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**Contact:** Jo Ann Faber  
(847) 427-1200 x240  
joannfaber@acaai.org

### **Allergen Immunotherapy Evolves as Faster, Safer and Longer-Lasting Treatment**

DALLAS – Time-tested for a century, allergen immunotherapy has evolved into revolutionary methods of administration, as well as faster, safer and longer-lasting treatments according to the latest research presented at the annual meeting of the American College of Allergy, Asthma and Immunology (ACAAI) in Dallas.

Recent studies have shown subcutaneous immunotherapy, or allergy shots, may prevent the progression of allergic disease and reduce the risk of developing asthma; reduce the need for medication; reduce utilization and costs of health care services; and provide long term remission after discontinuation of treatment.

“In a recent study of allergy immunotherapy among Florida Medicaid-enrolled children with allergic rhinitis, there was a significant reduction in utilization and costs of health care services, especially inpatient care,” said Linda S. Cox, M.D., assistant clinical professor of medicine at the Southeastern University Osteopathic College of Medicine, Miami, Fla., and chair of the ACAAI Immunotherapy and Diagnostics Committee.

In another study investigators demonstrated allergen immunotherapy has an economic advantage on standard anti-allergic drugs in patients with pollen-induced rhinitis and asthma, she said. Findings showed a cost reduction of approximately 15 percent the second year and 48 percent the third year, with a highly statistical significance that was maintained up to the sixth year – 3 years after stopping immunotherapy – when an 80 percent reduction was found. The net saving for each patient at the final evaluation corresponded to \$830 per year.

“These findings confirm some previous observations in studies from Germany and the United States that subcutaneous immunotherapy has significant economic advantages over anti-allergic drug treatment in the long term,” Dr. Cox said.

Immunotherapy decreases a patient’s sensitivity by introducing increasingly larger doses of the substances to which the patient is allergic. The treatment is a method for increasing the allergic patient’s natural resistance to the things that are triggering the allergic reactions. The immunization procedure begins with injections of small amounts of purified “extracts” of the substances that are causing allergic reactions. They are approved for this use by the Food and Drug Administration (FDA), and over the years they have been improved considerably.

Compared to conventional immunotherapy, rush immunotherapy (also known as rapid desensitization) provides the advantages of improved patient compliance, cost-effectiveness and therapeutic efficacy. Rush schedules, which have been used successfully for more than 70 years, can achieve a maintenance dose more quickly than weekly schedules. Rush immunotherapy is associated with an increased risk of systemic reaction, which is reduced with pre-medication.

### **Sublingual Immunotherapy**

Oral/sublingual immunotherapy has gained wide acceptance in the treatment of allergic disease throughout Europe and South America. The main advantage of sublingual immunotherapy over traditional immunotherapy is patient convenience, since it can be administered at home, and it appears to be safer than conventional immunotherapy, Dr. Cox said.

“However, without direct medical supervision, physicians would need to provide specific instructions to the patients on how to manage adverse reactions, unplanned treatment interruptions, situations in which the dose should be withheld, and dosing adjustments for any or all of these variables. Other considerations include whether injectable epinephrine should be prescribed, patients ability to comply with the regimen and patient’s response to potential adverse reactions,” she said.

In sublingual immunotherapy, the absorption of the allergens into the body is more gradual than by injection. Although adverse events are rare, efficacy is somewhat less than with subcutaneous immunotherapy. Other noted differences between sublingual immunotherapy and conventional immunotherapy include dosing, duration of effectiveness after discontinuation and treatment for multiple sensitivities.

A consistent relationship between allergen dose or treatment duration has not been established with sublingual administration. In contrast, the effective dosing range for conventional immunotherapy has been established for major allergens, and long-term effects of subcutaneous immunotherapy have been shown for allergic rhinitis and asthma after therapy has been discontinued. Clinical studies have demonstrated that subcutaneous immunotherapy also improves seasonal allergic asthma, whereas there have been inconclusive findings on the effect of sublingual immunotherapy on asthma.

With the exception of one study noted Dr. Cox, there have been no sublingual immunotherapy studies that have utilized more than one non-cross reacting allergen. The majority of allergic U.S. patients are sensitive to more than one allergen: in one large population skin test survey (NHANES III) the median number of positive skin test was three.

“Sublingual immunotherapy is a ‘younger’ form of immunotherapy, as the first clinical trials were conducted just 20 years ago in Italy with few patients,” said Désirée E.S. Larenas-Linnemann, M.D., consultant in allergy at Hospital Médica Sur in Mexico City, Mexico.

“Over the last three years the body of evidence on sublingual immunotherapy is growing fast. Large studies of over 800 patients have been conducted in Europe, and some meta-analysis have been published this year. Also during the last year, clinical trials in Europe in patients with latex allergy, food allergy and atopic dermatitis who cannot tolerate subcutaneous immunotherapy have shown good tolerability and statistically significant improvement with sublingual immunotherapy,” said Larenas-Linnemann.

In Europe and Latin America this form of delivery has broadened the number of patients that can benefit of immunotherapy she said. “One very interesting clinical trial investigates the usefulness of sublingual immunotherapy as prevention for the development of allergies in non-allergic very small children with high risk of developing allergies because of their family history.

“Based on our growing knowledge of the mechanisms of allergic disease and immunotherapy, altered allergen extracts are being tested in clinical trials. These allergen extracts are chemically or physically changed to cause less side effects. It is clear that allergic patients can still hope for even greater improvements of this treatment modality that, for the time being, continues to present the only alternative that attacks the cause of allergies,” Dr. Larenas-Linnemann said.

There is no FDA approved formulation for sublingual therapy in the United States, it is not covered by Medicare and most insurers do not reimburse for the treatment.

### **Anti-IgE**

The introduction of Omalizumab, a monoclonal IgE molecule with anti-IgE properties, has helped define asthma as an IgE-mediated disease. Anti-IgE (trade name Xolair) was approved by the FDA in June 2003 for use by patients who are age 12 and older, who have moderate-to-severe allergic asthma and have allergic asthma that has not responded well to other treatments such as subcutaneous immunotherapy, prescription antihistamines and inhaled corticosteroids.

For patients with asthma, the use of Omalizumab has decreased hospital stays and asthma medication use while improving pulmonary function and the quality of life. Further, several studies have shown a benefit of combining conventional and rush immunotherapy with administration of Omalizumab.

Patient information on allergic diseases is available by calling the ACAAI toll free number at (800) 842-7777 or visiting its Web site at [www.acaai.org](http://www.acaai.org).

### **About the American College of Allergy, Asthma & Immunology**

The ACAAI is a professional medical organization headquartered in Arlington Heights, Ill., that promotes excellence in the practice of the subspecialty of allergy and immunology. The College, comprising more than 5,000 allergists-immunologists and related health care professionals, fosters a culture of collaboration and congeniality in which its members work together and with others toward the common goals of patient care, education, advocacy and research.

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