

**IMPORTANCE OF ACCURATE DIAGNOSIS OF ALLERGY PRIOR TO USE OF
SECOND-GENERATION ANTIHISTAMINES**

Presented to:

Nonprescription Drugs and Pulmonary-Allergy Drugs Advisory Committees

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My name is Dr. Ivor Emanuel and I am a Clinical Assistant Professor in the Department of Otolaryngology at the University of California, San Francisco. My affiliations also include the University of California Teaching Hospitals and the California Pacific Medical Center in San Francisco. In addition, I am a Fellow and past President of the American Academy of Otolaryngic Allergy, and founding Fellow and President-elect of the American In Vitro Allergy/Immunology Society.

My comments today relate to the importance of establishing an accurate diagnosis prior to prescribing second-generation antihistamines such as fexofenadine, loratadine, or cetirizine. While these agents have been shown to be safe and effective in trials and clinical practice for patients who present with atopic symptoms, they are not appropriate for treating patients with symptoms that mimic allergy but have different etiology. Specific IgE antibody blood testing offers tremendous potential to avoid misdiagnosis in these types of patients and can be easily ordered by primary care practitioners. An appropriate prior diagnosis is essential regardless of whether second-generation antihistamines are available over-the-counter or not, as this will significantly reduce unnecessary use and/or over-prescribing of these products in cases of non-allergic rhinitis.

Nasal congestion, postnasal drip, cough, increased mucus production and ocular irritation are common symptoms of atopy, as well as a variety of upper respiratory diseases unrelated to allergies. Data from a recent study designed to assess diagnostic specificity with respect to utilization of second-generation antihistamines in the treatment of allergy-like symptoms highlight the difficulty of distinguishing between respiratory and ocular allergic disease and other conditions solely on the basis of symptom history and physical examination. The study found that only 35% of the patients prescribed a non-sedating antihistamine for allergy symptoms by a primary care physician were actually atopic (1). An accurate diagnosis would not only enhance the use of antihistamines by patients who would benefit from them, but also allow patients access to alternative management approaches for non-allergic conditions.

Unlike allergy skin tests, which require considerable expertise and commitment and are therefore, usually only performed by an allergy specialist, IgE blood tests can be easily and cost-effectively ordered by primary care physicians. The professional allergy community supports the utility of these tests in allowing primary care practitioners to diagnosis and manage uncomplicated allergies within their practices (2). Importantly, IgE blood tests are not affected by antihistamine or other commonly used medications, dermatitis, or dermatographism, all of which pose problems for skin testing. Because IgE blood tests are available for a diverse range of allergens, regional panels allow for easy ordering of appropriate common allergy tests. These tests allow for an accurate diagnosis and include indoor allergens such as dust mites, cats, dogs, and common molds, as well as outdoor allergens (pollens and certain common molds) related to seasonal symptoms. Several IgE antibody blood tests are commercially available. Physicians have been reluctant to use IgE tests due to concerns regarding the accuracy and reliability demonstrated by first-generation tests. The introduction of novel second-generation tests, along

with improvements in laboratory facilities have greatly increased the value of IgE testing and have allowed physicians other than allergists to undertake allergy diagnosis and treatment in their patient populations. This practice is supported by study results published in the current issue of the *Annals of Allergy, Asthma, & Immunology* (3) as well as an earlier report in the *Journal of Allergy and Clinical Immunology* (4). These results demonstrate that the second-generation test, ImmunoCap, exhibits outstanding performance characteristics, is robust, and can be used with confidence in identifying causative agents in individuals with allergic disease. In addition, ImmunoCap is the only IgE test to receive FDA quantitation clearance—it not only can demonstrate with accuracy if a patient is allergic, but it can also determine the extent to which that patient is allergic.

In summary, a positive allergy result from IgE blood testing now makes it possible to recommend appropriate avoidance measures for indoor allergies, to use a preventive medication for seasonal outdoor allergies, and rescue medicines for use as needed with symptom breakthrough. Greater utilization of IgE blood tests can enhance diagnostic specificity, improve outcomes in patients with uncomplicated upper respiratory and ocular allergies, and avoid the use of antihistamines whether available by prescription or over-the-counter, when not indicated.

I am hopeful that your deliberations today regarding the appropriateness of second-generation antihistamines for over-the-counter status will include a discussion of the importance of establishing an appropriate diagnosis prior to their use.

Thank you.

References

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3. Szeinbach S, Barnes J, Sullivan T, Williams B. Precision and accuracy of commercial laboratories' ability to classify positive and/or negative allergen-specific IgE results. *Annals of Allergy, Asthma, & Immunology*. 2001;86:373-381.
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