et al. in this issue supports this principle and reassures us that for rotavirus vaccines, immunization with a mixed series of vaccines is safe and results in an immune response that is non-inferior to that generated by immunization with a single product,” they said in the commentary.

Drs. Byington and Maldonado also said the study is a reminder of the importance of the National Institutes of Health-supported Vaccine Treatment Evaluation Units (VTEUs) and Clinical Translational Science Awards (CTSA). The VTEUs have conducted hundreds of clinical trials since they were established in 1962, many of which included children. The CTSA were established in 2006 to support translational science and research to improve health. Both played a role in this study.

“Without these federally funded resources, it is unlikely that the evaluation of multiple rotavirus vaccine combinations would have been conducted,” they said.

“We must remember that our advocacy should also include working to ensure that the research infrastructure of the nation is strong and that adequate resources are devoted to investigations that will benefit the health of children,” they concluded.

Resources

- [AAP Red Book chapter on rotavirus](#)
- [Information for parents on rotavirus](#)
- [Information from the CDC on rotavirus vaccine](#)

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