

Combination vaccines okay for infants, study shows

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A University of Rochester study brings relief to new parents who, while navigating a jam-packed childhood vaccine schedule, can expect to soothe their newborn through as many as 15 “pokes” by his or her six-month checkup.

The study, recently published in *The Journal of Pediatrics*, shows that no efficacy or safety is compromised when clinicians administer a new combination vaccine that streamlines the process – in effect, tripling up three of the recommended shots to reduce the “poke” total from five to three, at each of three bimonthly, well-child checkups.

“Only more immunizations will enter the schedule,” said Michael Pichichero, M.D., professor of Microbiology/Immunology, Pediatrics and Medicine at the University of Rochester and the study’s lead author. “Coupling or tripling of these vaccines is increasingly important, as this streamlining helps to promote parent compliance, timely vaccination and fewer administration errors.”

The study overturns findings (and fears) from a previous study that suggested problems when two specific vaccines were given at the same time – Pediarix, a combination of vaccines that guard against diphtheria, tetanus, whooping cough, hepatitis B and poliovirus, and Prevnar, which protects against 76 strains of *Streptococcus pneumoniae*. The earlier studies found that when the vaccines were co-administered, a suboptimal immune response was produced against whooping cough, and more uncomfortable reactions, such as swelling at the injection site, could be

expected.

Both Pediarix and Prevnar are recommended for administration at 2-, 4- and 6-month checkups; Prevnar was approved in 2000, shortly before the licensure of Pediarix.

“This newest study unseated both early reservations, showing that the combination vaccine was in fact just as safe and as immunogenic as separate shots, even in the midst of other vaccines in the schedule,” Pichichero said.

Study Details

A total of 575 healthy 2-month-olds were enrolled at 22 sites nationwide. Each infant was randomly assigned to one of three trial groups:

1. Combination Vaccine Group, which received three vaccines – the combination vaccine (DTaP-HepB-IPV, or brand name Pediarix), a second vaccine to protect against HiB, and a third, PCV-7 (or brand name Prevnar).
2. Separate Vaccine Group, which received five independent vaccines: DTaP, (for diphtheria, tetanus and whooping cough), HepB (for hepatitis B), IPV (for poliovirus), HiB, and PVC-7.
3. Staggered Vaccine Group that was identical to the Combination Group, save that PCV-7 vaccines were delayed by two weeks at every appointment, thereby demanding a total of six pediatric office visits, instead of three.

Blood samples were collected before the study began, and again when

infants were 7 months, to test for a robust immune response to each disease-trigger.

Parents were provided a diary and asked to record temperatures, general symptoms such as fussiness, irritability or loss of appetite, and local injection site symptoms such as pain or swelling.

Results

Minor symptoms were more common in the Combination Vaccine Group; however higher fevers and more severe shot site reactions were not significantly more likely to occur in infants in any of the three groups.

For example, swelling and pain were significantly higher at the injection site of the combination vaccine, but Pichichero said that is to be expected, given that there are more ingredients in that single shot (vaccines are made from killed or modified forms of bacteria or viruses, or only pieces or products of the germs). But, he added, it was noteworthy that at no time did any local symptoms (swelling, redness, pain) lead to an infant obtaining a medical attention visit.

“Vaccine opponents may liken the process of the body processing simultaneous vaccines to a computer running too many applications; the machine grows slow, and the programs, one by one, begin to terminate,” Pichichero said. “But those fears are unfounded; we have found no evidence that a child’s body is at any point approaching a maximum threshold as far as learning to produce immune responses.”

When you administer more vaccines, you expect more symptoms, more fevers, he said. Fever, swelling, redness are all indicators that the vaccine is working, that the body is busy creating the right immunity to prevent disease.

“So long as they are mild, they pale in comparison to benefits of convenience to the parent, the fewer number of pokes to the infant, and of course, the severity of the diseases we are preventing,” he said.

Perhaps most importantly, the study showed the Combination Vaccine Group enjoyed at least as good immunogenicity as the Separate and Staggered Groups, for all criteria – including the criterion for protecting against whooping cough, for which previous, smaller-scale studies had yielded inconsistent results.

“If pediatricians were holding out on making the switch to a combined vaccine for fear that its protection might be inferior, they no longer need be concerned,” Pichichero said. “It seems the clinical relevance of any previously observed differences with regard to whooping cough immunity have been dispelled.”

Source: University of Rochester Medical Center

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