

Burden of allergic rhinitis: Results from the Pediatric Allergies in America survey

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Allergic rhinitis (AR), a chronic inflammatory disease of the upper airway, is one of the most common chronic diseases in the United States and is estimated to affect up to 60 million people. Pediatric Allergies in America is the largest and most comprehensive survey to date of pediatric patients and parents of patients with allergy, as well as health care providers (HCPs), regarding AR in children and its treatment. The goals of the survey were to determine the prevalence of AR in the US pediatric population and to collect information on what effect the condition has on patients in terms of symptom burden, quality of life, productivity, disease management, and pharmacologic treatment. This national survey screened 35,757 households to identify 500 children with HCP-diagnosed nasal allergies and 504 children without nasal allergies who were between the ages of 4 and 17 years. Parents of young children, as well as children 10 to 17 years of age, were questioned about the condition and its treatment. In parallel, 501 HCPs were interviewed. This survey

has captured previously unavailable data on the prevalence of nasal allergies and their most common and most bothersome symptoms, on the effect of nasal allergies on the quality of life of children, and on medication use, including both over-the-counter and prescription medications, and has identified factors affecting satisfaction with treatment. The Pediatric Allergies in America survey also identifies distinct areas for improvement in the management of AR in children. In fact, based on the results of this survey, it appears that HCPs overestimate patients' and parents' satisfaction with disease management and the benefit of medications used for the treatment of nasal allergies in children. Findings from this national survey have identified important challenges to the management of AR, suggesting that its burden on children in the United States has been significantly underestimated. (*J Allergy Clin Immunol* 2009;124:S43-70.)

Key words: Allergic rhinitis, nasal allergies, pediatric allergy, prevalence, burden, intranasal corticosteroids

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Disclosure of sponsor involvement: In any sponsored investigation the issue of bias is invariably of concern for the pharmaceutical company and the authors, as well as for the journal's reviewers and readers. During the conduct of this study, much effort was made to mitigate potential bias, and safeguards were put in place to limit the sponsor's participation. The Pediatric Allergies in America survey was designed by a panel of experts within the allergy and ear, nose, and throat specialties. The sponsor had negligible input during these meetings, except for stating that it had hoped the project would study the current magnitude of the prevalence and burden of nasal allergies. This limited sponsor involvement was not an attempt to shape or otherwise influence the direction or outcome of the survey. The survey questions, in concert with the expert panel, were written by and administered through Abt SRBI, a respected global strategy, public policy, and opinion polling organization that has as clients multiple Fortune 500 companies; federal, state, and local governments; foundations; and universities. Data from the survey were not revealed to the sponsor before a follow-up meeting that was held with the clinician advisory committee, thus further minimizing any risk of sponsor bias of the data. Finally, the authorship includes only 1 person from the sponsoring company, Dr Wingertzahn, a PhD within their clinical development department. Dr Wingertzahn has a solid foundation in ethical research and has authored numerous manuscripts in peer-reviewed journals within the area of allergy. He was not a member of the core writing committee but was a reviewer of the supplement. We believe that pharmaceutical companies, no less than clinicians, are appropriately interested in learning as much as possible about the needs of their market and patients.

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Allergic rhinitis (AR) is a chronic inflammatory disease of the upper airways that is characterized by the symptoms of nasal congestion, rhinorrhea, sneezing, and nasal itching. AR is estimated to affect approximately 60 million people in the United States, and its prevalence is increasing.¹⁻³ The Agency for Healthcare Research and Quality estimates the prevalence of AR in adults to be between 10% and 30%, and several studies have estimated the prevalence of AR in children to be closer to 40%.⁴⁻⁶ Allergies in America, a recent survey of adults with nasal allergy in the United States, estimates that 1 (14%) in 7 adults is diagnosed by a health care practitioner with AR, nasal allergies, or "hay fever."^{7,8} Most (80%) individuals develop symptoms of AR before 20 years of age, with 40% of patients becoming symptomatic by age 6 years.⁹

AR can be categorized as seasonal or perennial depending on allergen sensitivity. Among US adults diagnosed with AR, 40% have perennial AR, and 20% have seasonal AR; an additional 40% have perennial AR with seasonal flare-ups.⁹ It is noteworthy that approximately 50% of adults with AR report that their symptoms last for more than 4 months of the year and that 20% report symptoms for more than 9 months.²

Although AR can be associated with significant morbidity, its effects are not limited to its physical symptoms. Often, the true effect of this disease involves the profound consequences it imposes on the patient's quality of life (QoL), emotional well-being, productivity, and cognitive functioning. Many of these health-related QoL issues appear to stem, in part, from sleep disturbances associated with AR.² In addition to the physical and emotional toll that AR elicits in patients, it also places a considerable economic burden on the US health care system. This burden includes both direct costs to patients and insurance providers and indirect costs that include patient absenteeism (missed days at work/school) and presenteeism (decreased productivity at work/school).²

Although treatment of AR often begins with environmental control to reduce allergen exposure, pharmacologic intervention is often required for control of moderate-to-severe symptoms. Intranasal corticosteroid (INCS) sprays are generally considered the gold-standard pharmacotherapy for AR in both adults and children.¹⁰ Over-the-counter (OTC), as well as prescription, oral and intranasal antihistamines, oral and topical decongestants, and leukotriene receptor antagonists are also commonly used pharmacotherapies in both adult and pediatric patient populations.¹ Although these medications can be effective at controlling the symptoms of nasal allergies, they can be associated with adverse effects, such as local epistaxis, nasal dryness, and irritation from intranasal medications and drowsiness from antihistamines.^{1,11,12} The systemic effects of INCSs are of particular concern in children because of the absence of weight-based dosing, as well as reports of cortisol suppression and growth slowing during treatment with INCSs.¹³⁻¹⁶ In addition, currently available INCSs and other prescription nasal sprays might not provide complete or long-term symptom relief in children. Limitations in the extent and duration of action of INCSs or other prescription nasal sprays might decrease patient satisfaction with treatment, thereby reducing adherence.

Oral and intranasal antihistamines, although clinically effective for the treatment of both seasonal and perennial AR as a monotherapy, are generally considered to be less effective than INCSs for control of nasal allergy symptoms; as a result, antihistamines are frequently paired with either a decongestant

Abbreviations used

AR:	Allergic rhinitis
HCP:	Health care provider
INCS:	Intranasal corticosteroid
ISAAC:	International Study of Asthma and Allergies in Childhood
NHANES:	National Health and Nutrition Examination Survey
NP:	Nurse practitioner
OTC:	Over the counter
PA:	Physician assistant
QoL:	Quality of life
URI:	Upper respiratory tract infection

or leukotriene receptor antagonist to improve their efficacy.^{17,18} In contrast, topical decongestants are very effective for improving nasal congestion but are inappropriate for daily use because of the potential for rebound of symptoms (rhinitis medicamentosa).¹⁷

Much of the data available in the adult literature regarding prevalence, burden, and QoL effects of AR have not been available with regard to children. Information regarding how side effects from treatment affect the daily lives of children and their adherence to medication is not known. Therefore the Pediatric Allergies in America national survey was conducted to gain insights into the prevalence of AR in children, its symptoms, its effect on QoL, its comorbidities, the use of OTC and prescription treatments, patient satisfaction with symptom relief from treatment, and the side effects from AR treatment and their role in the adherence and discontinuation of AR treatment in children. Because current practice guidelines for AR and AR with comorbid asthma recommend the use of INCSs as first-line agents over other approved therapies, this supplement places an emphasis on INCSs and nasal sprays in general when reporting patient satisfaction with symptom relief, side effects of treatment, and treatment adherence and discontinuation rates (Allergic Rhinitis and Its Impact on Asthma Guidelines; 2008 Practice Parameters).

METHODS

Survey design

Pediatric Allergies in America, a comprehensive national telephone screening of 35,757 households in the United States, was conducted to identify subjects with nasal allergy between 4 and 17 years of age. This national survey was designed to use a credible data-collection approach to determine the prevalence of AR in the US pediatric population. This survey interviewed the parents of children 4 through 9 years of age and both the parents and children 10 years of age and older and collected information on what this condition means to those who have it in terms of morbidity and management of the disease.

During the interviews, an adult member of each household was asked to report the number of children in the household between 4 and 17 years of age who had been diagnosed with AR, nasal allergies, or "hay fever." The survey identified 500 children who were diagnosed with AR by a health care provider (HCP) and who had symptoms and had taken medication in the previous 12 months. A comparison group of 504 children without nasal allergies was also identified (Table I). The calculation of overall prevalence of the disease in children was based on all children who were reported by parents to have been diagnosed with nasal allergies of all households surveyed that had children younger than 18 years. All other calculations were based on children with (n = 500) and without (n = 504) nasal allergies, as specified above.

The telephone survey lasted an average of 36 minutes (269 questions) in the AR parent group and 18 minutes (123 questions) in the allergy-free parent group. When parents consented, children 10 to 17 years of age responded to a

TABLE I. Survey demographics

	AR (n = 500), no. (%)	No AR (n = 504), no. (%)
Sex		
Male	263 (53)	251 (50)
Female	235 (47)	253 (50)
Age (y)		
Mean (range)	7.9 (4-17)	10.4 (4-17)
≤7	133 (26)	166 (33)
8-12	168 (34)	157 (32)
13-17	197 (40)	181 (37)
Race*		
White	367 (73)	381 (76)
Black	51 (10)	44 (9)
Asian/Pacific Islander	10 (2)	14 (3)
Hispanic	19 (4)	29 (6)
Mixed	35 (7)	13 (3)
Other	16 (4)	8 (2)
Refused	10 (2)	6 (1)

Percentages do not equal 100% within columns as a result of rounding.

*Represents race of parent responder.

subset of up to 98 questions in addition to the parents' responses. Where relevant (ie, outcomes different), data from parents' responses are reported separately from those of the children's responses. The average interview length of 36 minutes at a rate of approximately 4 questions per minute meant that a respondent answered about 140 questions. However, many of the questions were contingent on a gatekeeper question (eg, "Have you taken an OTC medication for your AR in the past 4 weeks?"), and subsequent questions would only be asked of those who answered in the affirmative. Hence respondents were only asked the subset of all possible questions that were appropriate to their condition and treatment.

A parallel survey was conducted among 501 HCPs, including 100 physicians in family practice, 101 allergists, 100 otolaryngologists, and 100 pediatricians, as well as 50 nurse practitioners (NPs) and 50 physician assistants (PAs), to determine HCP's perspectives on children's nasal allergies and their treatment. Physician survey participants were drawn as probability samples from the American Medical Association and the American Osteopathic Association Master List of physicians in the United States. The samples were restricted to physicians in 4 specialty strata who were in active practice and in direct patient care in an outpatient setting. The NP sample was drawn from state licensing board lists, and the PA sample was drawn from the membership list of the American Academy of Physician Assistants. HCP interviews were approximately 20 minutes in length and were composed of 76 questions. Physician respondents were compensated \$50, and NPs and physician assistants were compensated \$25 for their time. Parents were not compensated; however, children aged 10 to 17 years who agreed to participate in a follow-up questionnaire were compensated \$10.

Schulman, Ronca and Bucuvalas, Inc, a national public opinion research organization and leading physician experts in the field of AR, collaborated to develop the Pediatric Allergies in America questionnaire. Survey questions were developed through analysis of the relevant literature and identification of questions used to study similar diseases in other accepted health surveys, including the adult Allergies in America survey conducted in January 2006.⁷ The AR patient questionnaire focused on general health, AR triggers, AR symptoms, the effects of allergies on QoL and productivity, AR comorbidities, and the effectiveness and side effects of nasal allergy medications in children.

Statistics

The surveys were conducted by Schulman, Ronca and Bucuvalas, Inc, between March and April 2007. Sampling was conducted by using list-assisted random-digit dialing within a geographically stratified design for the US household population. List-assisted random-digit dialing samples are based on a sampling frame that includes all hundred-series telephone banks

(eg, 123-456-78xx) with listed telephone numbers to which 2-digit randomized numbers are appended to complete a full telephone number. Although the restriction of the sampling frame to banks with listed numbers excludes an estimated 4% of US households with landlines, it permits an efficient way to generate a simple random sample of telephone numbers.

For a simple random sampling of 500 respondents (ie, the sample of children with AR and the sample of children without AR), the maximum expected sampling error would be $\pm 4.4\%$ at the 95% CI. For the comparisons between the samples of children with allergies and children without allergies, the maximum expected pooled error would be $\pm 6.2\%$ (95% CI). For the survey of HCPs, in which the simple random sample consisted of 100 respondents (eg, pediatricians), the maximum expected sampling error would be $\pm 9.8\%$ (95% CI). This survey approach allowed for a relevant and statistically accurate reflection of parents' and physicians' perspectives on the management of AR in the 4- to 17-year-old population of US subjects with allergy.

Where appropriate, the comparisons of responses by parents of children with nasal allergies and parents of children without nasal allergies were conducted by means of ANOVA (SAS Institute, Inc, Cary, NC), and *P* values were reported. However, surveys such as the Pediatric Allergies in America telephone survey tend to obtain responses and opinions that cannot be formally verified. Much like the analysis of reported adverse events that occur in a clinical trial, results from surveys are typically reported by using descriptive measures. Therefore except where noted, most survey results have been reported descriptively.

Survey questions

The questions in the patient survey relevant to this publication are detailed by chapter in [Appendix 1](#).

PREVALENCE OF PEDIATRIC ALLERGIC RHINITIS

Although AR is currently estimated to affect approximately 60 million people in the United States and prevalence is increasing, it is still considered by many to be a nuisance condition of childhood rather than a serious disease.¹⁻³ Many children become symptomatic and are given diagnoses of AR by age 6 years; 80% of all individuals with AR have symptoms before age 20 years.⁹ According to the Agency for Healthcare Research and Quality, the self-reported prevalence of AR in adults is estimated to be between 10% and 30%, whereas in children numerous studies estimate the prevalence of AR to be nearer to 40%.⁴⁻⁶ Allergies in America, a recent survey of subjects with nasal allergy in the United States, estimates that 1 (14%) in 7 adults has a physician's diagnosis of AR, nasal allergies, or hay fever.⁷

Similar to the prevalence rate observed in Allergies in America for US adults, the Pediatric Allergies in America survey found that 13% of children had an HCP-confirmed diagnosis of AR and were symptomatic during the year before the survey. This value was based on parents' responses that of the 8,119 households surveyed with children 18 years of age or younger, 1,068 children had been diagnosed with nasal allergies. With the exception of this calculation of prevalence, subsequent analyses were conducted based on 500 children with nasal allergies and 504 children without nasal allergies, as noted in the Methods section. These estimates of symptomatic AR in children fall at the lower end of previous estimates of AR in the US pediatric population (10% to 40%).⁴⁻⁶ Among households having children diagnosed with AR, 80% of parents reported that their children had used medication to control nasal allergy symptoms during the previous 12 months. More than half (61%) of all children were diagnosed with AR by age 6 years ([Fig 1, A](#)), and the plurality of diagnoses

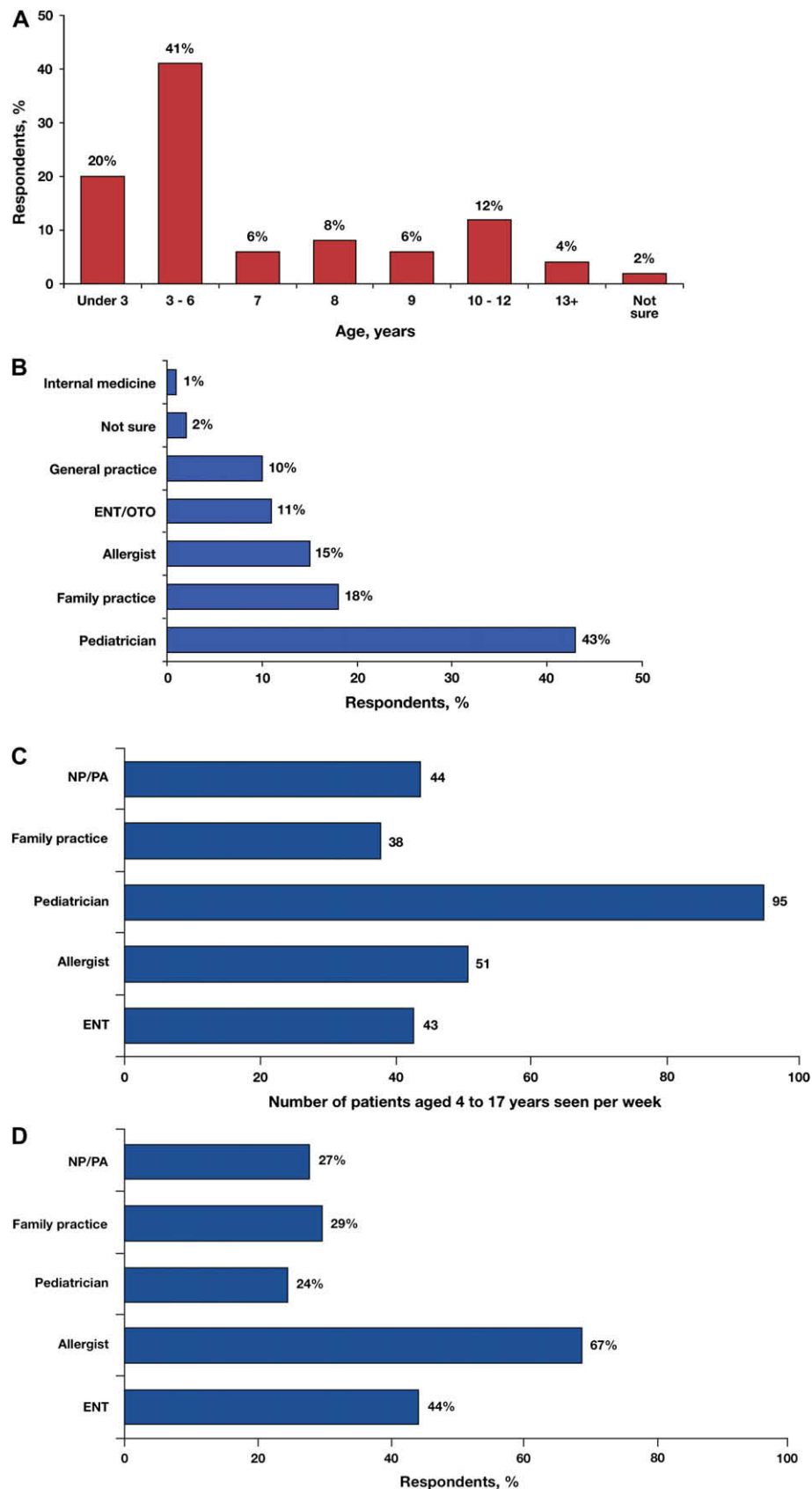


FIG 1. Diagnosis of AR in children. **A**, Age at diagnosis of children with AR. **B**, Diagnosing HCP. **C**, Mean number of patients aged 4 to 17 years seen per week by the HCP. **D**, Percentage of patients diagnosed with AR by the HCP. **E**, HCP's awareness of professional guidelines. ENT, Ear, nose, and throat specialist; OTO, otolaryngologist.

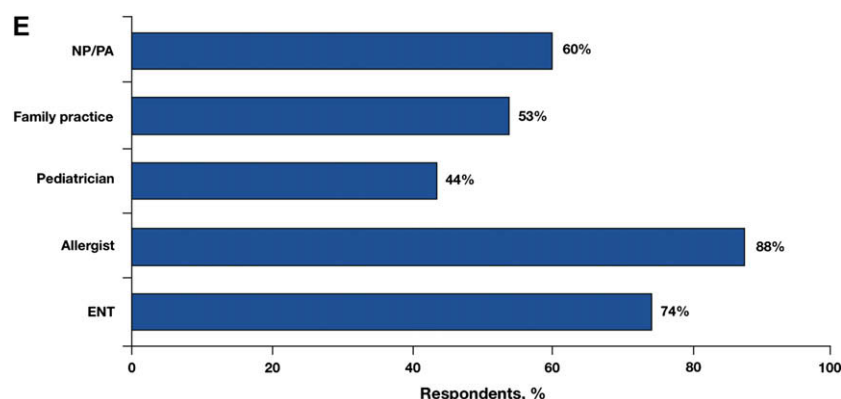


FIG 1. (Continued)

(43%) were made by the child's pediatrician (Fig 1, B). Interestingly, the pediatricians surveyed estimated that among 95 patients (4-17 years of age) seen on average each week (Fig 1, C), 24% ($n = 23$) of patients had AR. These physician estimates of AR prevalence are similar to those reported by family practice physicians (29%), as well as by NPs and PAs (27%). Ear, nose, and throat specialists estimated that 44% of their patients 4 to 17 years of age had AR; allergists estimated that 67% of patients seen each week had AR (Fig 1, D). Although pediatricians see more patients, make more AR diagnoses, and provide the bulk of the general management and treatment of pediatric AR, only 44% reported that they are familiar with professional guidelines for the diagnosis and management of nasal allergies (Fig 1, E).

The survey found that, with the exception of allergists, few HCPs routinely use skin or blood tests to confirm a diagnosis of AR. In order of decreasing frequency of diagnostic test use, allergists (99%); ear, nose, and throat specialists (28%); NPs/PAs (12%); and pediatricians and family practitioners (7%) say they perform skin tests all or most of the time. Even fewer ($\leq 17\%$) HCPs use blood tests to confirm an AR diagnosis. Despite the relatively low percentage of HCPs who reported that they routinely used diagnostic tests to confirm AR, 24% of parents said that their child with nasal allergies had a skin test, 11% said that their child had a blood test, and 13% said that their child had both to confirm a diagnosis of AR (Fig 2).

Nasal allergies are commonly diagnosed as either seasonal or perennial, although many patients had both types of allergy triggers. When asked whether their nasal allergies were seasonal or persisted throughout the year, 313 (62%) parents reported that their children's allergies were seasonal only, whereas 183 (37%) indicated that their children's allergies occurred throughout the year (Fig 3, A). Similarly, most (54%) HCPs agreed that their pediatric patients primarily had seasonal rather than perennial allergies. Among parents of patients who reported seasonal AR, 76% said that their child's allergies were worse during the spring season, whereas 34% reported that their children's allergies were worse during the fall season (multiple answers were permitted; Fig 3, B). More parents report that their children's nasal allergy symptoms were worse outside (44%) rather than inside (3%), although the remaining 52% of parents reported that the severity of their children's allergies was about the same inside and outside (Fig 3, C).

Triggers of nasal symptoms can be divided into allergic and nonallergic types, and most patients reported multiple sensitivities. In keeping with the high percentage of seasonal allergies

reported, the most common triggers of nasal symptoms in the allergic children were pollen (54%; including grass [25%], as well as tree and weed allergens), dust (29%), and animal dander (15%). In addition, nonallergic triggers, such as weather (19%), fumes and odors (7%), and exercise (6%), are commonly reported (Fig 3, D).

The results of the Pediatric Allergies in America and Allergies in America questionnaires indicate that diagnosed nasal allergies are equally prevalent in children and adults in the United States; however, because they do not include adults or children without a formal HCP-confirmed diagnosis of AR, these surveys likely underreport the overall population prevalence of the disease. Most diagnoses in children are made by a pediatrician who is likely also the child's primary care physician. Most parents and physicians report that children appear to have seasonal allergies, although many also have perennial allergies. In contrast, the Allergies in America survey of US adults found that most adults had perennial allergies, with a slightly lower prevalence of seasonal allergies. When seasonal exacerbations occurred in children with AR, the majority of parents reported that their child's worst allergy symptoms occurred during the spring season, followed by fall. Adults also reported that spring, followed by fall, was the worst time of year for allergy symptoms.

SYMPTOMS OF PEDIATRIC AR

AR is characterized by nasal congestion, rhinorrhea, repeated sneezing, and nasal itching, common symptoms brought on by the body's immunologic inflammatory response to allergen exposure.¹⁹⁻²² Ocular symptoms, such as eye itching, tearing, redness, and lid puffiness, collectively referred to as allergic conjunctivitis, are also common symptoms of AR.²³

Because the types of allergy symptoms experienced by children often vary in frequency, parents were asked which of 12 common allergy symptoms were experienced by their children during the worst 1-month period in the previous year. The single most frequently experienced nasal allergy symptom reported by parents was nasal congestion or a stuffy nose (52%), which was said to occur either every day (25%) or most days (27%) each week during their children's worst month for allergy symptoms. Repeated sneezing was also reported by nearly half (46%) of parents as occurring every day or most days during their child's worst allergy month. One third of parents reported runny nose (34%) and watering eyes (34%) as occurring every day or most days of their child's worst allergy month. In addition, more than

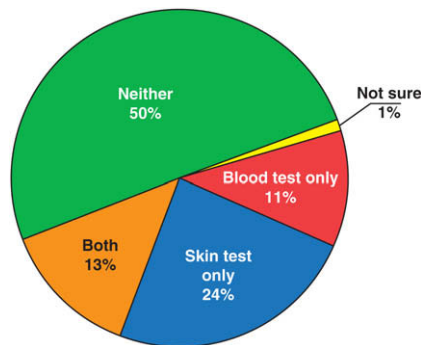


FIG 2. Percentage of parent respondents who reported use of a skin test, blood test, or both to confirm the diagnosis of their children.

1 in 4 parents stated that symptoms such as postnasal drip, red and itching eyes, and nasal itching affected their children on all or most days during the worst month in the previous year. Although less commonly reported as occurring every day or most days, dry cough, sleep disturbance, headache, facial pain, and ear pain were also reported as common symptoms during children's worst month for nasal allergy symptoms (Fig 4, A).

Parents were also asked how bothersome specific symptoms of nasal allergies were for their children during nasal allergy flares. In addition to being the most frequently described symptom of nasal allergies, nasal congestion was also considered by parents to be a bothersome symptom experienced by their children. Three in 4 parents reported nasal congestion as either extremely (32%) or moderately (43%) bothersome during their children's nasal allergy attacks. Postnasal drip (70%) and runny nose (65%) were also reported as extremely or moderately bothersome symptoms. Many parents reported headache, nasal itching, and ear pain, as well as red, itching eyes, to be extremely or moderately bothersome. Facial pain, dry cough, repeated sneezing, and watering eyes were considered by at least half of all parents to be the least bothersome symptoms of nasal allergies (Fig 4, B).

Parents (88%) who reported their children's symptoms as being either extremely or moderately bothersome were also asked which symptoms were most bothersome to their child. Most (27%) parents identified nasal congestion or stuffed-up nose as the most bothersome symptom, whereas headache (13%) and runny nose (12%) were the next most common replies. Dry cough, red, itching eyes, postnasal drip, and repeated sneezing were less commonly described as the most bothersome nasal allergy symptoms. Although frequently considered to be bothersome, symptoms of nasal allergies, such as watering eyes, nasal itching, ear pain, and facial pain, were only infrequently considered by parents to be the most bothersome symptom of their children's nasal allergies (Fig 4, C).

In addition to parental responses, children 10 to 17 years of age were asked which nasal allergy symptoms they experienced every day or most days during their worst allergy month in the past year. Nasal congestion or stuffed-up nose (39%), repeated sneezing (36%), runny nose (35%), and watering eyes (20%) were frequently reported as occurring either every day or on most days of the worst month. A comparison of parents' and children's responses for symptoms occurring either every day or on most days of the worst month of allergy symptoms indicates that either parents overestimate the frequency of most nasal allergy

symptoms in their children or that children underreport the frequency of their symptoms (Fig 5, A).

Although there were some discrepancies between parents' and children's responses for the frequency of nasal allergies, parental reports of bothersome nasal allergy symptoms were generally in agreement with children's views regarding allergy symptoms considered extremely or moderately bothersome. During nasal allergy attacks, the most bothersome symptoms of nasal allergies reported by children were nasal congestion (26%), headache (17%), runny nose (12%), and repeated sneezing (11%; Fig 5, B). Additionally, nasal congestion, postnasal drip, headache, and runny nose were consistently rated as being either extremely or moderately bothersome by 60% of parents and children.

HCPs were also asked to rank the nasal allergy symptoms that were among the most bothersome to their pediatric patients (multiple answers were permitted). Like parents and children, the majority of HCPs considered nasal congestion (91%) to be one of the most bothersome symptoms of nasal allergies. Additionally, runny nose (72%) and postnasal drip (67%) were reported as being among the symptoms that are most bothersome to their pediatric patients. Watery and red itchy eyes were also considered the most bothersome symptoms by approximately half of all practitioners (Fig 5, C). Regardless of symptom category, the vast majority (86%) of HCPs indicated that their patients' symptoms were moderately or extremely bothersome; a further 67% of practitioners reported that their pediatric patients experienced symptoms that were moderate to severe in intensity during nasal allergy attacks.

Nasal allergy symptoms have a profound effect on the lives of both children and adults. This survey identified nasal congestion, or stuffy nose, as both the most frequent and the most bothersome symptom of allergies in children, as reported by parents, patients, and physicians. Nasal congestion was considered moderately or extremely bothersome by more than 3 in 4 parents and 2 in 3 children with nasal allergies.

These results are similar to findings in the Allergies in America survey of US adults that helped establish that although children and adults had the same disease, they reported subtle differences in the frequency and severity of nasal allergy symptoms. AR symptoms are generally localized to the nose, nasal and oral pharynx, eyes, sinuses, and ears. Given the differences in anatomic structure (eg, Eustachian tube length and smaller lumen size of the nares) observed in young children compared with older children and adults, it is not surprising that the frequency and severity of symptoms should vary slightly between the 2 populations. For instance, more children than adults reported facial pain and ear pain as being moderately to extremely bothersome. Nasal congestion in the smaller airway lumens in children might result in the retention of fluids and increased pain in the ears and paranasal sinuses. In contrast, the increased drainage of mucus in adults compared with smaller children can manifest as postnasal drip: twice as many adults as children reported postnasal drip as one of the most bothersome of their nasal allergy symptoms. Indeed, bothersome symptoms of nasal allergies in children and adults contribute to the heavy burden of nasal allergies such that AR is ranked as one of the top 10 reasons for primary care physician visits in the United States.^{23,24}

BURDEN OF PEDIATRIC AR

Traditionally, AR has been regarded as more of a nuisance than a substantive disease. However, in 2006, Allergies in

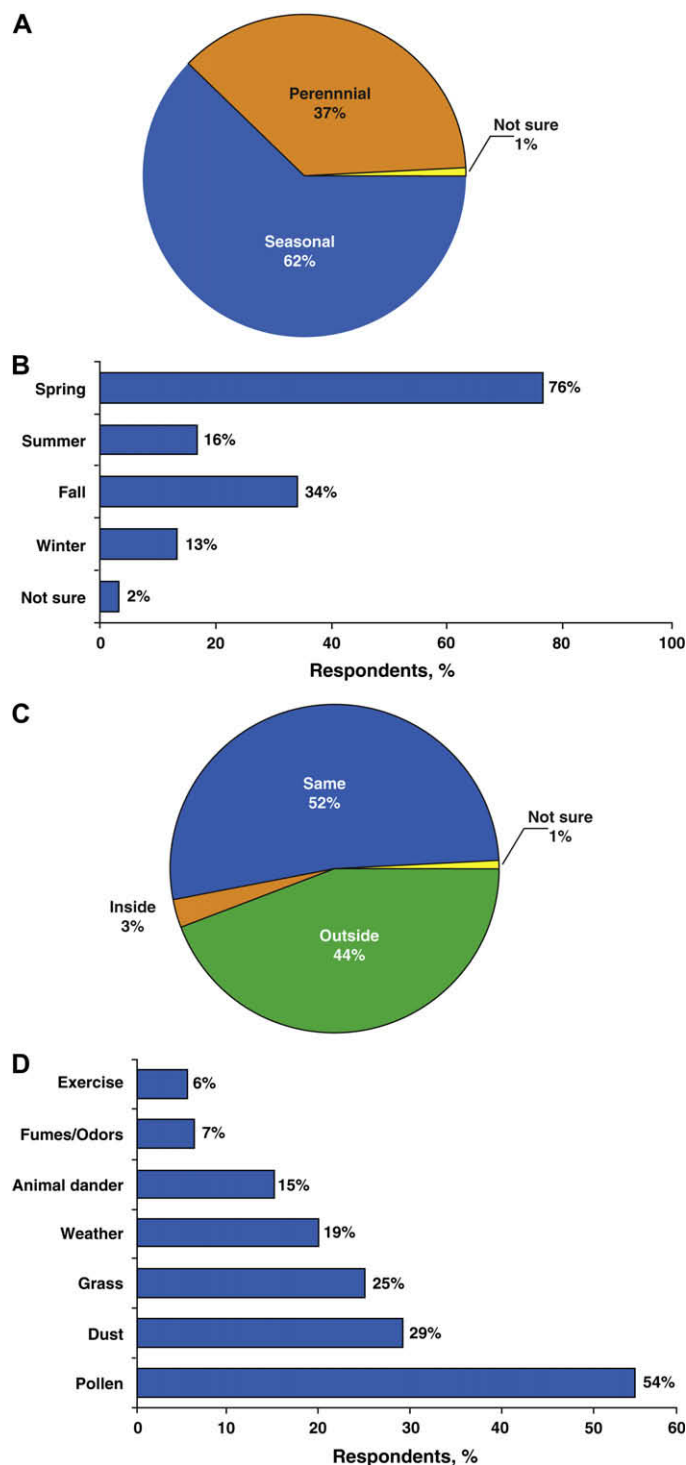


FIG 3. Seasonal prevalence of AR in children. **A**, Percentage of patients with seasonal or perennial allergies. **B**, Reported incidence of AR by season. **C**, Percentage of patients reporting severity of symptoms indoors versus outdoors. **D**, Common triggers of nasal allergy symptoms.

America, a national survey of patients 18 years of age and older with nasal allergy, helped to describe the true burden of this disease on US adults.^{7,8} In 2007, after this adult study, the Pediatric Allergies in America survey was conducted to qualify and quantify the effect of AR on the lives of children in the United States. It appears that in children, as well as in adults, the burden of nasal allergy symptoms has a profoundly adverse effect on

overall physical and emotional health, quality of sleep, and daily lives of children.

Physical health

In general, children with nasal allergies were significantly less likely to receive an excellent health rating by their parents than

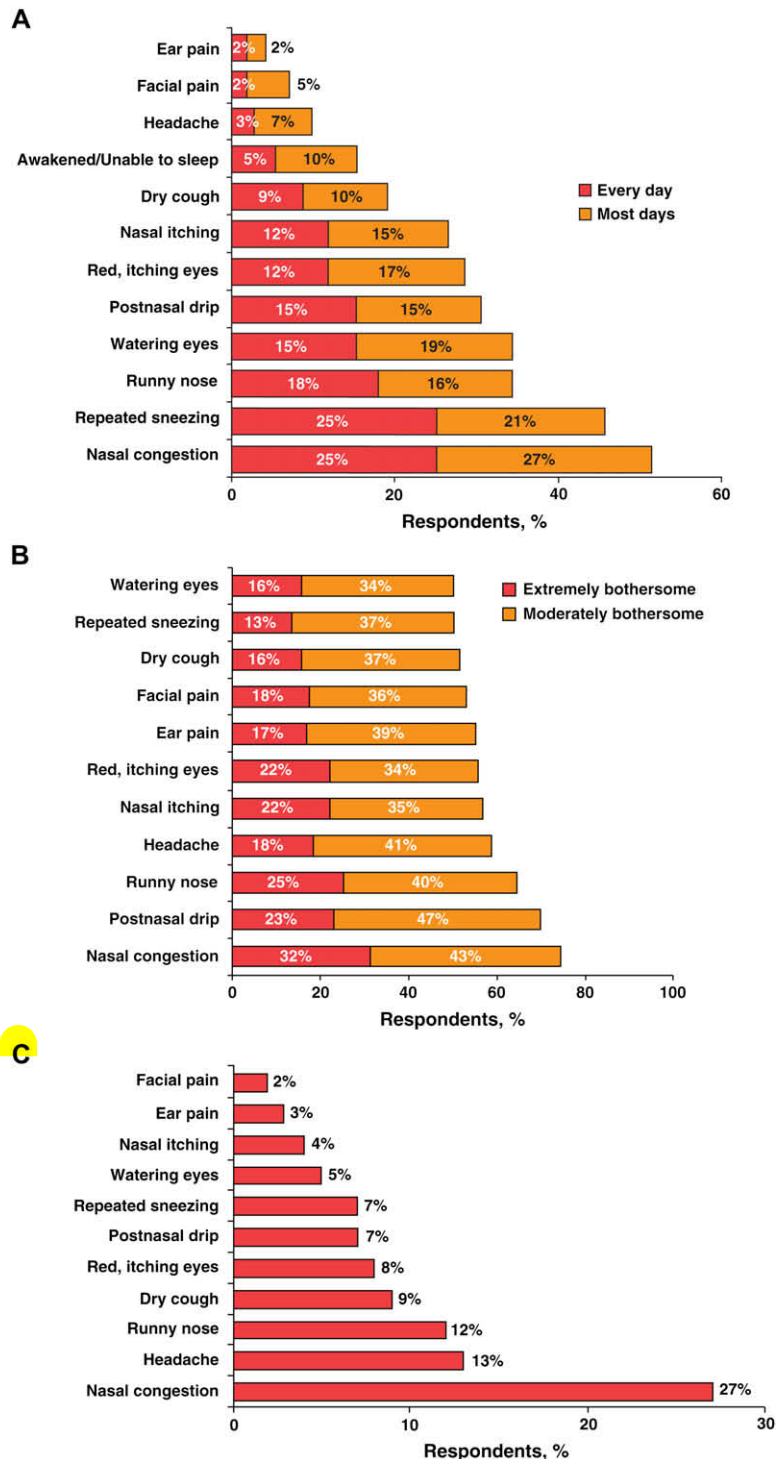


FIG 4. Common bothersome symptoms of AR in children. **A**, Parental reports of nasal allergy symptoms during the worst month in the past year. **B**, Parental reports of the severity of nasal allergy symptoms, extremely or moderately bothersome. **C**, Parental reports of the most bothersome nasal allergy symptoms.

were children without allergies. In fact, only 43% of children with nasal allergies were rated as having “excellent” health by their parents compared with 59% of children without allergies ($P < .001$; Fig 6, A). Parents of children with nasal allergy compared with parents of children without allergies were more likely to describe physical, mental and emotional, and social problems in their children.

Emotional health

Parents of children with nasal allergy and allergy-free children were asked a series of descriptive questions regarding their children’s typical emotional state over the previous 4 weeks to explore the association of allergy symptoms and children’s emotional health. Children with allergies were found to experience significantly fewer positive feelings such that only one third

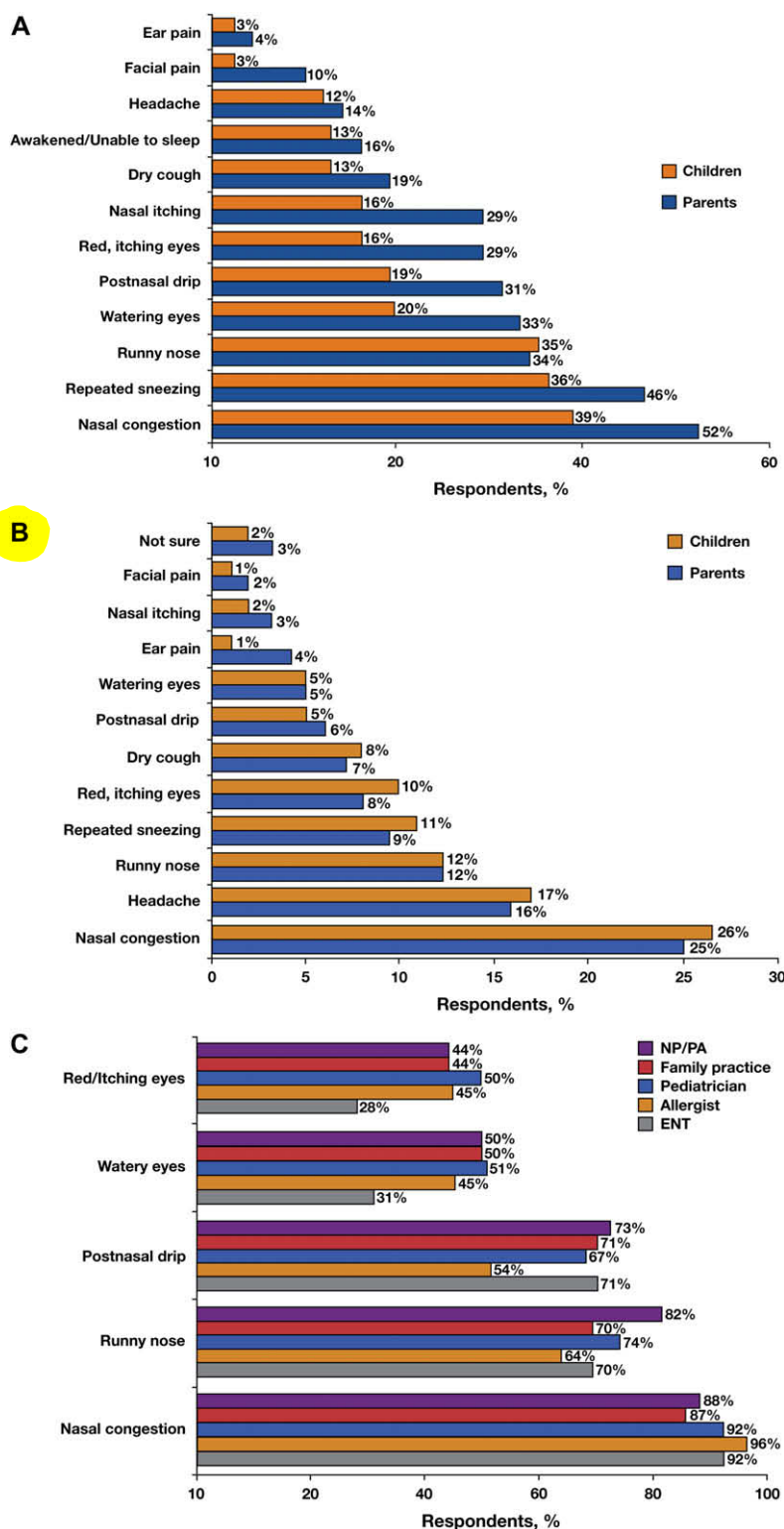


FIG 5. Comparison of parents', children's, and practitioners' perceptions of AR symptoms in children. **A**, Comparison of parent's and children's perceptions on the frequency of nasal allergy symptoms during the worst month in the past year. **B**, Comparison of parent's and children's perceptions on the most bothersome nasal allergy symptoms. **C**, HCP's perceptions on the most bothersome nasal allergy symptoms. ENT, Ear, nose, and throat specialist.

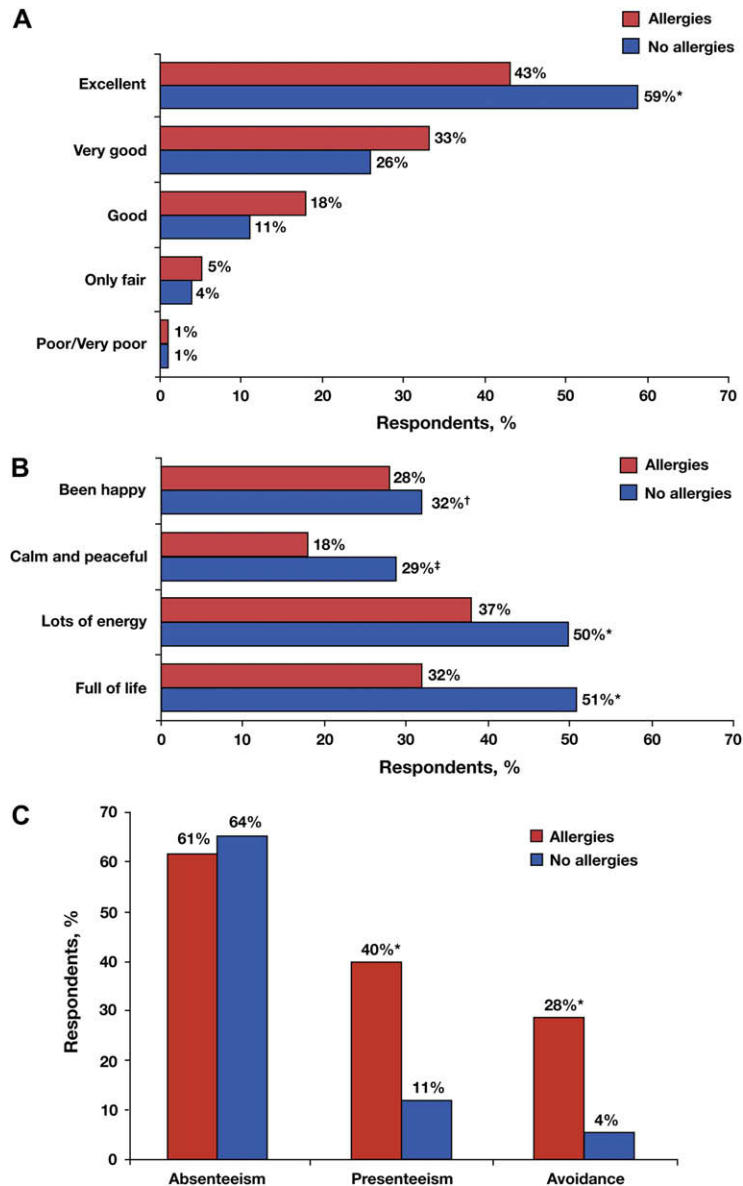


FIG 6. Effect of AR on the physical and mental health of children. **A**, General health comparison by parents of children with and without AR. **B**, Parent's perceptions on overall feelings of well-being in children with and without AR. **C**, Parent's perceptions of allergy/health effects on absenteeism, presenteeism, and avoidance of daily activities in children with and without AR. **D**, Parent's perceptions on the effect of nasal allergy symptoms on productivity of children. **E**, Parent's perceptions on the effect of nasal allergy symptoms on type and amount of work performed by children. * $P < .001$; † $P < .05$; ‡ $P < .01$.

(32%) of parents believed that their children with allergies were “full of life” all of the time versus approximately half of parents of children without allergies ($P < .001$). Similar disparities existed for other questions relating to their children's emotional health. Parents of children with nasal allergy and allergy-free children, respectively, answered whether their children had lots of energy (37% vs 50%, $P < .001$), whether they were calm and peaceful all of the time (18% vs 29%, $P < .01$), or whether they had generally been happy all of the time (28% vs 32%, $P < .05$) in the previous 4 weeks (Fig 6, B). With regard to measures of physical and emotional health, the survey appears to indicate that children with nasal allergies, although heretofore generally

considered physically and emotionally healthy and happy, consistently were rated significantly lower on specific measures of happiness and emotional health than children without this affliction.

Social health

The Pediatric Allergies in America survey was also designed to assess the influence of children's allergies on their social health. When parents were asked whether their children's allergies or general health interfered with normal childhood activities, a significant gap was found between the responses of parents of children with allergy and parents of allergy-free children. These responses suggest that the

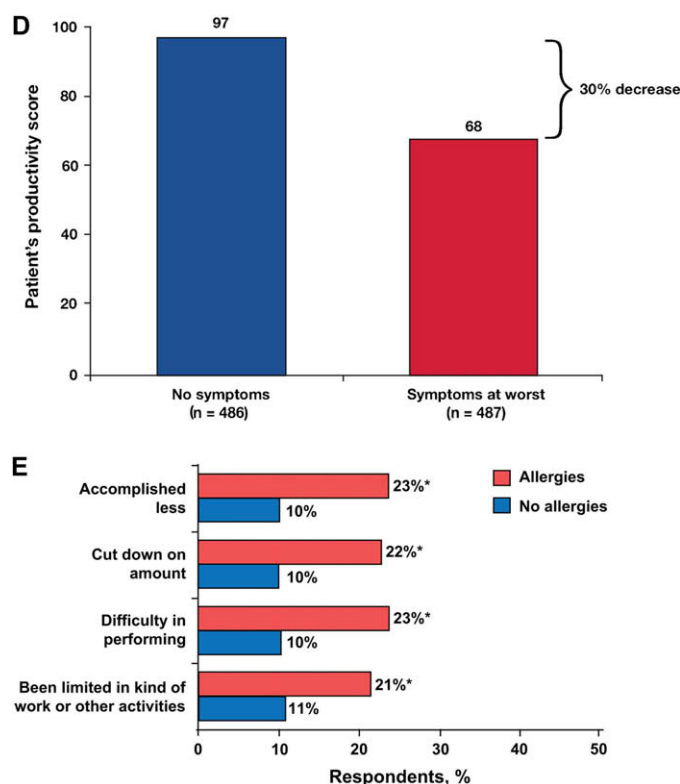


FIG 6. (Continued)

effect of nasal allergies on children's social lives and productivity can be assessed in 3 ways: effect on absenteeism, effect on productivity (presenteeism), and effect on daily activities (avoidance).

Nasal allergies, health, or both interfered with the daily school activities of US children such that approximately two thirds of children (with or without AR) had missed school or day care in the past 12 months because of allergies, health reasons, or both (absenteeism). Although the rate of absenteeism is roughly equal among children with and without AR, presenteeism (or diminished performance while at school) appears to be a significant burden of AR that is frequently overlooked: a large percentage of parents (40%) report that their children's condition interferes with their performance at school ($P < .001$). The true effect of presenteeism has not generally been considered in previous studies on the burden of AR in children. In addition to the survey's findings on absenteeism and presenteeism, 28% of parents reported that their children with nasal allergies avoided daily activities because of their symptoms ($P < 0.001$; Fig 6, C). Furthermore, when the Pediatric Allergies in America survey asked parents to quantify the effect of their children's nasal allergies, health, or both, parents of children with allergies reported a 30% decrease in their children's productivity at school and at home when allergy symptoms were at their worst (Fig 6, D).

Children with nasal allergies are also more limited in their daily activities than children without allergies. Almost twice as many (21%) parents of children with nasal allergy reported that their children's condition or health limited the kind of work or other activities they could do compared with parents of allergy-free children (11%, $P < .001$). In addition, when compared with the parents of allergy-free children, more than twice as many parents reported that their children with nasal allergies found performing

work or other activities difficult (23% vs 10%, $P < .001$). It is suggestive that the difficulty in completing assigned tasks that was observed by parents might explain the overall reduction (22%) in the amount of time spent by the child with nasal allergies on daily activities compared with the allergy-free child (10%, $P < .001$). Parents' reports of decreased productivity, difficulty in completing tasks, and reduced amount of time spent on daily activities resulted in reductions in what the child with nasal allergies was perceived to accomplish on a daily basis. Parents of children with nasal allergies were more than twice as likely to report decreased productivity in their children as a result of their condition or health compared with parents of children without allergies (23% vs 10%, respectively; $P < .001$; Fig 6, E).

Activity avoidance can be an insidious effect of nasal allergies on children's social lives. For instance, among children of school age, 17% experienced a lot or some interference with school activities related to AR compared with 5% of children without allergies ($P < 0.001$; Fig 7, A). Similarly, when parents were asked whether allergy symptoms or health interfered with their children's daily activities, parents of children with AR were approximately 3 times more likely to report that allergies affect whether their child performs well in school (26% vs 9%, $P < .001$). General outdoor activities, going outside or playing with friends, and organized sports or exercise participation were limited approximately 3 to 4 times more frequently in children with nasal allergy than in allergy-free children ($P < .001$ for all). These reductions may contribute to the high prevalence of US children who are overweight (16%) or at risk for being overweight (32%), which is defined as the 95th percentile or greater or the 85th percentile or greater of the Centers for Disease Control and Prevention sex-adjusted body mass index-for-age growth charts, respectively.²⁵ The smallest

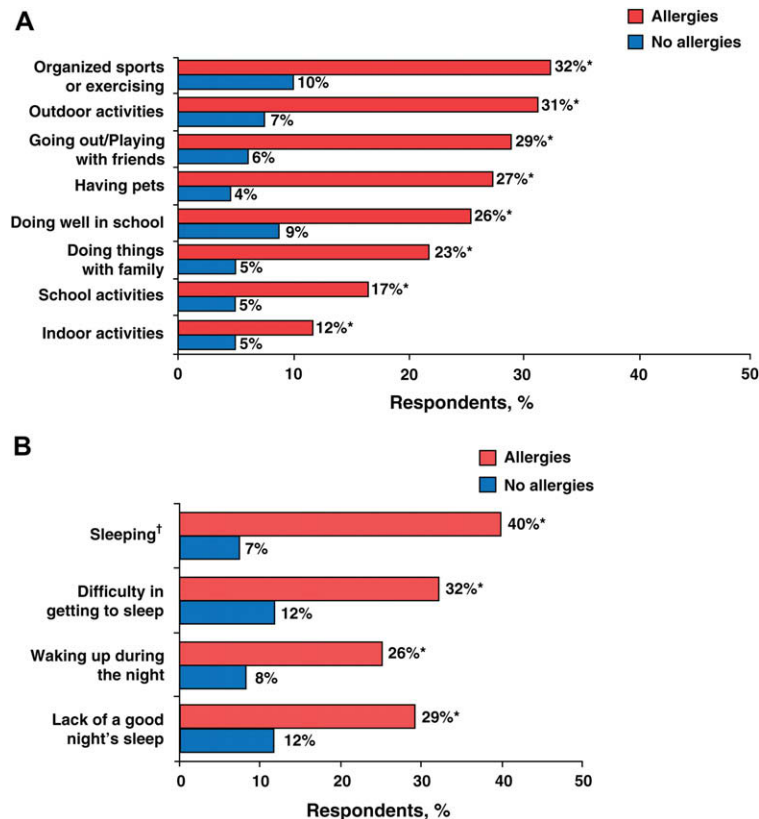


FIG 7. Effect of AR on the social health of children. **A**, Parent's perceptions on the effect of nasal allergy symptoms on children's activities. **B**, Parent's perceptions on the effect of nasal allergy symptoms on children's sleep. * $P < .001$. [†]Allergies affect sleep "a lot or some."

difference in parental opinion between these 2 groups of children was whether indoor activities were limited: 12% of parents of children with nasal allergy said that their children's allergies or health interfered a lot or some with indoor activities compared with only 5% of parents of children without nasal allergies ($P < .001$).

Sleep problems

In addition to the general effects of nasal allergy symptoms on daily activities, the symptoms of AR have a profound effect on the ability to sleep for both adults and children with the disease. Several studies have demonstrated that nasal obstruction or congestion, such as occurs with AR, is associated with a disruption in the normal pattern of breathing in adults.^{26,27} In fact, more than half (57%) of adult patients and 88% of pediatric patients with AR are estimated to experience difficulty sleeping.²⁸⁻³⁰ One such study in adults, the Burden of Allergic Rhinitis, found that adults with AR have a reduced quality of sleep as measured by the sleep-problems index or the sleep-adequacy scale. Furthermore, this study found that adult patients with AR were approximately 10 times more likely to experience brief awakenings, or microarousals, during sleep when allergy symptoms were at their worst.³¹ These disruptions were thought to be a result of increased upper airway resistance brought about by symptoms such as nasal congestion and runny nose. Sleep disruption contributes to daytime fatigue in many patients with AR; however, for reasons not completely understood, there appears to be an added effect of AR on daytime drowsiness that might be independent of nighttime sleep impairment.^{32,33}

Furthermore, during childhood and adolescence, sleep-disordered breathing has been associated with an increased frequency of learning performance disorders, behavioral disorders, and attention-deficit disorders.^{34,35} AR has also been demonstrated to adversely affect childhood learning and decrease cognitive functioning.³⁶

The data from the Pediatric Allergies in America survey support the assertion that nasal allergy symptoms commonly experienced by children disrupt both the pattern and quality of sleep. In fact, 40% of parents of children with nasal allergy report that their children's allergies/health interfere a lot or some with sleep compared with only 7% of parents of children without allergies ($P < .001$). Parents of children with nasal allergy were more than twice as likely to describe sleep problems, such as difficulty in falling asleep (32% vs 12%, $P < .001$), waking during the night (26% vs 8%, $P < .001$), and lack of a good night's sleep (29% vs 12%, $P < .001$), in their children compared with parents of children without allergies (Fig 7, B). These findings support the assertion that AR exerts a profound effect on the physical, mental and emotional, and social health of children in the United States.

Comorbid conditions

Comorbid conditions occurring with AR include eye symptoms, such as conjunctivitis, ear problems (otitis), and headaches.^{17,29} For example, allergic conjunctivitis (red itchy eyes) was reported by parents to occur in 29% of children with AR every day or most days during their worst month for nasal allergy symptoms. Other common upper airway issues in children with

TABLE II. Nasal allergies contribute to other upper airway problems

	Patients or parents (%)		Fold difference
	AR	No AR	
Pain or pressure			
Headache*	54	19	2.8
Face*	28	4	7.0
Ear*	24	5	4.9
Surgery			
Tubes placed†	16	9	1.8
Tonsils and/or adenoids removed‡	18	11	1.6
Sinus problems*	43	4	10.8
Snoring*			
Every day	14	5	2.8
Most days	10	4	2.5

* $P < .001$.† $P < .05$.‡ $P < .01$.

AR include sinusitis, snoring, and dental issues, such as malocclusion.^{9,17,37,38} Previous studies have estimated the prevalence of otitis media in children with nasal allergies to be 21%, whereas 35% to 50% of children with otitis with effusion were found to have nasal allergies.^{39,40} Parents' responses in the Pediatric Allergies in America survey support these data. Parents reported that children diagnosed with AR were approximately 5 times more likely to experience pressure-related ear pain at least a few days during their worst month for allergy symptoms than children without AR ($P < .001$). Among children with AR, more than half (56%) reported their ear pain as moderately or extremely bothersome. Interestingly, the peak season for both ragweed- and mold-induced allergies coincides with the peak season for Eustachian tube problems in children with nasal allergies.⁴¹ In fact, 16% of children with AR have had tubes placed in their ears compared with 9% of children without allergies ($P < .05$). Additionally, 18% of children with AR had their tonsils, adenoids, or both removed compared with 11% of children without allergies ($P < .01$). These findings demonstrate a nearly 2-fold increased incidence of surgery to treat ear and upper airway infections in children with AR versus children without AR, a finding that might suggest either an increased susceptibility to upper airway diseases in children with symptomatic AR or the frustration of patients, parents, and clinicians with the results of previous interventions (Table II).

Several studies have clearly demonstrated that a strong correlation exists between allergy and sinus problems in the general population, which are estimated to range from 25% to 80%.^{17,38} The Allergies in America surveys found that 50% of adults and 43% of children diagnosed with AR had sinus problems, supporting the notion that nasal allergies might be a common factor contributing to acute or chronic sinus problems.⁸ Furthermore, parents reported that sinus problems occur more frequently in their children diagnosed with AR (43%) compared with children without AR (4%), a 10-fold increase ($P < .001$, Table II). Snoring is also a common association with nighttime symptoms of AR. Nasal congestion and obstruction as a result of AR might contribute to mouth breathing, with a resultant increase in snoring, which can then be considered an additional nighttime symptom of the

TABLE III. Comorbidity of AR and asthma

	Patients or parents (%)		Fold difference
	AR	No AR	
Asthma diagnosis*	39	13	3
Asthma in last 12 mo*	28	7	4

* $P < .001$.

disease.⁹ In a study of adults who regularly (>15 nights per month) experienced nighttime nasal allergy symptoms, 47% were found to be chronic snorers. In comparison, the Pediatric Allergies in America survey found that more than twice as many children with nasal allergies snore every night (14%) or most nights (10%) compared with children without nasal allergies (5% and 4%, respectively; $P < .001$; Table II).

In addition, frequent nighttime AR symptoms were also strongly associated with excessive daytime sleepiness and chronic nonrestorative sleep in adults.²⁷ This is likely to be true in children as well, with 40% of parents noting that their children's allergies interfered with sleep. Chronic mouth breathing in children, a common result of the frequent nasal congestion observed in patients with AR, has also been associated with orthodontic malocclusions. Children with nasal congestion are likely to breathe through their mouths, and mouth breathing has been linked to an almost 3-fold increase in incidence of orthodontic malocclusions compared with nose breathing.³⁷

Parents report that significantly more children with AR compared with children without AR had headaches (54% vs 19%, $P < .001$) and facial pain or pressure (28% vs 4%, $P < .001$), respectively, at least a few days during their worst month in the previous year. Headache (59% vs 68%) and facial pain (53% vs 54%) were considered moderately or extremely bothersome by more than half of the parents of children with AR and older children with AR (10-17 years of age) surveyed, respectively. These figures represent a nearly 3-fold increase in headaches and a 7-fold increase in facial pain or pressure in children with nasal allergies compared with children without allergies. These findings suggest that children with inadequately controlled symptomatic AR might experience an underappreciated degree of head and facial discomfort that is not shared in children free of nasal allergies (Table II).

In patients with AR, concomitant lower airway involvement is common. There appears to be both neurologic and inflammatory crosstalk between these conditions.⁴² Furthermore, AR is not only a risk factor for asthma, but asthma might also be exacerbated as a result of uncontrolled AR. There is increasing evidence supporting the concept that AR and asthma are similar chronic inflammatory diseases affecting the upper and lower airways, respectively.⁴³ Recent surveys suggest a solid link between them: approximately 78% of patients with asthma have AR, and 38% of patients with AR have concomitant asthma.^{44,45} In many ways, AR and asthma have significant effects on patient QoL.

The Pediatric Allergies in America survey found that among children diagnosed with AR, 39% also were diagnosed with asthma, and 28% of children diagnosed with AR also had asthma symptoms in the past 12 months. These figures represent a significant 3- to 4-fold higher incidence of asthma in children with AR than in children with no AR ($P < .001$ for each comparison). Interestingly, when compared with data uncovered in the Allergies in America survey of adults with AR, the prevalence of

comorbid asthma in children observed in the Pediatric Allergies in America survey differed by sex. Forty-five percent of male children and 33% of female children with AR had concomitant asthma, whereas 29% of adult male and 34% of adult female patients had concomitant asthma. These surveys show that although asthma is common in both pediatric and adult patients with symptomatic AR, the diagnosis of asthma appears to be more common in pediatric male patients than in adult male patients. Numerous studies have shown that among children with AR, the ratio of concomitant asthma in boys to girls is roughly 2:1.⁴⁶⁻⁵¹ Although the Pediatric Allergies in America study describes a similar finding that male children might be more prone to concomitant asthma than female children, the finding is closer to a 1.4-fold higher frequency in male than in female children. This discrepancy between sexes appears to even out by adulthood, a finding that is supported by the Allergies in America surveys.^{7,9} Overall, pediatric patients with AR have a 3- to 4-fold increased incidence of asthma versus children without AR. Treatment of AR symptoms in adults has been demonstrated in several studies to reduce the incidence and severity of asthma.⁵²⁻⁵⁶ These findings suggest that the putative link between AR and asthma warrants further examination and that an expanded understanding of AR treatment effect on the incidence and symptoms of asthma in children is also warranted (Table III).

The Pediatric Allergies in America survey has generated compelling evidence that children with nasal allergies might experience substantially more physical, mental, emotional, and social problems than children who do not have allergies. The increased burden of symptoms frequently undermines restful sleep, leaving children fatigued throughout the day. Daytime drowsiness as a result of AR can result in impairments in learning and cognition through absenteeism, presenteeism, and activity avoidance. In addition, the chronic inflammation associated with AR frequently causes comorbid conditions, such as allergic conjunctivitis; generalized facial, head, and ear pain, sometimes leading to surgery (eg, adenoidectomy, tonsillectomy, and placement of tympanostomy tubes); and other significant airway diseases, such as sinusitis and asthma. These findings are in concordance with those obtained in the Allergies in America survey of adults with nasal allergies.

NEED FOR TREATMENT OF AR SYMPTOMS

Through the combination of bothersome symptoms, compromised sleep, and effect on physical, mental, and emotional health, AR has a profound effect on the daily lives of children with the disease. When asked to estimate the effect of nasal allergy symptoms on their children, 1 in 4 parents felt that nasal allergies affected their child's life a lot (9%) or a moderate amount (17%) during the allergy season. Interestingly, compared with parents, HCPs reported that AR has a far greater effect on their patients' lives: more than 3 in 4 HCPs estimated that nasal allergies affect the lives of their pediatric patients a lot (26%) or a moderate amount (51%; Fig 8, A).

Many children cannot tolerate the discomfort associated with nasal allergy attacks without symptom relief. Parents reported that the amount of discomfort their children with nasal allergies experienced during nasal allergy attacks was significant. The majority (57%) of parents said that although their child's discomfort during an allergy attack could not be ignored, it was tolerable.

Only 8% of parents believed that their children could ignore the discomfort caused by a nasal allergy attack. Similarly, more than 60% of HCPs agreed that although their pediatric patients cannot ignore nasal allergy symptoms, they could tolerate them. One would expect that a child's ability to ignore nasal allergy symptoms plays a large role in their effect on that child's daily life. Both parents (33%) and HCPs (35%) agreed that the discomfort some children experienced during a nasal allergy attack was not tolerable without relief (Fig 8, B).

In general, children with nasal allergies are more likely to be seen by a physician or allied HCP than children without nasal allergies. Most (83%) parents of children with nasal allergies reported 2 or more visits to their child's HCPs in the preceding 12 months for general health concerns compared with 61% of parents of children without nasal allergies. HCP visits for nasal allergy symptoms were also frequent, with 62% of parents reporting that their children had seen an HCP about their nasal allergies in the preceding 12 months. Remarkably, 17% of parents of children with nasal allergies reported that their children had seen an HCP 5 or more times in the past 12 months primarily for their nasal allergy symptoms. Although practitioner visits were frequent, in-office immunotherapy for nasal allergies was uncommon: only 8% of patients received allergy injection treatments by their HCP during those office visits within the past year.

Most children with nasal allergies take medication to control their symptoms. Three fourths (76%) of parents of children with nasal allergies said that their children took either an OTC or prescription medicine for their nasal allergies in the past 4 weeks. It is apparently not uncommon for OTC and prescription medications to be used in combination for treatment of the bothersome symptoms of nasal allergies. In fact, a recent survey reported that many adults with AR use 2 to 4 medications simultaneously to control their AR symptoms.⁵⁷ When parents were asked what types of medication their children used for allergy symptom relief during the past 4 weeks, more than half (54%) reported the use of an OTC medicine, whereas slightly fewer (48%) reported use of prescription medications. One fourth (26%) of parents said that their children had used a prescription nasal spray, and one third (34%) of parents reported that their children had taken some other prescription medications (excluding nasal sprays) to control their allergy symptoms in the past 4 weeks. Only 24% of parents reported that their children used no medication in the past 4 weeks. Historically, parents report that 34% of their children use prescription allergy medications only, 25% use OTC medications only, and 39% use a combination of both prescription and OTC medications for nasal allergy relief. Only 2% report that they do not use any medication for AR (Fig 8, C).

Parents and physicians recognize that nasal allergies have a moderate-to-severe effect on the lives of children. Although the discomfort associated with nasal allergies is generally considered by parents and practitioners to be tolerable for children, most parents and practitioners acknowledge that without symptom relief from medication, these symptoms cannot be ignored. Children with nasal allergies are more prone than children without nasal allergies to require visits to their HCP for relief of symptoms or for general health concerns. As a result of the discomfort and health effects caused by nasal allergies, most children take prescription or OTC medication to relieve bothersome symptoms of their nasal allergies.

These findings on the need for treatment of nasal allergies in children are similar to data obtained in the Allergies in America survey of adults with nasal allergies. Forty percent of adults believed

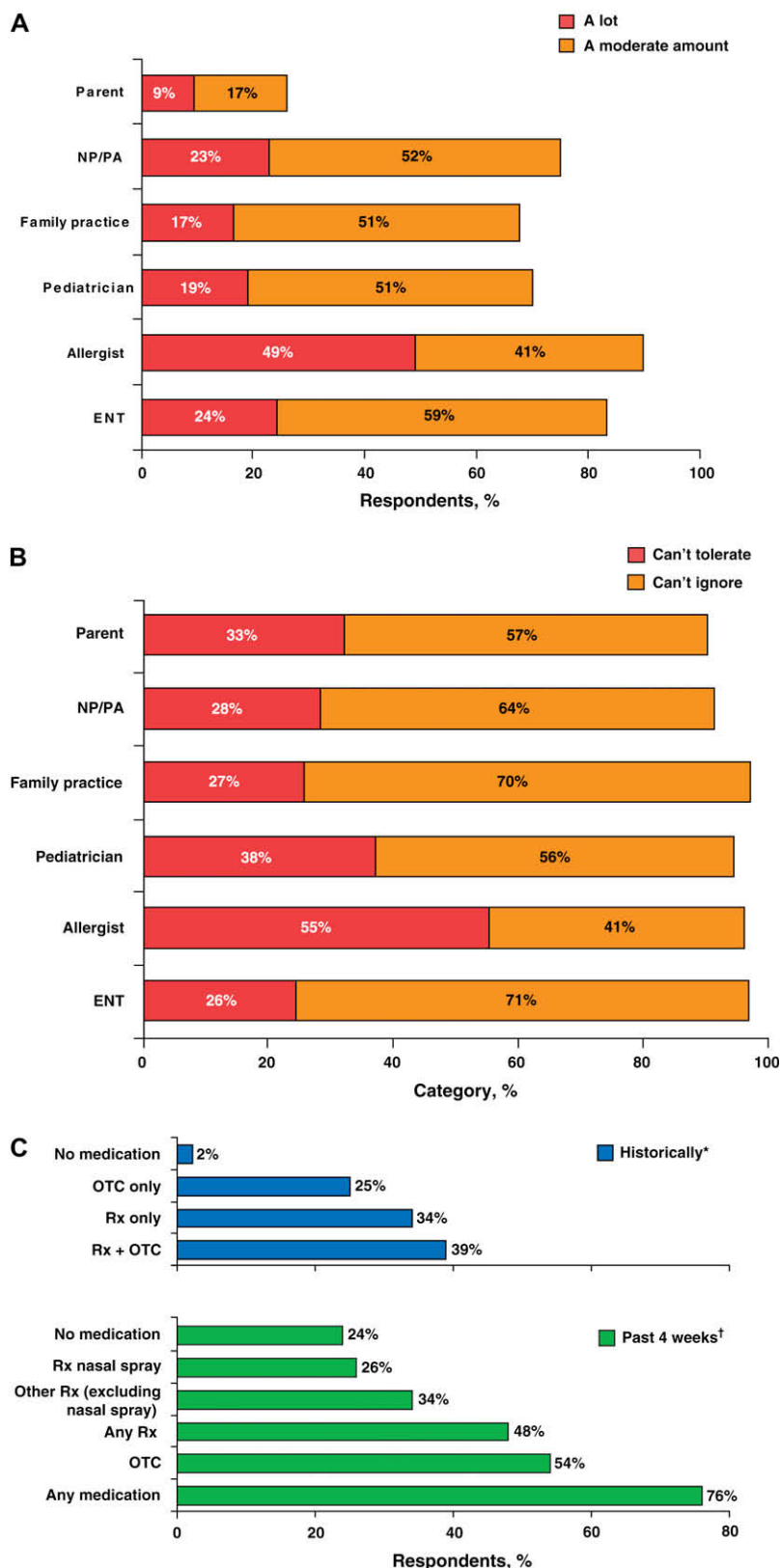


FIG 8. Need for treatment of AR in children. **A**, Percentage of parent's and HCP's responses that nasal allergies affect the daily lives of children. **B**, HCP's perceptions on ability of children to tolerate or ignore nasal allergy symptoms. **C**, Percentage of children receiving medications to control nasal allergy symptoms. ENT, Ear, nose, and throat specialist; Rx, prescription. *Responses to the question, "For the management and treatment of your nasal allergy symptoms, do you use prescription medications only, nonprescription medications only, or both?" †Responses to the question, "In the past 4 weeks, has your child used any OTC nonprescription medicine, any prescription nasal spray, or any other prescription medication to give relief from nasal allergy symptoms?"

that their nasal allergy symptoms had a moderate-to-large effect on their daily lives compared with 26% of children.⁸ As a result, 69% of adults with nasal allergies reported that they were currently taking either a prescription or OTC medication to control their symptoms. Remarkably, when adult patients and practitioners were asked whether the discomfort caused by their nasal allergy symptoms could be tolerated or ignored, nearly half of adult patients (44%) and HCPs (49%) said that the discomfort could not be tolerated without relief, whereas 51% of adult patients and HCPs alike said that the discomfort could be tolerated but not ignored. These findings are in contrast to the Pediatric Allergies in America survey, which reported much lower parent and practitioner estimates of whether children's nasal allergy symptoms were tolerable without relief. This discrepancy might suggest a reduced emphasis on how complaints of nasal allergy symptoms in children are regarded by parents and HCPs compared with nasal allergy symptoms in adults. Taken together, the data on the need for treatment obtained from the 2 Allergies in America surveys strengthen the assertion that nasal allergies have a profound effect on the lives of both adults and children with AR. Furthermore, it appears that medication is often required to alleviate these symptoms of nasal allergies and to reduce the burden of this disease on the daily lives of Americans with AR.

EFFICACY OF CURRENT NASAL ALLERGY MEDICATIONS IN PEDIATRIC PATIENTS WITH AR

Ideally, children experiencing uncontrolled rhinitis symptoms should be referred by their pediatrician to an allergy specialist for consultation and specific allergen testing. Once the determination that a specific allergen is responsible for the nasal symptoms, ocular symptoms, or both has been made, appropriate steps to remove the allergen or otherwise limit exposure to the allergen should be made. The benefit would be that identifying the causative allergen or allergens could dramatically improve the likelihood of encouraging reduction of the allergen burden in the home and of education to reduce allergen exposure outdoors. Methods to effectively decrease the indoor allergen threshold (albeit with mixed results) have been extensively described elsewhere.^{58,59} Environmental controls, such as allergen avoidance, removal of indoor allergy triggers, or both, can be an important first step to the general management of AR and asthma, although, with the exceptions of avoidance of pet dander and tobacco, they are not usually of major benefit.^{17,18,20,60} Avoidance can reduce overall allergen exposure and the severity of AR symptoms. Allergen avoidance can also be effective, to some degree, in controlling exposure to dust mites, mold, and fungi in the home (through humidity control, high-efficiency particulate air filtration, and cleaning with a dilute bleach solution for mold and fungi).¹⁸ Limiting exposure to outdoor triggers on high-pollen-count days can be difficult for individuals who are sensitive to pollen,¹⁷ although reporting of pollen counts as part of a daily news broadcast during the peak pollen season is becoming increasingly common in many areas and might help sensitive individuals minimize their exposure. Although environmental control of allergen exposure is a necessary step in preventing AR symptoms, pharmacologic therapy is often required for control of moderate-to-severe symptoms of nasal allergies.⁶⁰

Numerous options exist for both OTC and prescription pharmacologic management of AR, including oral and intranasal antihistamines, decongestants, leukotriene inhibitors, immunotherapy, and INCSs. Despite reasonably effective control of nasal allergy symptoms, these medications can have local side effects, such as

epistaxis, nasal dryness, irritation, and burning from the intranasal medications, and systemic side effects, such as drowsiness from antihistamines.^{11,12} Immunotherapy, an established adjunct to AR pharmacologic management, decreases nasal tissue reactivity through increased allergen tolerance or IgE attenuation by mAbs.^{19,61} Although shown to be safe and effective for the treatment of AR, immunotherapy is not generally considered a first-line treatment and might suffer from poor patient adherence because of the prolonged treatment needed to obtain durable efficacy.²⁰

INCSs are currently the pharmacologic standard of care for treatment of moderate-to-severe persistent AR. INCSs provide effective symptom relief by controlling the underlying allergic inflammation that results in the disease. Although INCSs are the gold standard for pharmacotherapy of AR, the extent that unwanted systemic effects, including bone mineral loss, growth retardation, adrenal suppression, and ocular disturbances, occur in children with long-term use is an appropriate concern.^{14,62} Of particular note are reports of cortisol suppression and growth slowing during treatment with some INCSs.¹³⁻¹⁵ Cortisol suppression might be problematic in children because of the absence of weight-based dosing of INCSs to effectively relieve symptoms.^{13,15,16}

Currently available INCSs and other prescription nasal sprays appear to also vary in speed of relief and duration of action and might not provide complete or long-lasting relief of nasal allergy symptoms.⁶³ Failure of nasal allergy medications to effectively control all symptoms of nasal allergies in all patients might reduce satisfaction with treatment and decrease adherence to treatment.

Sixty-three percent of children with nasal allergies who were participants in the Pediatric Allergies in America survey have used a prescription nasal spray (INCSs or antihistamines) to treat their AR, and 53% have used one in the past year. To better assess treatment satisfaction of current prescription nasal sprays in children with AR, parents were asked how their children's current medications performed in terms of completeness, speed, and duration of relief. Parents and patients alike were unhappy with the incomplete relief of AR symptoms obtained with their current medications. Most parents considered treatment to be ineffective if it did not provide rapid, long-lasting relief of all or most of their children's symptoms. Parents of children who had used a prescription nasal spray in the past 4 weeks were asked whether their children's current prescription relieved all, most, some, or none of their symptoms. Only 17% reported relief of all of their children's symptoms, but in addition, nearly half (47%) said that most of their children's symptoms were relieved by their current prescription. However, almost one third (29%) said that their children's current prescription nasal spray relieved only some symptoms, and 4% said that it did not relieve any of their children's symptoms (Fig 9, A).

In addition to completeness of relief, factors such as speed and duration of relief obtained with nasal allergy medications play a large role in parent and patient satisfaction with medications. Generally, and surprisingly, INCSs are rated by both parents and children as having a very rapid onset of action. Indeed, half of parents reported that their children's current INCSs provided symptom relief in less than 1 hour (19%) or in 1 hour (31%). Notably, 23% of parents reported a 24-hour or longer delay in symptom relief with their children's current prescription. These findings suggest that current treatments for AR suffer from a great deal of variability in time to onset of symptom relief (Fig 9, B).

Few parents believe that their children's current medication provides long-lasting relief of symptoms. Parents feel that

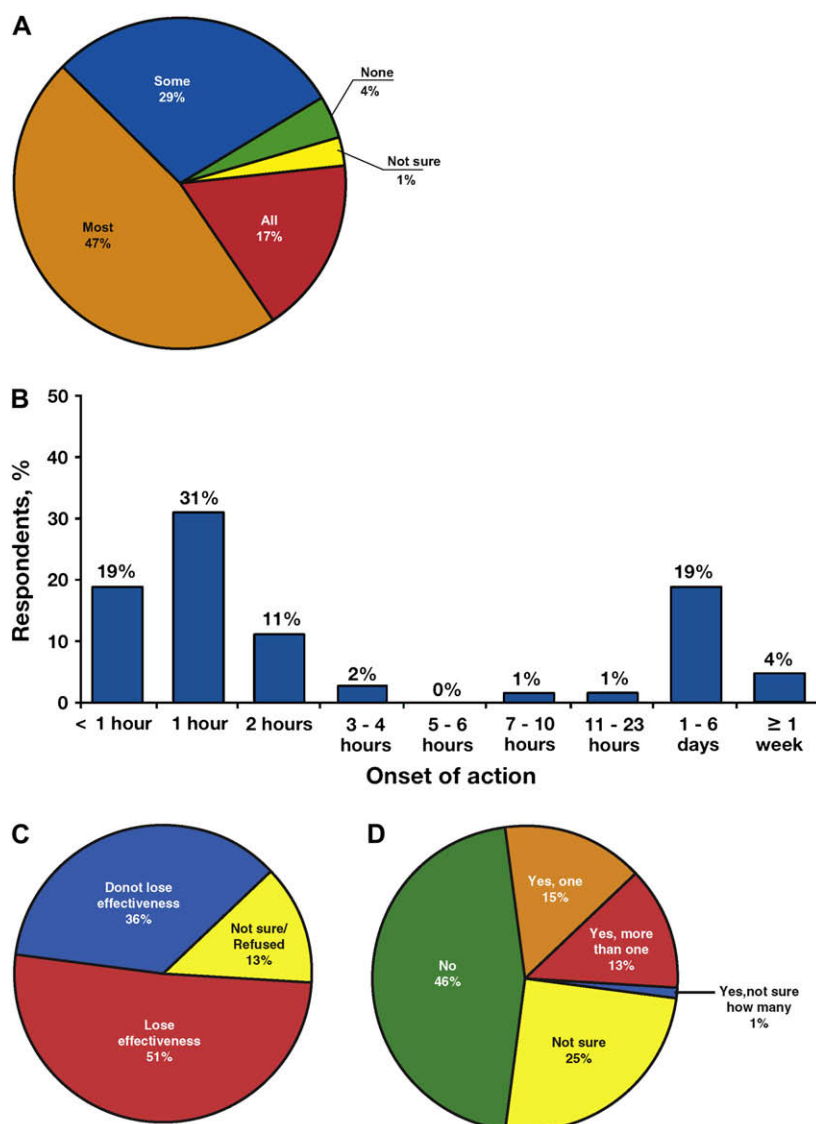


FIG 9. Efficacy of INCS treatment in children. **A**, Nasal allergy symptoms treated by INCSs. **B**, Onset of action of INCSs in children. **C**, Duration of INCSs symptom relief in children. **D**, Effectiveness of prescription nasal sprays over time (includes all prescription nasal sprays).

24-hour relief is a prerequisite for effective treatment. Among parents of children who used a prescription nasal spray in the previous 4 weeks, more than half (51%) reported that their children's current nasal spray lost effectiveness over the course of the day or night. Furthermore, only 36% of parents said that the medication relieved symptoms as effectively after 24 hours as when their children first took it. The perception among parents and patients that medication does not last 24 hours plays a large role in parent and patient dissatisfaction with treatment (Fig 9, C).

Loss of effectiveness over time might be another characteristic of nasal allergy medications because 29% of parents of children with AR reported that their children's medication had lost effectiveness, even when it was taken as prescribed. Thirteen percent of parents said that their children had experienced a loss of effectiveness over time with more than 1 nasal allergy medication, and another 15% said that their children had experienced a loss of effectiveness with only 1 medication (Fig 9, D).

Parents of children with AR were also asked about their children's experience with common unfavorable attributes of prescription nasal sprays for allergies. Parents were asked how many of the prescription nasal sprays (all, most, some, few, or none) their children had taken for allergy symptoms had unwanted attributes. According to nearly half of parents, nasal spray dripping down their children's throats was the most commonly occurring side effect of nasal allergy medications. This side effect was said to occur with all (21%), most (8%), or some (13%) of their children's nasal allergy medication. The next most frequently reported common attribute of current nasal allergy medication was bad taste. Nearly 2 of 5 parents reported that all, most, or some of the nasal allergy medications taken by their children had a bad taste. Fewer parents reported that their children experienced a drying feeling, burning, drowsiness, and headaches as unwanted attributes of their nasal allergy medication (Fig 10, A).

In addition to being reported as occurring most frequently, dripping down the throat and bad taste were reported by parents as

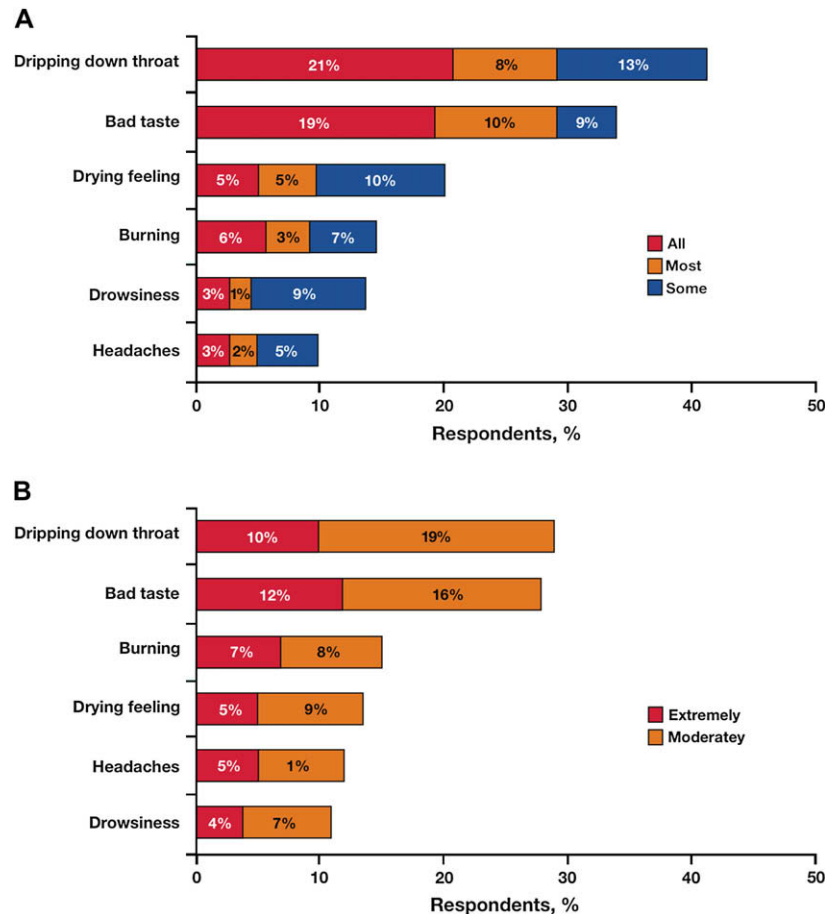


FIG 10. Bothersome attributes of prescription nasal sprays in children. **A**, Bothersome side effects of prescription nasal allergy sprays experienced by children. **B**, Most bothersome attributes of nasal allergy medications in children.

being the most bothersome attributes of their children's prescription nasal spray. Nearly 3 of 10 parents of children with AR reported that nasal allergy medication dripping down the throat was moderately (19%) or extremely (10%) bothersome to their children. Slightly fewer reported that the bad taste of nasal allergy medication was moderately or extremely bothersome. A burning sensation, drying feeling, headaches, and drowsiness with medication use were considered less bothersome by parents (Fig 10, B).

Notably, 59% of parents report that they have changed their children's nasal allergy medication at least once in the past few years. Parents reported changing medication more than once per year (8%), once per year (8%), or every few years (10%). Among parents whose children had changed nasal allergy medications, the most frequently cited reasons for changing medication were that the nasal allergy medicine was not effective enough (40%) or that their doctor had wanted to try a new medication (22%). Children wanting to try another medication or the feeling that the medication did not treat their children's allergy symptoms were reported by only 7% of parents as reason for discontinuation. Bothersome side effects, insufficient insurance coverage, and short-acting relief of symptoms were mentioned much less frequently as reasons for changing their children's nasal allergy medication (Fig 11, A).

Parents and children were occasionally dissatisfied with their nasal allergy medication. Among parents and children who had

asked their doctors for a change of medication, ineffectiveness (63%) and bothersome side effects (18%) were the most frequent reasons for dissatisfaction with a child's nasal allergy medication. Similarly, effectiveness wearing off over time (10%) and incomplete 24-hour symptom relief (9%) were reasons that the parent or child had been dissatisfied with nasal allergy medications. Difficulty in administration or problems with the dosing schedule, incomplete insurance coverage or high copay, or product safety concerns were mentioned less frequently by parents as reasons for dissatisfaction with medication (Fig 11, B).

Dissatisfaction with nasal allergy medications can occasionally lead to poor adherence, as well as discontinuation of medication. Simply put, children often do not take their nasal allergy medication as prescribed. In addition to times when symptoms have abated, children also stop taking their medication as prescribed when it does not relieve their symptoms (26%) or when it loses effectiveness over time (24%). Troublesome side effects (20%) and worry about side effects (19%) were also reported by parents as reasons that their children stopped taking their allergy medication as prescribed. Nearly as many parents (17%) reported poor tolerance and a concern about long-term use as reasons. To a lesser extent, safety concerns and medication cost were reported as reasons why their children had failed to follow their physician's instructions regarding their nasal allergy medications (Fig 11, C).

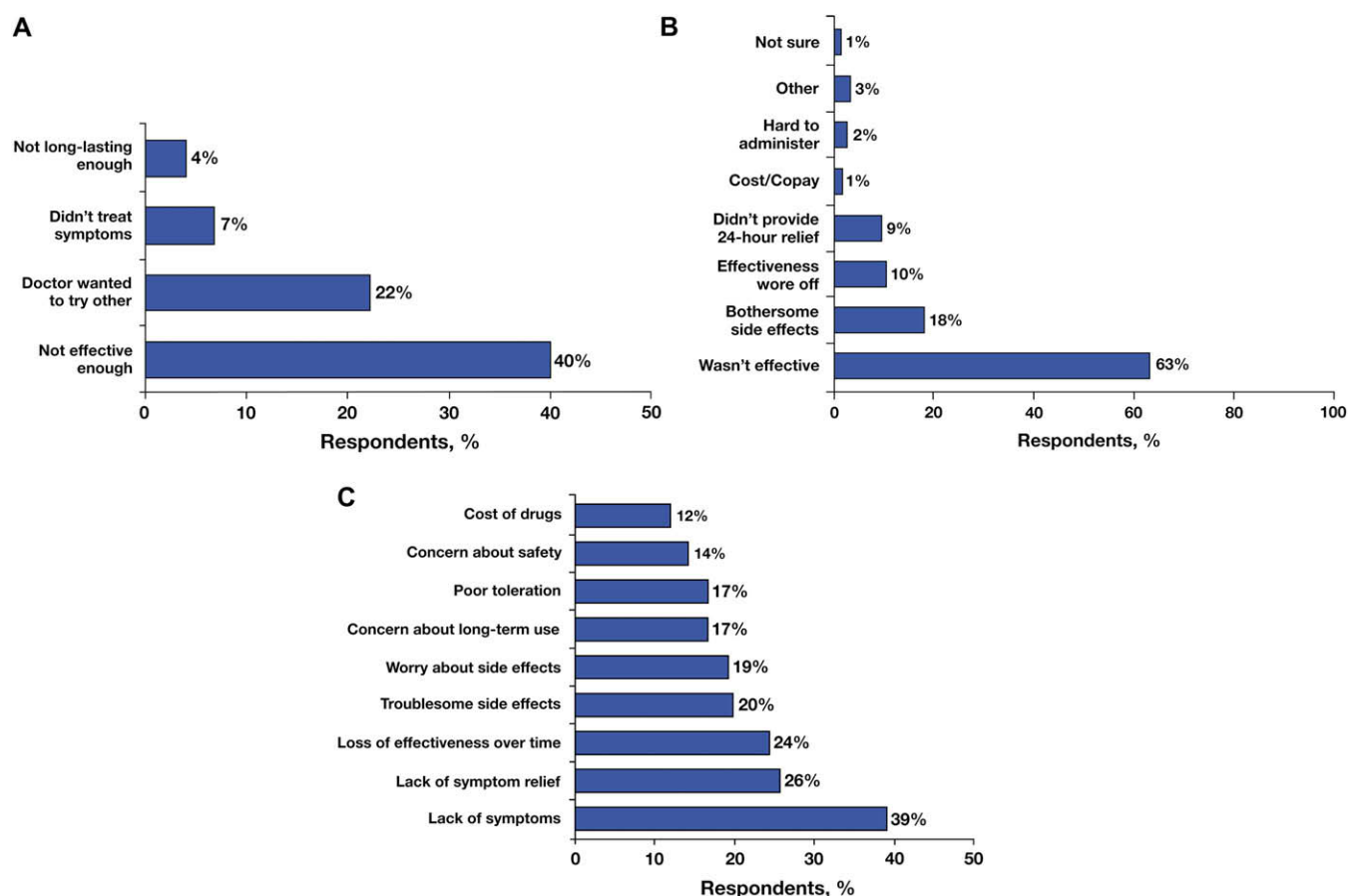


FIG 11. Reasons for dissatisfaction with medication and reduced adherence to treatment. **A**, Reasons for requesting a change in prescription nasal allergy medications. **B**, Reasons for dissatisfaction with prescription nasal allergy medication. **C**, Reasons for poor adherence to prescribed dosing regimen.

Although relatively few parents reported being dissatisfied with their children's current OTC or prescription nasal allergy medicines, 26% asked their children's doctors to change their medication because of dissatisfaction. The most common reason for parents asking their children's doctors to change prescriptions was that the medication was not effective enough at controlling their children's nasal allergy symptoms. Bothersome side effects, effectiveness wearing off over weeks to months, and ineffective 24-hour relief of symptoms also resulted in the parent or child asking the doctor to change nasal allergy medication.

In summary, most parents reported that they or their children were unhappy with the incomplete relief of symptoms provided by their current nasal allergy medication. These medications are not viewed by parents as providing rapid, long-lasting relief of all or most of their children's symptoms. Many parents and patients feel that 24-hour relief of symptoms is a prerequisite for an effective nasal allergy medication yet their children's current nasal allergy medication does not relieve symptoms for a full 24 hours. Parents and patients also believe that the effectiveness of current nasal allergy medications can wear off over weeks to months.

For comparison, the Allergies in America survey reported similar findings on the efficacy of prescription nasal sprays for the treatment of AR. Adults (61%) and parents of children (64%) with AR reported that INCSs relieved all or most of their nasal allergy symptoms.⁸ Relief was also achieved in 1 hour or

less by most adults (59%) and children (50%), although similar numbers of adults (17%) and children (23%) waited at least 1 day to more than a week for the onset of symptom relief. Approximately one half of adults and children reported that their current nasal allergy medication did not provide 24-hour relief of nasal allergy symptoms. Interestingly, it appears that adults might experience loss of effectiveness of their nasal allergy medications over time more frequently than children. Adult patients (55%) and parents of children with nasal allergies (29%) reported a loss of effectiveness over time with 1 or more nasal allergy medications.

Bothersome side effects were reported by both parents of children with AR (16%) and adult patients (21%) as reasons for dissatisfaction with INCSs and other prescription nasal sprays. Although adult and pediatric patients experienced similar bothersome side effects of nasal allergies, a drying feeling, drowsiness, and headaches occurred more commonly and were considered much more bothersome to adults than to children. A drying feeling in response to the medication was considered moderately or extremely bothersome by 34% of adults and 14% of children. Drowsiness experienced with nasal allergy medication was reported as moderately or extremely bothersome by 33% of adults compared with 11% of children. Finally, 25% of adults compared with 13% of children experienced headaches that were considered to be moderately to extremely bothersome. Taken together, the Allergies in America surveys have identified similar

reasons for patient dissatisfaction with their nasal allergy medication or disease management that might result in discontinuation of treatment: incomplete relief, slow time to onset of relief, loss of effectiveness over time, and bothersome side effects contribute to this dissatisfaction in adult patients, parents of children, and children with AR.

PEDIATRIC PATIENT SATISFACTION WITH PRESCRIPTION NASAL SPRAYS FOR AR

Because AR is a chronic inflammatory condition, regular prophylactic use of medication might be required to achieve effective long-term control of nasal allergy symptoms. Adherence to the prescribed AR regimen is needed to maintain reduction of inflammation and resultant nasal allergy symptoms. However, as many as 1 in 3 adults might be inconsistent in the regular use of their prescribed AR medications, and 40% to 80% of these patients might discontinue treatment within 6 weeks.⁶⁴

Results of the Pediatric Allergies in America survey strongly support assertions that patients' concerns over the efficacy, slow onset of action, and duration of symptom relief achieved with INCSs and other nasal allergy medications contribute to patients' dissatisfaction and nonadherence. In addition, the survey indicates that the bothersome attributes of prescription nasal sprays, such as medication dripping down the throat, bad taste, and nasal drying, which are reported to occur frequently in most of the currently available prescription nasal sprays formulations, also contribute to patient dissatisfaction with prescription nasal sprays.

Parent and HCP perspectives on patient satisfaction with current prescription nasal sprays

Parents of children with AR and HCPs are in reasonable agreement in their perceptions of patients' satisfaction with disease management and treatment. When HCPs were asked to estimate the percentage of their patients who were "very satisfied" with the management of their AR, 3 of 4 providers reported that, on average, all (3%) or most (70%) of their patients 4 to 17 years of age were very satisfied with disease management. Broken down by HCP category, allergists, pediatricians, otolaryngologists, family practice doctors, and NPs/PAs believed that all or most of their patients with AR were very satisfied with the management of their disease. Similarly, 68% of parents were very satisfied with the management of their children's AR (Fig 12, A).

HCP perspectives on patient satisfaction with prescription nasal sprays

In addition to satisfaction with disease management, HCPs were asked to estimate how satisfied their pediatric patients were with their prescription nasal sprays. Approximately 9 of 10 HCPs said that their patients were very or somewhat satisfied with their current prescription nasal sprays. In contrast to HCP assessments, however, only 3 (76%) of 4 parents said that they were very or somewhat satisfied with their children's prescription nasal sprays (Fig 12, B). When asked to weigh in on the cost benefit of prescription nasal sprays for children, the vast majority (82%) of HCPs reported that the medication was worth the money. In contrast, only 63% of parents believed that they get their money's worth out of prescription medicines for their children's nasal allergies (Fig 12, C).

HCPs were asked which types of medication they preferred for their patients with AR (with multiple answers permitted). Forty-one percent of providers reported that their medication of choice was an INCS, 27% preferred prescription antihistamines, 7% preferred OTC antihistamines, 6% preferred leukotriene receptor antagonists, 4% preferred a prescription antihistamine/decongestant combination, and 4% preferred intranasal antihistamines. The remaining 10% of HCP responses included preferences for anticholinergic nasal sprays, OTC decongestants, and mast cell stabilizers. Among family practice and internal medicine HCPs, INCSs and prescription antihistamines were equally preferred (34% each). In contrast, providers who specialized in allergy, immunology, or otolaryngology preferred INCSs to prescription antihistamines by a considerable margin (47% vs 26%, respectively). Similarly, pediatricians also preferred INCSs to prescription antihistamines by nearly 2 to 1 (40% vs 23%, respectively).

Comparison of perspectives on AR

Both parents of children with nasal allergies and parents of allergy-free children provided similar responses when asked about their attitudes concerning AR, its treatment, and its effect on their children's lifestyle. When asked whether nasal allergies usually cause some lifestyle limitations, nearly 7 of 10 parents from both groups believed they did. Both groups of parents also agreed that frequent nasal allergy symptoms can be prevented. When asked about the effect of AR on comorbid conditions, approximately three fourths of parents were aware that nasal allergies can make asthma worse and that nasal allergies can cause sinus infections. Although parents of children with allergy and allergy-free children alike agreed that nasal allergies can negatively affect children's lives, only 75% of parents of children without allergies believed that nasal allergies are a serious health problem in the United States compared with nearly 9 of 10 parents of children with allergies ($P < .001$). In addition, 35% of parents of children with nasal allergies and 25% of parents of allergy-free children believed that there are no truly effective treatments for nasal allergies ($P < .001$). Finally, parents with a child with allergies were significantly less likely to agree with the statement that prescription nasal sprays are not safe for children ($P < .05$), a belief that appears to be more widely held by parents of allergy-free children (Fig 12, D). This finding suggests that efforts have been made to make parents of children with allergies aware of the side effect profile of prescription nasal sprays.

Patient and provider education

Parents and HCPs agree that better education about nasal allergies is needed for both parents of children with nasal allergy and the children themselves. Nearly all parents and providers answered that there was at least a moderate to a strong need for improved education for parents of children with AR (Fig 12, E). Improved educational resources should provide an understanding of the burden of AR, its symptoms and available treatment options, and reasons for poor adherence and reduced efficacy of prescription nasal sprays. Improved access to education should not be directed solely toward the patient and family, however. Despite an understanding of the AR burden, many HCPs appear to overestimate patient satisfaction with their prescription medications. This affects not only patient satisfaction with treatment but also

satisfaction with HCPs. Dissatisfaction with prescription nasal sprays in children appears to stem predominantly from failure of the medication to provide rapid, complete, sustained relief of nasal allergy symptoms, as well as from bothersome side effects of the medication's formulation. Greater HCP awareness of this issue might encourage education about the typical onset of action of prescription medications and the need for adherence to dose and schedule to maintain effectiveness, as well as the proper use of the delivery device to reduce side effects.

Patient dissatisfaction decreases adherence to medication and results in lower-than-anticipated efficacy. In patients with asthma, nonadherence to the prescribed regimen has been suggested to occur for many reasons, including inconvenient dosing frequency, difficulty of use, and the side effect profile of the medication.⁶⁵ Because asthma and AR are both chronic diseases with a similar cause, improving the formulation characteristics of prescription nasal sprays (ie, dosing, ease of use, and sensory attributes) might increase patient adherence to AR therapy and enhance patient response to treatment. This survey has identified a number of formulation considerations for prescription nasal sprays for use in children. The development of prescription nasal sprays with favorable formulation characteristics might improve efficacy and tolerability and reduce side effects common with prescription nasal spray treatment. Improving the sensory attributes of these medications might also improve patient satisfaction and adherence to therapy.

DISCUSSION

The Pediatric Allergies in America survey has highlighted gaps in our understanding of AR and the profound effect AR has on children. During the times when allergy symptoms are at their worst, children experience nasal congestion, headache, postnasal drip, repeated sneezing, runny nose, and other symptoms on a near-daily basis. These symptoms were described as being moderately to extremely bothersome by most parents of children with nasal allergies. Because of the effect of these allergy symptoms on sleep quality, most children with AR tend to feel tired, miserable, and irritable at least sometimes during peak allergy exacerbations.

In addition to examining the prevalence, symptoms, and burden of AR in the US pediatric population, the survey addressed the role of nasal allergy medications in the treatment of AR, including patient and provider perspectives on both the effectiveness and bothersome side effects of INCSs and other prescription nasal sprays. Parents and physicians generally agree that about one third of patients do not achieve relief of all or most of their nasal allergy symptoms from prescription nasal sprays. In addition to low perceptions of effectiveness, onset of relief was reported to be delayed for 24 hours or longer by more than 1 in 5 parents. Many children have also experienced decreased effectiveness of prescription sprays in treating their nasal allergy symptoms over weeks to months. Taken together, these perceptions on the overall lack of full effectiveness of INCSs and other prescription nasal sprays in many children might result in discontinuation of medication and reduced adherence to therapy.

Parents reported that the most bothersome side effects of prescription nasal sprays were dripping down the throat, bad taste, and a burning sensation, which were moderately or extremely bothersome to many children. Often, these side effects were sufficiently bothersome to cause the child to stop taking the

medication, request a new medication, or be nonadherent with their physician's instructions. The survey has also identified a number of reasons for the perceived lack of efficacy of current prescription nasal sprays and patient dissatisfaction with disease management.

There appears to be a general consensus among both parents and practitioners that nasal allergy medications are lacking, whether for reasons of ineffective relief of symptoms, slow onset of effect, lack of 24-hour relief, or bothersome side effects. However, more than 85% of parents of children with nasal allergies report being generally satisfied with the nasal allergy medication used by their child in the past 4 weeks, whether it was an OTC medication, a prescription nasal spray, or another prescription medication. This suggests that parents might not have high expectations for relief of their children's nasal allergies and do not have a preference for type of medication. HCPs, however, overwhelmingly prefer INCSs (41%) and prescription antihistamines (27%) to OTC medications or other prescription medications (<16%) for the treatment of their pediatric patients with AR.

Allergies in America, a survey of adults with AR, was also examined to identify differences in prevalence, treatment, and other aspects of AR in children compared with adults. The prevalence of AR was similar in adults (14%) and children (13%). Symptoms were similar for adults and children; however, the frequency and severity of some symptoms varied slightly between populations. The burden of compromised sleep on daytime activities was substantial in both populations. Additionally, both studies support the assertion that lack of efficacy and adverse effects of prescription nasal allergy medications affect patient satisfaction and adherence to treatment in both adult and pediatric populations.⁷

In addition to their effect on sleep quantity and quality, nasal allergy symptoms can have a profound effect on children's lives and activities. Children with AR were almost twice as likely to be limited in their activities compared with children without AR. Compromised health interfered with school performance in 4 of 10 children with the condition compared with only 1 in 10 children without AR. Furthermore, parents report a nearly 30% decrease in their children's productivity when allergy symptoms are at their worst.

Few children can ignore allergy symptoms or tolerate their discomfort without relief, and nearly 3 in 4 have used medication for relief within the past 4 weeks. Although INCS sprays are considered gold-standard pharmacotherapy for moderate-to-severe allergy symptoms, only 1 in 4 children with AR use an INCS. It also appears that despite INCSs being the pharmacologic standard of care for AR, nearly 25% of patients remain somewhat dissatisfied or dissatisfied with their children's INCSs compared with only 9% of HCPs. Dissatisfaction among parents and patients seems to stem from loss of efficacy over a 24-hour dosing period. Many parents also report reduced efficacy over weeks to months of INCS use.

In addition to lack of efficacy, bothersome side effects of prescription nasal allergy sprays often lead to patient dissatisfaction with medication. Bad taste and medication dripping down the throat were the most frequently reported reasons for both dissatisfaction with prescription nasal sprays and poor adherence to a prescribed dosing regimen. Development of prescription nasal sprays with formulation attributes that maximize efficacy and duration and minimize unfavorable attributes should result in

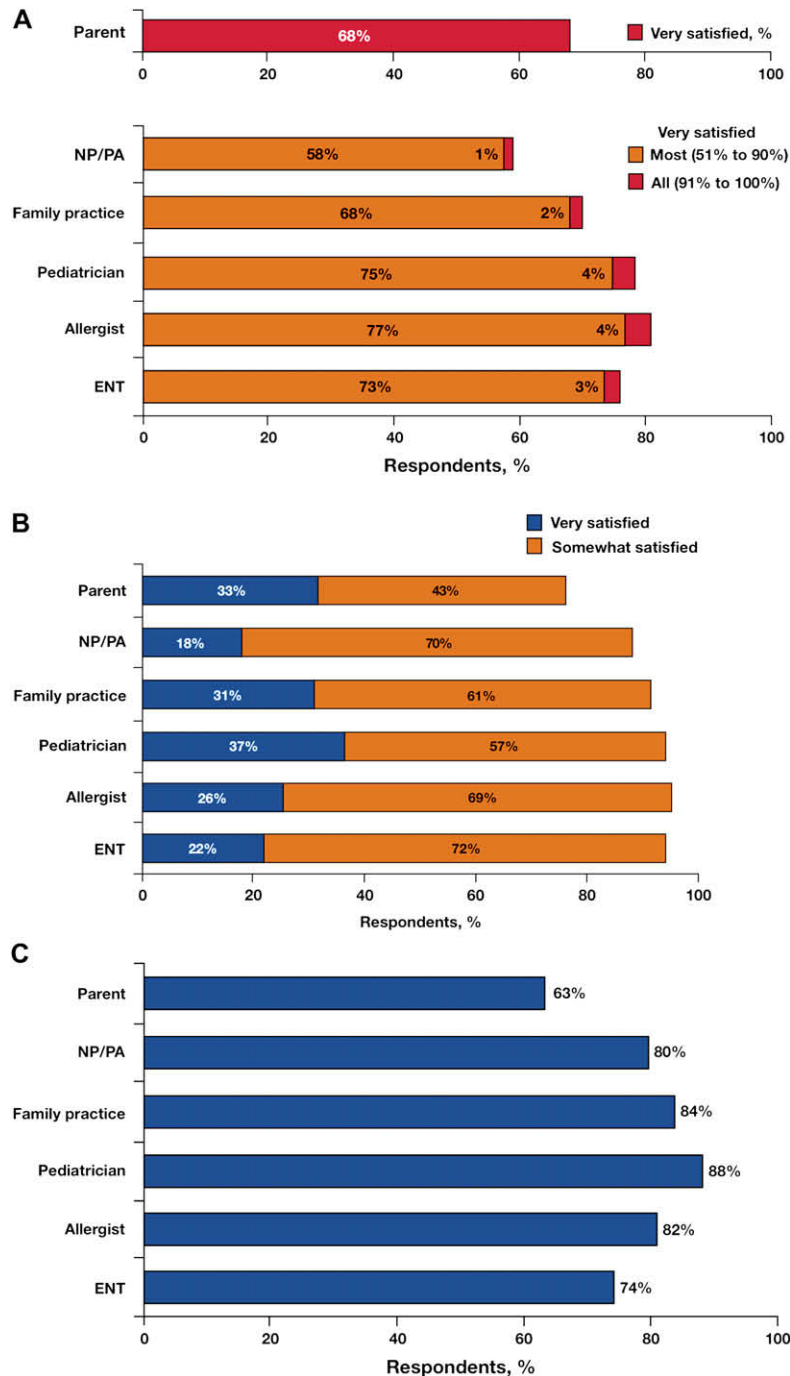


FIG 12. Parent's and practitioner's perspectives on patient satisfaction with treatment. **A**, Parent's and practitioner's perceptions on pediatric patient satisfaction with disease management. **B**, Parent's and practitioner's perspectives on pediatric patient satisfaction with current INCSs. **C**, Parent's and practitioner's perspectives on the cost benefit of current INCSs. **D**, Opinions on nasal allergies, a comparison of parents of children with and without nasal allergies. **E**, Parent's and practitioner's perspectives on the need for improved patient/parent education on AR. ENT, Ear, nose, and throat specialist; Rx, prescription. * $P < .001$; † $P < .05$; ‡ $P < .01$.

improved patient and parent satisfaction with their prescription nasal spray, improved HCP management of their condition, and improved adherence to therapy.

The Pediatric Allergies in America survey data provide significant and important new information but have inherent limitations. This survey required that respondents state that their children had a physician's diagnosis of nasal allergy and ongoing

symptoms or was receiving specific therapy for nasal allergy. The authors acknowledge that it would have been optimal for all children participating in the survey to have been referred for allergen testing to further confirm the AR diagnosis and to determine the sensitivity, specificity, or both of the survey questionnaire in diagnosing AR. However, this type of survey approach is used in the public health surveillance activities of the

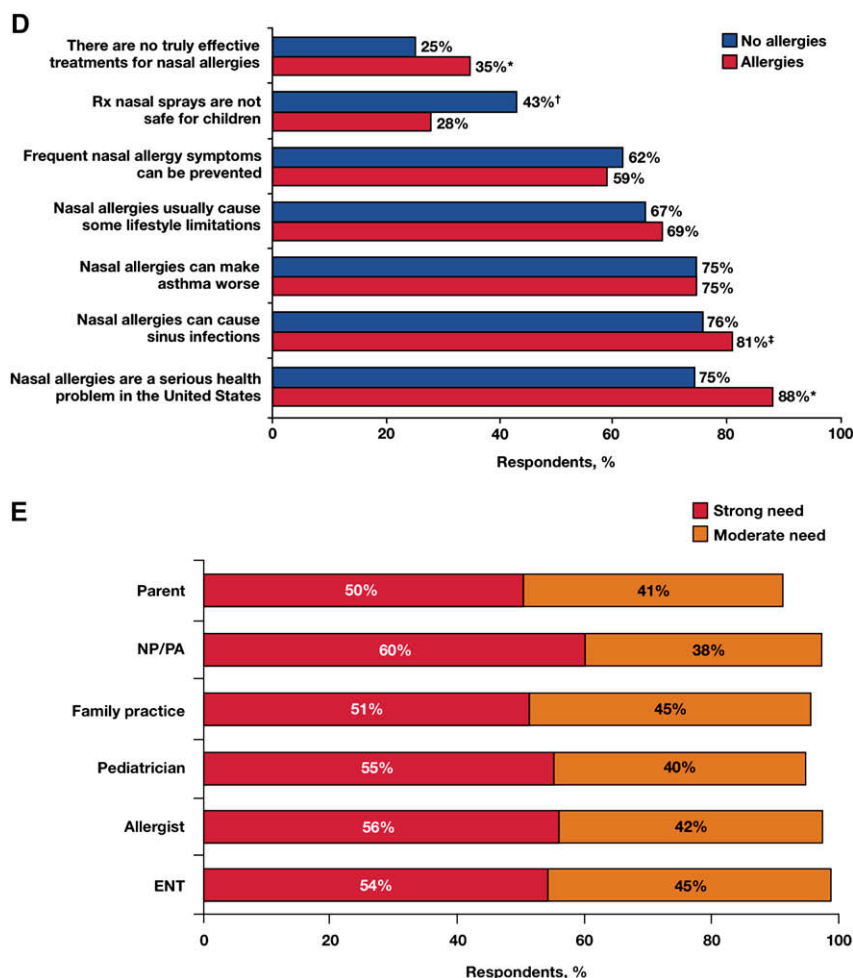


FIG 12. (Continued)

National Center for Health Statistics and the Centers for Disease Control and Prevention, including the National Health Interview Survey, the National Immunization Survey, the Behavioral Risk Factor Surveillance Surveys, and the National Health and Nutrition Examination Survey (NHANES). In addition, the International Study of Asthma and Allergies in Childhood (ISAAC) study used a survey for the diagnosis of asthma and allergies without diagnostic follow-up. The NHANES and ISAAC data sets are used routinely in the medical literature to estimate the prevalence of both asthma and AR. Although documenting IgE sensitization would have contributed to the strength of the data by validating the survey's ability to appropriately diagnose nasal allergy in pediatric patients, the authors believe that the approach used in the Pediatric Allergies in America survey (as well as the ISAAC and NHANES surveys) is in line with current clinical practices for an accurate diagnosis of AR. Because parental report of nasal allergy symptoms is what physicians typically rely on in the clinical care of children, whether in an office visit or a telephone survey, the authors believe that the lack of an HCP-validated diagnosis is not an insurmountable limitation of this survey.

Furthermore, it is acknowledged that although the Pediatric Allergies in America survey was formulated and conducted in conjunction with the national public research organization SRBI, the questionnaire that was used in the survey was not formally

validated. A validated test or scale is one that has been shown to measure what it purports to measure regardless of who responds, when they respond, and to whom they respond. The validation of multiple-item scales has been adopted in health research to measure multidimensional concepts, such as health (eg, Short Form 36) and QoL, where health and QoL are key outcome measures. By contrast, population surveys, such as Pediatric Allergies in America, do not have "validated questionnaires" and might or might not use "validated scales" within the questionnaire, depending on their focus. The 3 major health surveys conducted by the federal government, the National Health Interview Survey, the NHANES, and the Behavioral Risk Factor Surveillance Survey, do not have validated questionnaires and include only a few validated scales. Most of the survey findings, as distinct from clinical trial findings reported in peer-reviewed journals, are not based on validated questionnaires or scales. Additionally, the primary tool used to measure efficacy in AR, the total nasal symptom score, has never been formally validated. Nonetheless, it is considered the gold standard in measuring the efficacy of agents that treat AR. In this regard another way to informally validate a questionnaire is through the repeated use of the same questions within the same study population (in this case patients with AR), an approach used by the Pediatric Allergies in America survey to test the reliability of responses and to identify ambiguity in questions. As an added precaution, the Pediatric

Allergies in America survey attempted to identify the extent of nonallergic rhinitis in our survey population by asking parents and children whether environmental triggers suggestive of vasomotor rhinitis (eg, fumes/odors, weather, and exercise) contributed to their nasal allergy symptoms. Weather was identified by 19%, fumes/odors by 7%, and exercise by 6% of respondents, suggesting that nonallergic forms of the disease can contribute to the rhinitis symptoms observed in the survey respondents. However, at least 1 study has demonstrated that subjects diagnosed with AR might also be affected by nonallergic triggers⁶⁶; therefore response to nonallergic triggers does not preclude response to allergic triggers or a valid diagnosis of AR. In contrast, a positive IgE test result obtained by an allergist still might not rule out nonallergic factors contributing to rhinitis symptoms.⁶⁷ The informal validation approaches used in this survey (eg, incorporation of duplicate questions and the attempt to quantify the effect of nonallergic rhinitis in our patient population) give the authors confidence that the data obtained in this survey are valid with respect to the stated goals.

The HCPs who were treating the specific pediatric patients interviewed were not necessarily part of the survey. Not having the patient's personal physician respond to these questions was an inherent limitation of this survey. Although the physician respondents were not specifically responding for the parent and child respondents (a limitation of any telephone survey), the perceptions of the participating HCPs about their own patients are valid and should represent their general perceptions.

In addition, information gained in this survey on diagnosis and treatment is limited to the parent's or child's understanding of the information and the condition. About 95% of parent respondents and their children had health insurance. Approximately half of parents (both allergy and nonallergy) had a household income of more than \$50,000 per year, 40% had a household income of \$50,000 per year or less, and 10% were not sure or refused to answer the question.

Another potential limitation of a telephone survey is that, given that 67% of the children were age 7 years or less at the time of diagnosis, AR could not be positively distinguished from recurrent upper respiratory tract infections (URIs). AR has been associated with frequent URIs,¹⁷ and therefore even if the physician diagnosis was confirmed, one could not preclude that the frequent URIs occurred because the patient's airway was inflamed as a result of AR. Indeed, it was a noteworthy finding that few physicians used diagnostic tests to confirm allergen sensitivity, and most patients were not seen by allergists. One factor that could limit the possibility for misdiagnosis, however, is that the most common time of the year for viral URIs in children is from September through February. This survey was performed in March and April, months that have lower infection rates and higher tree and grass pollination, and therefore the possibility that putative nasal allergy symptoms were in fact caused by an undiagnosed URI is greatly reduced.

Both physicians and parents strongly agree that better education about AR and its treatment is necessary. The results of this survey suggest that improvement in communication between HCPs and parents and patients is also needed. Finally, the survey results recommend the development of more effective, better-tolerated treatment to improve adherence to prescribed therapy in order to reduce the burden of allergies in both adults and children in the United States.

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Key messages

- **Pediatric Allergies in America is the largest and most comprehensive survey of HCPs, pediatric patients, and parents of children with allergy regarding AR and its treatment.**
- **This survey has captured previously unavailable data on the prevalence and most common symptoms of nasal allergies, the effect of nasal allergies on children's QoL, medication use, and factors affecting satisfaction with treatment.**
- **Findings from this national survey have identified important challenges to the management of AR, suggesting that its burden on children in the United States has been substantially underestimated.**

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APPENDIX 1

SURVEY QUESTIONS

All questions were asked of adults. When noted in parentheses, questions were also asked of children 10 to 17 years of age. In addition, questions included in the HCP survey are noted, where applicable.

Prevalence of pediatric AR Parents and children

1. At what age was your child first diagnosed with nasal allergies, rhinitis, or hay fever?
2. What was the medical specialty of the doctor/HCP who diagnosed your child with nasal allergies?
3. Was your child given a skin test to see to what he or she was allergic?
4. Was your child given a blood test to see to what he or she was allergic?
5. Would you describe your child's nasal allergies as seasonal, or do they occur throughout the year?
6. During what times of the year are your child's nasal allergies the worst?

7. Are your child's (your) nasal allergies worse when (you are) outdoors or inside, or are they about the same? (children ages 10 to 17 years)
8. What things usually trigger or make your child's (your) nasal allergy symptoms worse? (children ages 10 to 17 years)

HCPs

1. Are you aware of any professional guidelines for the diagnosis and management of AR?
2. Of the patients aged 4 to 17 years you see each week, about what percentage have AR?
3. How often do you conduct a skin test, either in your office or by referral, when making or confirming a diagnosis of AR in patients 4 to 17 years of age?
4. How often do you conduct a blood test, either in your office or by referral, when making or confirming a diagnosis of AR in patients 4 to 17 years of age?
5. Of the patients aged 4 to 17 years you see each week with AR, about what percentage would you classify as having perennial allergies?

Symptoms of pediatric AR

Parents and children

1. During the worst 1-month period in the last year, did your child have [symptoms]—every day, most days a week, a few days a week, a few days a month, less than that, or never?
2. When your child had nasal allergy attacks, how bothersome are [symptoms] usually—extremely bothersome, moderately bothersome, slightly bothersome, or not bothersome?
3. Which of these symptoms was most bothersome to your child?
 - A. nasal congestion
 - B. repeated sneezing
 - C. runny nose
 - D. watering eyes
 - E. postnasal drip
 - F. red, itching eyes
 - G. nasal itching
 - H. dry cough
 - I. awakened/unable to sleep
 - J. headache
 - K. facial pain
 - L. ear pain

Burden of pediatric AR

Parents

1. In general, would you say that your child's health is excellent, very good, good, only fair, or poor/very poor?
2. During the past 4 weeks, how often has your child been [description]—all of the time, most of the time, a good bit of the time, some of the time, little of the time, or none of the time?
 - A. full of life
 - B. calm and peaceful
 - C. lots of energy

- D. happy
3. Thinking about your child's ability to do things he or she wants to do, on a scale of 0 to 100, where 100 means 100% able, where would you rank his or her ability on days when he or she does not have nasal allergy symptoms? Where would you rank your child's ability on the same scale of 0 to 100 when his or her nasal allergies are at their worst?
4. During the past 4 weeks, has your child—
 - A. been limited in the kind of work or other activities he or she could do as a result of his or her health?
 - B. had difficulty in performing work or other activities?
 - C. had to cut down on the amount of time spent on his or her regular daily activities?
 - D. accomplished less than he or she would like to?
5. How much do you feel your child's allergies/health limit what he or she can do in the following areas—a lot, some, only a little, or not at all? (*excludes 4- and 5-year-olds)
 - A. sleeping
 - B. organized sports or exercising
 - C. outdoor activities
 - D. going out/playing with friends
 - E. having pets
 - F. doing well in school*
 - G. doing things with family
 - H. school activities*
 - I. indoor activities
6. How troubled has your child been by each of these symptoms during the last week as a result of his or her nasal symptoms—not troubled, hardly troubled, somewhat troubled, moderately troubled, quite a bit troubled, very troubled, or extremely troubled?
 - A. lack of a good night's sleep
 - B. waking up during the night
 - C. difficulty in getting to sleep
7. During the worst 1-month period for allergy symptoms/health in the past year, did your child experience—
 - A. headaches?
 - B. ear pain/pressure?
 - C. facial pain/pressure?
8. When your child had nasal allergy attacks, how bothersome were those symptoms usually—extremely bothersome, moderately bothersome, slightly bothersome, not bothersome?
9. Items experienced in the last week—(yes/no)
 - A. migraines
 - B. sinus problems
 - C. earaches
10. How often does your child snore while sleeping—every night, most nights, some nights, rarely, or never?
11. Has your child had his or her tonsils or adenoids removed?
12. Has your child had tubes put in his or her ears?
13. Has your child ever had nasal or sinus surgery?
14. Has your child ever been diagnosed with asthma?
15. Has your child had asthma in the past 12 months?

Need for treatment of AR symptoms

Parents and children

1. During the allergy season, would you say the condition affected your child's daily life—a lot, a moderate amount, some, a little, or did not really impact his/her daily life?

2. In general, would you say that your child's discomfort during a nasal allergy attack is usually something he or she can ignore, he or she cannot ignore but can tolerate, or he or she cannot tolerate without relief?
3. For the current management and treatment of your nasal allergy symptoms, do you use prescription medications only, nonprescription medications only, or both? (children aged 10 to 17 years)

HCPs

1. For the average patient 4 to 17 years of age with AR, during the allergy season, would you say the condition affected his or her daily life—a lot, a moderate amount, some, a little, or does not really affect his or her daily life?
2. In general, would you say that a patient's discomfort during a nasal allergy attack is usually something he or she can ignore, he or she cannot ignore but can tolerate, or he or she cannot tolerate without relief?

Efficacy of current nasal allergy medications in pediatric patients with AR

Children aged 10 to 17 years

1. Does your current prescription nasal spray give you relief from all of your symptoms, most symptoms, some symptoms, or no symptoms?
2. Does your current prescription nasal spray lose effectiveness over the course of the day or night, or does it remain as effective as when you first took it?
3. Have you ever found that a product's effectiveness in treating your nasal allergy symptoms wears off over time, even when you are taking the product as prescribed?
4. About how long after you started taking it does a nasal allergy medicine's effectiveness begin wearing off, even when taken as prescribed?
5. How many of the medicines that you have taken for nasal allergy had the following types of side effects—all, most, some, few, or none?
 - A. bad taste
 - B. burning
 - C. dripping down throat
 - D. drying feeling
 - E. headaches
 - F. drowsiness
6. How bothersome are those side effects of nasal allergy medicines—extremely, moderately, slightly, or not bothersome?
7. How satisfied are you with the prescription nasal spray you used for your nasal allergies in the past 4 weeks?
8. In general, how satisfied have you been with the prescription nasal spray you have used for your nasal allergies in the past—very satisfied, somewhat satisfied, somewhat dissatisfied, or very dissatisfied?
9. Has your child ever stopped taking a nasal allergy medicine prescribed by his or her doctor because [reason]?
 - A. did not find it effective
 - B. effectiveness began wearing off
 - C. did not provide 24-hour relief
 - D. had bothersome side effects
 - E. not covered

- F. copay was too high
- G. dosing schedule was difficult
- H. was hard to administer
- I. concern about safety
- J. none of these

10. Why were you dissatisfied with that medicine?

HCPs

1. Do INCSs give most patients relief from all of their symptoms, most symptoms, some symptoms, few symptoms, or no symptoms?
2. Do INCSs lose effectiveness over the course of the day or night, or do they remain as effective as when the patient first took them?
3. Have you ever found that the effectiveness of INCS products in treating nasal allergy symptoms wears off over time, even when patients are taking the medicine as prescribed?
4. In general, how satisfied are your patients with AR with their INCSs? Would you say that they are very satisfied, somewhat satisfied, somewhat dissatisfied, or very dissatisfied?
5. Why are patients dissatisfied with their nasal allergy medicine?

Pediatric patient satisfaction with prescription nasal sprays for AR

Parents and children

1. Overall, how satisfied are you with your health practitioner's management and treatment of your child's nasal allergies—very satisfied, somewhat satisfied, somewhat dissatisfied, or very dissatisfied?
2. In general, how satisfied have you been with the prescription nasal spray used by your child in the past—very satisfied, somewhat satisfied, somewhat dissatisfied, or very dissatisfied?
3. How satisfied have you been with the OTC medicine used by your child in the past 4 weeks—very satisfied, somewhat satisfied, somewhat dissatisfied, or very dissatisfied?
4. How satisfied have you been with the prescription nasal spray used by your child in the past 4 weeks—very satisfied, somewhat satisfied, somewhat dissatisfied, or very dissatisfied?
5. How satisfied have you been with the other prescription medicine used by your child in the past 4 weeks—very satisfied, somewhat satisfied, somewhat dissatisfied, or very dissatisfied?
6. In general, do you believe that you get your money's worth out of your child's prescription allergy medication?
7. I am going to read you a series of statements. Tell me whether you agree strongly, agree somewhat, disagree somewhat, or disagree strongly with the statement.
 - A. Even with proper treatment, nasal allergies usually cause some lifestyle limitations.
 - B. Frequent nasal allergy symptoms can be prevented in most cases.
 - C. Nasal allergies can make asthma worse/nasal allergies can cause sinus infections.
 - D. Nasal allergies are a serious health problem in the United States.
 - E. There are no truly effective treatments for nasal allergies.

8. How much need is there for education for people with nasal allergies about their condition and its treatment? Do you think there is a strong need or a moderate need?

HCPs

1. Approximately what proportion of your patients 4 to 17 years of age with nasal allergies would you say are very satisfied with the management of their disease?
2. In general, how satisfied are your patients with AR 4 to 17 years of age with their prescription nasal spray—very satisfied, somewhat satisfied, somewhat dissatisfied, or very dissatisfied?
3. What is your preferred choice of medication?
 - A. anticholinergic nasal spray
 - B. antihistamines (OTC)
 - C. antihistamines (prescription)
 - D. antihistamine-decongestant combination (OTC)
 - E. antihistamine-decongestant combination (prescription)
 - F. decongestant (OTC)
 - G. inhaled corticosteroids
 - H. leukotriene inhibitors
 - I. mast cell stabilizers (cromolyn)
 - J. decongestant nasal sprays (OTC)
 - K. intranasal antihistamines/antihistamine nasal sprays
4. Overall, do your patients 4 to 17 years of age believe they get their money's worth out of prescription medicines for nasal allergies?
5. How much need do you think there is for better education of parents of children with nasal allergies about their condition and its treatment—a strong need or a moderate need?