

Are You Comfortable With Over-the-Counter Intranasal Steroids for Children? A Call to Action

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The early expression of allergic rhinitis in children is a potential red flag for lifelong problems and comorbid conditions. However, treating pediatric allergic rhinitis in the United States is trending toward a self-management or parental management model with little clinical supervision, which reflects changes in the delivery of health care. Of particular concern are the recent approval of an over-the-counter intranasal steroid to treat nasal allergy symptoms in adults and children as young as age 2 years and the push for a retail model of health care as exists in some other countries. For children with allergic rhinitis, treating nasal symptoms alone with over-the-counter products may further delay a diagnosis that is often already ignored due to its “annoyance factor” as opposed to being considered a serious health issue. How to ensure an appropriate diagnosis and management for these children remains a challenge, regardless of who is doing the treating. The call to action is for allergists and allergy medical organizations to drive the effort to ensure awareness of the why and how for appropriately diagnosing and treating allergic rhinitis in children. Starting points for the discussion are provided. © 2014 American Academy of Allergy, Asthma & Immunology (J Allergy Clin Immunol Pract 2014;2:271-4)

Key words: Allergic rhinitis; Pediatric rhinitis; Childhood rhinitis; Intranasal steroids; Over-the-counter; Pharmacy; Pharmacist; Health care provider; Allergy specialist

Allergic rhinitis (AR) in childhood is common and can adversely affect quality of life for both the child and the family. Treatment almost always starts at home, and medical decision making usually is in the hands of a primary care specialist, a trend that is not likely to be reversed despite comparative data that suggest better outcomes when pediatric AR is managed by allergists.¹⁻³ In their 2013 review of pediatric AR, Gentile et al¹

noted that the clinical management of these children is likely to “shift even more into the primary care arena” due to evolving reimbursement patterns by insurers and changes in prescription and/or over-the-counter (OTC) status of medications. Indeed, on October 11, 2013, it was announced that the US Food and Drug Administration (FDA) approved the intranasal steroid (INS) spray, triamcinolone acetonide (Nasacort Allergy 24HR; Sanofi US, Bridgewater, NJ) for OTC use to treat nasal allergy symptoms (nasal congestion, runny nose, sneezing, and itchy nose) in patients as young as 2 years of age.⁴ Other INS will undoubtedly follow.

WHO CHOOSES INTRANASAL STEROIDS FOR PEDIATRIC ALLERGIC RHINITIS: AN EVOLVING PARADIGM

All guidance documents recommend INS for patients who have moderate-to-severe AR,⁵⁻⁸ and the body of evidence strongly supports the superiority of INS over all other classes of medications for these patients: adults and children.^{1,9-11} It is especially important to treat early symptoms of AR in children. AR can have serious lifelong consequences, and treating children early with INS may improve disease control, which reduces the risk of developing comorbid conditions.¹¹ In a theoretical sense, the role of INS in AR treatment is not disputed by any health profession involved in treatment choice, including allergy specialists, primary care practitioners, and pharmacists.¹²⁻¹⁴ However, globally, the use of INS in primary care has lagged behind recommendations, a trend that has been attributed to concerns about the potential adverse effects of the drugs on the hypothalamic pituitary adrenal axis; on eyes; and, in children, on growth.^{15,16}

Early concerns about the effect of INS on growth were largely based on 1 study that showed reduced growth rates associated with beclomethasone dipropionate nasal spray;¹⁷ separate studies of mometasone, fluticasone furoate (FF), and budesonide were negative.¹⁸⁻²⁰ However, subsequent studies designed to meet stricter requirements from the FDA revealed growth inhibition with the INS, FF, and TAA.^{21,22} It is not clear whether catch-up growth occurs so that final adult height is reached. However, for asthma, a long-term study of school-age children treated for 4 to 6 years with low doses of inhaled corticosteroids showed little or no catch-up growth,²³ which raises the concern that INS also might affect final adult height. In addition, children who use inhaled corticosteroids along with INS may be at increased risk of growth effects due to the combined corticosteroid load, although there currently are no data. The FDA will continue to require INS to have labeling about potential adverse effects on growth, but the playing field has changed. Now that parents can choose to give their child an OTC INS without clinical supervision, how to monitor growth in relation to INS usage becomes an important consideration. The OTC label for TAA will

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No funding was received for this work.

Conflicts of interest: The authors declare that they have no relevant conflicts of interest.

Received for publication August 19, 2013; revised December 16, 2013; accepted for publication January 21, 2014.

Available online March 29, 2014.

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2213-2198/\$36.00

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<http://dx.doi.org/10.1016/j.jaip.2014.01.006>

Abbreviations used
 AR- Allergic rhinitis
 FDA- US Food and Drug Administration
 FF- Fluticasone furoate
 INS- Intranasal steroid
 OTC- Over-the-counter
 TAA- Triamcinolone acetonide

include information about the potential slowing of growth for some children as well as a recommendation that the nasal spray not be used for more than 2 months a year without seeing a physician.⁴ Ultimately, it will be up to the parents or caregivers to be mindful of these recommendations. So, regardless of the continued debate about using INS OTC, the reality is in play. Other INS, particularly those with higher therapeutic ratios and less patent life, will undoubtedly appear on the pharmacy shelves in the next few years, where, as with TAA, parents will be able to use them for their children’s nasal allergy symptoms, and,

without the supervision of a trusted clinician, that is really all a parent or caregiver can do, treat the symptom, not the disease.

Selecting an OTC medicine for a child with a runny or stuffy nose is already a choice complicated by the number of medicines on the shelves. There are no data on how parents “try medicines” to help their child with “common ailments,” such as allergies, hay fever, or the common cold, but results of surveys have shown that parents often rely on information from multiple sources, including family members, friends, other parents, and product information on the box.²⁴ For many OTC products, how information appears on the box, or on the label, is problematic. Analysis of data has shown that consumers often have difficulty understanding what is presented regardless of their level of education, but estimates that show that up to 25% of US parents have limited health literacy are especially troubling when it comes to choosing the right OTC medicine for a child.^{25,26} Making the scenario more complicated is the fact that parents may not understand or may not know about changes in regulations or recommendations regarding how a medicine should be used. This

TABLE I. The call to action: some discussion points for moving forward

<p>Keep information about AR simple, easy to use, and consistent for all audiences: health professionals as well as parents, caregivers, and children.</p>	<p>For health professionals, distill the key points from current guidance documents* and provide straightforward tools to help with the diagnosis, choosing treatment, and when to refer to the allergy specialist. For parents, answering the following questions is important: (1) when is it AR, (2) when is an INS the appropriate choice, (3) how do I give a nasal spray to my child, (4) what do we need to know about adverse effects, and (5) why and when should I bring my child to a physician?</p>
<p>Convey the message that AR in children goes beyond nasal allergy symptoms, and that early diagnosis is important to reduce a lifelong impact of the disease, including comorbidities, such as asthma, otitis media, and sinusitis.</p>	<p>The importance of “nontypical” symptoms for identifying AR in children (eg, “persistent colds,” chronic cough, recurrent otitis media, mouth breathing, snoring, daytime tiredness or lack of energy, irritability and behavioral changes, problems in school or daycare)† should be included in messaging to health professionals and parents. Parents should be advised, through media and pharmacy interactions, to have their child evaluated by a physician.</p>
<p>Simplify the presentation of drug information on packaging and on the label so that it is easily understood by parents and older children.</p>	<p>Format with words and pictures.‡ For OTC INS, this includes how to administer a nasal spray and clear information about dosing and local adverse effects as well as information on possible growth inhibition (without being scary). There also should be a way to notify parents about label and use changes, including actions for the parents to take in such situations. Electronic databases will be useful for follow-up.</p>
<p>Consider requiring parents and/or caregivers to talk to a health professional before purchasing an INS for their child.</p>	<p>This could be done by keeping OTC-approved INS on the other side of the counter, with the prescriptions, rather than on the shelves, so that the pharmacy could monitor use. Either the parent would have a prescription, with an assumption of education on use at the clinic or the parent would require counseling in the pharmacy before purchase. At the least, there should be discussion at the point of sale.</p>
<p>Use all media available to reach parents, caregivers, and children.</p>	<p>The medium is the message, especially for today’s parents. It is important to have information about AR as well as tools to help parents understand how to treat their child available through multiple media, particularly, online, which reflects how today’s parents (and caregivers) access information.</p>
<p>Involve all members of the health care community in data acquisition.</p>	<p>More studies are needed to both further assess how early diagnosis and appropriate treatment of AR in children reduce the risk of disease progression and expression of comorbid conditions as well as to understand how to optimize outcomes in the evolving OTC culture. The availability and use of expanding electronic databases should help with this effort.</p>

*From Refs 5-8.

†From Refs 1-3, 11.

‡From Ref 24.

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