

Study indicates use of nasal steroids can stunt growth in children.

Use of intranasal steroid medications for allergies causes a small but statistically significant growth reduction in children, an Allegheny Health Network clinical trial has determined, marking the first time such a connection has been shown.



From left, Maci Lee 11, sits with her father, Philadelphia pitcher Cliff Lee; mother Kristen; and brother , Jaxon. Maci nearly died and her growth was stunted because of steroids for steroids and asthma.

The study, to be published in today's online version of the journal *Pediatrics*, is the first such trial to be conducted in accordance with U.S. Food and Drug Administration guidelines. Previous studies had found that nasal corticosteroids had no impact on children's growth, but those clinical trials had design flaws that produced conflicting results, leading to the new FDA guidelines followed in the AHN study.

The clinical trial involving 216 children ages 3 to 9 with allergic rhinitis found

that those who used the steroid nasal spray had average growth of 5.65 centimeters over the 12-month study conducted at Allegheny General Hospital and numerous other sites nationwide as opposed to growth of 6.09 centimeters for those given a placebo. The danger to children is widespread because 10 percent to 40 percent of children worldwide have allergic rhinitis, also known as hay fever.

The risk is exacerbated by the fact the FDA in October 2013 approved triamcinolone acetonide nasal spray, with brand names including Nasacort, for over-the-counter sales, said David P. Skoner, the lead author of the study. That could lead to parents self-diagnosing children who aren't really allergic and improperly administering the medication to them, said Dr. Skoner, director of AHN's Division of Allergy, Asthma and Immunology.

Although the drug is an effective medication that can be used safely, it should be used only under a doctor's supervision and only after tests confirm the child has allergies, Dr. Skoner warned.

"It should not be available for unregulated, unmonitored use," said Dr. Skoner, who testified before the FDA in 2013 in opposition to making the medication available over the counter.

"A parent picking this up and giving it to a child, first of all, might not have the right diagnosis and if the recommended dose doesn't have the desired result, the natural tendency in the U.S. is to double the dose. If you do that and it's not monitored by a physician there are going to be side effects of excessive steroid use."

He said that because steroids are "the most effective therapy for nasal allergies and for asthma as well, therein lies part of the problem. You may have a child treated with inhaled steroids for asthma and then you start giving them nasal steroids. There have not been a lot of studies done, but my prediction is the outcome is worse with two steroids."

That's what happened to Maci Lee, the daughter of Philadelphia Phillies pitcher Cliff Lee, who three years ago, at the age of 8, developed growth and life-threatening adrenal gland suppression from long-term use of both nasal and inhaled corticosteroids for nasal allergies and suspected asthma.

Her mother, Kristen, said in an interview that even though Maci didn't look right or feel right, her pediatrician dismissed her mother's fears that it was because of the steroids. Years earlier Kristen Lee learned to question medical authority in dealing with the eventual successful cancer treatment of Maci's older brother, Jaxon. Again unsatisfied with medical treatment, she took Maci to an endocrinologist who diagnosed the problem and referred Maci to Dr.

Skoner.

Under Dr. Skoner's care, Maci was weaned off the medication and now at 11 years of age is healthy and of normal height and size but must daily take growth hormones until she reaches puberty.

In a prepared statement for the 2013 FDA hearing, Kristen Lee argued against making the drug available over the counter, saying it was "truly unbelievable" the agency was even considering the idea.

"Maci would have died if I didn't keep pushing. It's clear there's not enough awareness. Parents need to be informed," she said.

That's why she and Dr. Skoner are forming a nonprofit corporation named Maci's TEAMS (Teaching Everyone About Medication Safety). The foundation will present Web-based and in-person instruction for physicians about the dosing of steroids for children and the side effects and a website for parents of children seeking guidance about steroid use.

"There are a lot of steroids being used by children, many with combined nasal and lung administration, so there is a great need for education by doctors and patients," Dr. Skoner said. "Kristen's case nicely illustrates that."

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