Value-Based Perspectives on the Management of Allergic Rhinitis

Contributing Authors

Eli O. Meltzer, MD
Don A. Bukstein, MD
Paul M. Hamrah, MS, PharmD
Nikkia Scott, PharmD
John A. Welz, MPH
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<table>
<thead>
<tr>
<th>Section</th>
<th>Topic</th>
</tr>
</thead>
<tbody>
<tr>
<td>S4</td>
<td>Allergic Rhinitis Overview</td>
</tr>
<tr>
<td>S5</td>
<td>Burden of Allergic Rhinitis</td>
</tr>
<tr>
<td>S6</td>
<td>Unmet Patient Needs</td>
</tr>
<tr>
<td>S6</td>
<td>Approach to Treatment</td>
</tr>
<tr>
<td>S8</td>
<td>Value-Based Treatment Paradigm: Differing Perspectives</td>
</tr>
<tr>
<td>S9</td>
<td>Communicating the Evidence to Key Stakeholders</td>
</tr>
<tr>
<td>S10</td>
<td>Conclusion</td>
</tr>
</tbody>
</table>
Allergic rhinitis is a common immune-mediated health condition that affects up to 60 million Americans annually. A chronic, inflammatory disease of the upper airways, allergic rhinitis can significantly affect patients’ quality of life (QOL) and productivity. Despite the associated negative consequences, however, allergic rhinitis remains an underdiagnosed, undertreated, and underappreciated medical condition.

To discuss the challenges faced by the medical community in managing patients with allergic rhinitis, and to brainstorm potential strategies to improve the identification and treatment of allergic rhinitis, an advisory group of allergy experts and payer representatives was convened on May 6, 2017, in Jersey City, NJ, to develop actionable, strategic, and tactical recommendations for all healthcare system stakeholders committed to delivering high-quality care for patients with allergic rhinitis. To that end, the sponsor of the panel discussion sought to identify reasons for variation in the care of patients with allergic rhinitis, discuss systemwide opportunities for providers and payers to improve patient care, and share with clinicians and payers best practices to consider when developing optimal allergic rhinitis management strategies.

This advisory panel reviewed the current standards of allergic rhinitis care based on clinical guidelines and discussed the central role of pharmacotherapy in maintaining disease control and minimizing the burden of illness, recognizing the balance between burden of disease and burden of therapy. The panel also discussed potential research avenues to generate evidence supporting timely allergic rhinitis identification and treatment. Within this context, the group also addressed the role of combination pharmacotherapy for the treatment of patients with allergic rhinitis in a value-based care paradigm, particularly with respect to clinical outcomes and patient adherence to therapy.

**Allergic Rhinitis Overview**

Allergic rhinitis is characterized by inflammation of the nasal mucosa associated with exposure to an allergen such as animal dander or pollen. Multiple allergens may be responsible for allergic rhinitis in a given individual.

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utal patients’ symptoms. Depending on disease severity and other factors, treatment strategies usually include environmental controls, pharmacotherapy, and immunotherapy. Infrequently, surgery is recommended. Common pharmacologic options for allergic rhinitis include antihistamines, corticosteroids, and decongestants, which may be administered orally or intranasally. Less frequently prescribed options include oral leukotriene receptor antagonists and intranasal cromolyn sodium.

Optimal control of patient symptoms often requires treatment with multiple classes of allergic rhinitis drugs. For those whose symptoms are inadequately controlled by environmental controls or pharmacotherapy, immunotherapy (subcutaneous or sublingual) may be recommended. Surgery may also be considered for some patients who have failed medical management and have nasal airway obstruction and enlarged inferior turbinates.

### Burden of Allergic Rhinitis

In the United States, allergic rhinitis is the fifth leading cause of chronic illness and is estimated to affect up to 30% of adults and up to 40% of children. Physicians have reported that more than 11 million office visits are attributable to allergic rhinitis as the primary diagnosis. Allergic rhinitis poses a significant economic burden to the healthcare system, with approximately $3.4 billion in annual direct medical costs, office and emergency department visits, medications, and diagnostic testing, and up to $9.7 billion annually in indirect costs.

Overall, 2 of 5 patients report that allergic rhinitis greatly or moderately affects their daily life. Symptoms related to allergic rhinitis can cause sleep disturbance issues, fatigue, irritability, depression, as well as attention, learning, and memory deficits, all of which can negatively influence patients’ overall QOL, workplace productivity, and school performance.

Allergic rhinitis can affect all 4 domains of the World Health Organization instrument for measuring QOL, including physical health, psychological state, social relationships, and mental acuity.

Overall in the United States, uncontrolled allergic rhinitis symptoms result in more than 3.5 million workdays and 2 million school days lost annually. Compared with other chronic conditions, such as high blood pressure or type 2 diabetes, allergic rhinitis has a greater impact on productivity and ability to work than either of these diseases.

The National Allergy Survey Assessing Limitations (NASAL) study on allergic rhinitis reported a significantly higher incidence of comorbidities in patients with allergic rhinitis versus the general population (P ≤ 0.05). Among the survey population, more adults with allergies were affected by rhinosinusitis and/or sinus problems than patients without allergies (66% vs 20%, respectively), sleep disturbances (29% vs 7%), sleep apnea (9% vs 5%), gastrointestinal symptoms (36% vs 16%), and migraines (17% vs 9%).

In addition, skin rashes, earaches, and conjunctivitis were identified as relatively common comorbidities in patients with allergic rhinitis compared with people without allergic rhinitis. Furthermore, 38% of adults with allergic rhinitis reported a previous diagnosis of asthma compared with only 8% of adults without allergies. Overall, 52% of patients with comorbid asthma reported that their asthma got better when their allergic rhinitis symptoms were controlled, and 37% reported no change.

Similarly, improvement in disease control generally leads to reduction of the consequences of other comorbidities associated with allergic rhinitis.

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Comorbid allergic rhinitis is present in more than 80% of patients with asthma; conversely, asthma is present in 10% to 40% of patients with allergic rhinitis. Studies have shown that the severity of allergic rhinitis is positively correlated with asthma severity. This relationship has been substantiated by several studies. In patients with moderate-to-severe allergic rhinitis, one study reported a 12.7-fold increased risk for uncontrolled asthma compared with patients without allergic rhinitis. In a cross-sectional study that examined children with persistent asthma, Butz and colleagues noted that exposure to indoor allergens and pollutants is highly associated with increased asthma morbidity and unscheduled healthcare use and is a potential indicator of high-risk asthma.

Another study of adult patients with concomitant asthma and allergic rhinitis showed a 50% increase in the odds of being hospitalized and a mean increase of 0.42 in doctor visits per patient. Furthermore, published evidence shows that treatment of allergic rhinitis reduces the incidence and severity of asthma exacerbations. On a positive note, the treatment of comorbid allergic rhinitis can reduce the odds of asthma-related healthcare utilization, specifically emergency department visits and hospitalizations, by up to 80%.

Studies have reported that 57% of adult patients and 88% of pediatric patients with allergic rhinitis experience...
sleep disorders or disturbances, often because of the impact of allergic rhinitis on normal nocturnal breathing.\textsuperscript{21} Loss of sleep in patients with allergic rhinitis can lead to fatigue and lack of concentration during the day, deleterious psychological effects, and deterioration in daily activities, including workplace productivity. In children, this can affect their school performance and their ability to learn.\textsuperscript{22} Another study demonstrated that a history of allergic rhinitis can be a risk factor for sleep disturbance in the elderly as well as in younger adults.\textsuperscript{23} When allergic rhinitis is treated, however, nocturnal breathing and sleep quality improve.\textsuperscript{1,4}

**Unmet Patient Needs**

Although the symptoms can be debilitating, allergic rhinitis may remain undiagnosed when patients do not seek medical attention. In a European telephone survey, 45% of patients who reported signs and symptoms of allergic rhinitis had never been diagnosed by a physician.\textsuperscript{3} These findings are consistent with the professional experience of the allergists represented on the advisory panel, who noted that many patients self-treat with over-the-counter drugs, whereas others do not use treatment at all, resulting in a substantial proportion of patients never being clinician-diagnosed with allergic rhinitis.

Undiagnosed allergic rhinitis can lead to an impairment of a patient’s QOL, exacerbations of allergic rhinitis symptoms, negative impact on sleep and mental health, and an increased risk for additional comorbid conditions.

In some cases, allergic rhinitis is captured as a secondary or later diagnosis when patients see their physician for a comorbid condition. Undiagnosed allergic rhinitis can lead to an impairment of a patient’s QOL, exacerbations of allergic rhinitis symptoms, negative impact on sleep and mental health, and an increased risk for additional comorbid conditions.\textsuperscript{24,25} Despite the relative ease of access to a variety of treatment options for allergic rhinitis, many already-diagnosed patients are either undertreated or have uncontrolled allergy symptoms. The Allergies in America survey noted that 34% of patients had asked their physician to change their allergy medication, because they were dissatisfied with it.\textsuperscript{26} Of these patients, 66% cited the medication’s ineffectiveness as the reason for the request. The lack of 24-hour symptom relief and diminished medication effectiveness over time were also cited as major concerns by patients.\textsuperscript{26}

Access to a board-certified allergy specialist may also be an unmet need for some patients. A recent review evaluating the delivery of allergy services worldwide showed that demand for allergy services is outpacing supply and that inadequate allergy-related care pathways are leading to poor referral practices, delays in patient management, and suboptimal patient outcomes.\textsuperscript{27}

**Approach to Treatment**

The rhinitis practice parameter from the Joint Task Force (JTF) on Practice Parameters, developed in collaboration between the American Academy of Allergy, Asthma & Immunology and the American College of Allergy, Asthma & Immunology, is intended for allergy specialists and other physicians who treat allergic rhinitis.\textsuperscript{6} The practice parameter, last updated in 2008, is currently undergoing review, and an updated parameter is expected to be published in 2017.

The JTF on Practice Parameters categorizes allergic rhinitis treatment recommendations in a stepwise process according to disease severity level, as shown in the Figure.\textsuperscript{6} Another goal is to proactively intervene before allergen exposure to reduce the risk for an acute event.

Several interventional strategies are used to help patients manage their allergic rhinitis symptoms. Environmental controls, such as pet removal, air filtration systems, and acaricides to kill dust mites, may help to alleviate symptoms for some patients.\textsuperscript{6,6} Nasal saline irrigation is generally well-tolerated and may also be beneficial.\textsuperscript{28} For the majority of patients, however, pharmacotherapy will be required.

Participating allergy specialists on the advisory panel noted that oral decongestants, such as pseudoephedrine or phenylephrine, and intranasal decongestants, such as phenylephrine and oxymetazoline, are sometimes used to treat the congestion of episodic allergic rhinitis; however, they have limited effectiveness in controlling other allergic rhinitis symptoms. Oral antihistamines are very often used but are limited in addressing nasal congestion—again, the most bothersome symptom of allergic rhinitis. Intranasal antihistamine therapies offer several advantages, including faster onset than oral antihistamines and greater efficacy. Intranasal corticosteroids were cited as the most effective monotherapy in allergic rhinitis. Immunotherapy may also be considered for patients who have not achieved control with pharmacotherapy.

The panel agreed that multiple medications were typically necessary to achieve disease control in patients with moderate-to-severe allergic rhinitis. Several allergy specialists noted that concomitant therapy with an intranasal antihistamine and an intranasal corticosteroid worked well for many patients. Available combination formulations allow patients to administer 2 agents simultaneously in a single dose.
### Figure  Sample Rhinitis Action Plan

<table>
<thead>
<tr>
<th>Patient Name</th>
<th>DOB</th>
<th>Phone number</th>
<th>Pharmacy Phone number</th>
</tr>
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</table>

#### Sample Rhinitis Action Plan

**Date Completed:**

**Physician Name**

**Address**

**Phone number**

**Signature MD/Physician Encoder**

#### These are Your Rhinitis and Allergic Conjunctivitis Medications

<table>
<thead>
<tr>
<th>Antihistamines</th>
<th>Nasal Corticosteroids</th>
<th>Oral Decongestants</th>
</tr>
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#### Nasal Antihistamines

<table>
<thead>
<tr>
<th>Combinations</th>
<th>Nasal Saline/moisturizer</th>
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#### Rhinitis Steps

**Prophylaxis before allergen exposure**

**Step 1: Episode**

- NasalCrom
- Decongestant
- Antihistamine
- Eye Drops
- NasalCrom
- Nasal Corticosteroid
- Atrovent
- Oral antihistamine
- Nasal antihistamine
- Singular
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- Nasal Corticosteroid
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- Atrovent
| What to do | times a day as needed | before exposure |

### What to do for Increased Nasal Symptoms

- **Green Zone**
  - **Mild Episode**
    - Complete response to medicine
    - No Nasal Symptoms
    - Step up 1 level

- **Yellow Zone**
  - **Moderate Episode**
    - Fair response to medicine
    - Mild Nasal Symptoms
    - Step up 2 levels

- **Red Zone**
  - **Severe Episode**
    - Poor response to reliever medicine
    - Moderate to severe Nasal Symptoms
    - Step up 3 levels

### Long-Term Management of Nasal Symptoms

<table>
<thead>
<tr>
<th>Controlled</th>
<th>Fair Control</th>
<th>Not Controlled</th>
</tr>
</thead>
<tbody>
<tr>
<td>No interference with activities</td>
<td>Mild interference with activities</td>
<td>Severe interference with activities</td>
</tr>
<tr>
<td>&lt; 2 days per week sneezing, itching, congestion, eye symptoms</td>
<td>2 – 6 days per week sneezing, itching, congestion, eye symptoms</td>
<td>Daily sneezing, itching, congestion, eye symptoms</td>
</tr>
<tr>
<td>Stay at the same step or consider stepping down</td>
<td>Increase treatment by one step</td>
<td>Increase treatment by 2 steps</td>
</tr>
</tbody>
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Dymista, for example, is a fixed-dose intranasal combination therapy that includes fluticasone propionate (a corticosteroid) plus azelastine hydrochloride (an H1-receptor antagonist). Panel participants agreed that the efficacy and safety data in support of the use of this fixed-dose combination treatment were compelling, particularly because Dymista was studied in head-to-head clinical trials and not just in studies comparing each of the individual components versus placebo. Similarly, they noted that a lower spray volume in the combination medication was required to achieve clinical benefit compared with sequential use of individual agents.

Panel participants agreed that the efficacy and safety data in support of the use of this fixed-dose combination treatment were compelling, particularly because Dymista was studied in head-to-head clinical trials and not just in studies comparing each of the individual components versus placebo.

Although the panel experts were supportive of the clinical trials data, participating payers expressed some concern about the use of the combination medication, seeking to ensure that Dymista is used according to the drug label and prescribing information in patient populations most likely to benefit from such combination treatment. The participants were therefore interested in characterizing the optimal patient profile for Dymista, noting that a combination of clinical and real-world data may be needed to develop this evidence.

**Value-Based Treatment Paradigm: Differing Perspectives**

Increasingly, US healthcare has been shifting to value-based care, where the “value” of treatment is defined as cost relative to health outcomes. In this new paradigm, it is assumed that enhancing value will benefit patients and other stakeholders as the economic sustainability of the healthcare system improves. However, value measurements in healthcare remain limited and imperfect. Furthermore, although most stakeholders can agree on the overarching goal of improving health outcomes for a given health condition, their perspectives may vary widely on how it should be achieved.

For example, the practicing healthcare provider has historically focused on the needs of individual patients rather than on populations of patients. This has changed to some degree as physicians are increasingly held to standards of performance measurement and “accountability.” Nonetheless, in allergic rhinitis, allergy specialists are focused on risk reduction and symptom control, which directly affect patient health outcomes. Allergists participating on the panel cited the additional importance of the relationship between the upper and lower airways, and individualizing treatment to respond to the patient’s full spectrum of pathology rather than focusing only on the upper airways. Clinicians are also concerned about patient access to treatment. Although clinicians understand the need for payers to control costs, the increased use of step-therapy protocols can frustrate physicians and increase the burden on patients.

Within the value-based healthcare paradigm, increasing emphasis is placed on shared decision-making, and patients (as the recipients of healthcare) are encouraged and educated to be more accountable for their own care; thus, their perspective is critical. However, in allergic rhinitis, the data show that the majority of patients are dissatisfied with their allergy treatment and expect better outcomes than they are currently experiencing. At the same time, patients may be self-treating their allergic rhinitis without being aware of the treatment options that are likely to provide them with the best therapeutic benefits.

As discussed at the advisory board meeting, payers and employers have a more economically directed perception of value that focuses on the health of populations rather than on individual patients. Payers typically regard the clinical utility of a treatment or procedure relative to net cost, where clinical utility is measured by the outcome experienced by the patient. Payers will often weigh the relative value of treating various diseases as well as the relative value of one treatment versus another. This perspective may lead to the implementation of a number of utilization management strategies that may encourage providers and/or patients to favor one option over another.

In addition, payers stratify their member populations in an effort to recommend treatments that provide the most benefit to subgroups of members based on specific demographic or disease characteristics. Employers also focus on population health; however, their primary goals are to reduce workplace absenteeism and maintain employee productivity, while containing their contribution to healthcare premiums.

Regardless of their different perspectives toward healthcare, participating allergy specialists and payers were able to reach some areas of consensus with regard to allergic rhinitis. Overall, there was universal agreement about the paramount importance of disease control in allergic rhinitis. However, payers questioned the tools currently used to assess disease control and the consistency in the way they are used. Participating allergy specialists cited the Rhinitis Control Assessment Test (RCAT)
as a self-reported, validated questionnaire with a 1-week recall that is often used to help measure severity of illness and disease control. In validation testing, the RCAT showed significant correlations with physician-rated disease severity, total nasal symptom score, and physician-recommended change in therapy.32,33

Like allergy specialists, participating payers also sought to improve outcomes, albeit usually in an economic context. However, they noted that direct cost-savings from averted emergency department visits and hospitalizations are more challenging to quantify in allergic rhinitis than in conditions such as asthma and chronic obstructive pulmonary disease, for example, because allergic rhinitis is frequently listed as a secondary diagnosis, and it may be difficult to ascertain the contribution of allergic rhinitis to an acute event relative to other comorbidities that may be involved. Because of this limitation, it may be impractical for some health systems to evaluate risk reduction in allergic rhinitis. However, a payer representative on the panel stated that his organization, a large integrated health system, had successfully implemented an intervention to reduce hospitalizations and emergency department utilization in patients with asthma and chronic obstructive pulmonary disease, noting that comorbid allergic rhinitis was a criterion used to flag patients for intervention.

Participating advisors also agreed on the importance of medication adherence in reducing risk and disease burden. A randomized controlled trial showed that negotiating patients’ treatment decisions significantly improved adherence to asthma pharmacotherapy and clinical outcomes.34 Similarly, a participating allergy specialist noted that shared patient–provider decision-making plays an important role in influencing adherence in allergic rhinitis, because the patient feels more invested in the treatment decision. Nonadherence to allergic rhinitis treatments is less well-understood than in other chronic conditions, because many medications are used only as needed, making adherence more difficult to define. In addition, patients often self-treat with over-the-counter allergic rhinitis therapies without consulting a physician. Nonetheless, effective communication through the use of a well-accepted, shared decision-making aid, as well as other communication techniques, can help address modifiable adherence barriers and improve adherence to allergic rhinitis treatments.34,35

According to participating advisors, gaps also remain in allergic rhinitis identification and treatment in the primary care setting. Despite existing guidelines, allergic rhinitis primary care is often delivered independent of guideline recommendations. Studies have also identified specialty-specific knowledge and agreement gaps among allergists, otolaryngologists, and pediatricians, pointing to the need for a greater level of consensus between the different specialties involved in treating patients with allergic rhinitis.36

Communicating the Evidence to Key Stakeholders

To elevate the perceived importance of allergic rhinitis in the national healthcare discussion, participating allergy specialists noted that it was critical to effectively communicate the burden of illness to key policy influencers, including payers, employers, the Centers for Medicare & Medicaid Services, and state Medicaid agencies. To fully understand the burden of allergic rhinitis, these discussions should center on the full range of pathophysiologic changes that take place in response to allergen sensitization, which can result in a broad spectrum of associated comorbidities affecting the upper airways, lower airways, and other body sites. Real-world observational studies as well as clinical data can provide evidence to help facilitate this discourse. For example, results of the BALANCE study provided insights regarding allergic rhinitis–related symptom control, satisfaction with therapy, impairment of work and activity, sleep quality, and QOL from the patient perspective.37

To fully understand the burden of allergic rhinitis, these discussions should center on the full range of pathophysiologic changes that take place in response to allergen sensitization, which can result in a broad spectrum of associated comorbidities.

As the first point of contact for patients seeking medical care, primary care providers (PCPs) play a critical role in identifying and managing allergic rhinitis. Because these physicians often diagnose and initiate allergic rhinitis therapy in patients, there is a need for education that promotes treatment strategies that align with current clinical practice guidelines and treatment paradigms. However, advisors noted that many PCPs and some otolaryngologists were unfamiliar with the JTF on Practice Parameters and cited the need for heightened awareness of this consensus document to help guide treatment decisions in an evidence-based, stepwise process. According to participating advisors, these discussions should include broader efforts to educate PCPs using interactive teaching techniques on the proper use of over-the-counter versus prescription products.

However, patient factors may sometimes hinder clinical evaluation of allergic rhinitis. For example, patients, including children, may not recognize or accurately char-
Allergic rhinitis is often underdiagnosed and undertreated. A limited awareness of allergic rhinitis, its associated comorbidities, and effective treatment strategies all contribute to suboptimal identification and management of allergic rhinitis.

Conclusion

Allergic rhinitis is often underdiagnosed and undertreated. A limited awareness of allergic rhinitis, its associated comorbidities, and effective treatment strategies all contribute to suboptimal identification and management of allergic rhinitis. In addition, patients often self-treat, and when they seek medical care, they may be seen by providers representing different disciplines, including primary care, otolaryngology, and allergy/immunology.

At this advisory event, participating allergists and payers agreed that high priority should be given to interventions aimed at promoting disease control and mitigating risk in patients with allergic rhinitis. Improved disease control results in better QOL for patients with allergic rhinitis and can reduce healthcare utilization, particularly for the substantial number of patients with asthma and comorbid allergic rhinitis.

The lack of awareness of and adherence to consensus guidelines was repeatedly cited as a key barrier to improved care and better patient outcomes. It is important for providers to ensure that allergic rhinitis therapy is individualized, because each patient has varying levels of severity and duration of symptoms, disease etiology, and environmental triggers, as well as the presence or absence of various comorbidities that can impact treatment.

The JTF on Practice Parameters recommends that providers take a stepwise approach to treatment using efficient shared decision-making aids for patients with moderate-to-severe allergic rhinitis. Because evidence suggests that fixed-dose combination therapies, such as Dymista, are safe and effective in helping patients maintain disease control, they should be offered as an alternative treatment for patients with poorly controlled allergic rhinitis. Finally, patients who cannot achieve disease control using pharmacotherapies may be considered for immunotherapy and, in specific cases, surgery.

Advisors agreed that ongoing synergistic and simultaneous education of providers and patients is needed to improve the delivery of guideline-concordant care, which, in turn, leads to better adherence to treatment and thereby better patient outcomes. Policymakers, professional organizations, payers, and manufacturers can all play a role in helping develop and disseminate evidence-based programs and resources that can serve to educate patients and healthcare professionals on effective strategies to reduce the negative impact of allergic rhinitis and improve QOL.

Disclosure Statement

Dr Meltzer is Consultant to Allergan, AstraZeneca, Boehringer Ingelheim, Johnson & Johnson, and Regeneron/Sanofi; Speaker for Merck; and Consultant to and Speaker for GlaxoSmithKline, Glenmark, Stallergenes Greer, Mylan, and Teva. Dr Bulstein is Speaker for ALK, AstraZeneca, Circassia, Genentech, Mylan, Novartis, Stallergenes Greer, and Teva. Dr Hamrah is a member of the Advisory Board of Mylan. Dr Scott and Mr Welz are employees of The Lynx Group.

References
