

## No clear criteria for diagnosing food allergies, researcher finds

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A new study shows that confusion over how to identify and treat food allergies is creating the potential for misdiagnosis of this condition.

In a review of existing literature on the subject, researchers with RAND Corp., Stanford University and the Veterans Affairs Palo Alto Health Care System found differing definitions of food allergy. "There is lack of agreement over what criteria should be used to diagnose this type of allergy," said Jennifer Chafen, MD, a fellow with the Stanford Center for Health Policy/Center for Primary Care and Outcomes Research and the VA-Palo Alto. "There needs to be standardized criteria of what constitutes a food allergy — then we can move forward more quickly on management and prevention."

Chafen is lead author of the study, which will appear in the May 12 issue of the Journal of the American Medical Association.

Food allergies, by some accounts, affect about 4 percent of adults and 5 percent of children under the age of 6 in the United States, though this study raises questions about the reliability of such figures.

Food allergies can cause a variety of problems, ranging from mild skin rashes or nausea to a life-threatening, whole-body reaction known as anaphylaxis. The allergies can also have serious effects on patients' social interactions, school and work attendance, family economics and overall quality of life. "It's a life-defining diagnosis in a way," said Chafen.



The National Institute of Allergy and <u>Infectious Diseases</u> is working on new <u>clinical practice guidelines</u> and, as part of its efforts, enlisted Chafen and her colleagues to review the current evidence on food allergies.

The researchers started their work by sifting through thousands of scientific papers, published between 1988 and 2009, that focused on the four foods — milk, eggs, fish and peanut and tree nuts — responsible for more than half of all allergies. They ultimately reviewed 72 studies, including one meta-analysis on prevalence, 18 studies on diagnosis, 28 studies on management, and four meta-analyses and 21 additional studies on prevention.

When examining the literature, the researchers found there was no universal definition of "food allergy," in spite of NIAID's defining it as an "adverse immune response" that is "distinct from other adverse responses" such as a food intolerance. In fact, 82 percent of the studies provided their own definition of food allergy.

"This validates the idea that there exists a great deal of complexity and confusion in the field of food allergy, even at the level of the medical literature," said co-author Marc Riedl, MD, MS, section head of clinical immunology and allergy at UCLA.

Along the same lines, there was a lack of uniformity for criteria in making a diagnosis. The current gold standard is the food challenge, during which a physician gives a patient a sample of the suspected offending food, sometimes in capsule form, and then monitors for allergic reaction. However, this test requires specialized personnel, is expensive and has a risk of anaphylaxis. Office-based tests were used to diagnose many patients; these include a skin-prick test, during which a dilute extract of the potential allergen is placed on the skin, and a blood test that determines the presence of food-specific allergic antibodies



## known as IgE.

As the researchers discuss in their paper, the concern with the latter two tests is that they're not definitive: Patients with non-specific symptoms, such as a rash or digestive troubles, and positive skin-prick or blood tests actually have less than a 50 percent chance of having a food allergy. In order to make a proper diagnosis, they pointed out, physicians need to evaluate the data within the context of a patient's history and have a great understanding of symptoms consistent with true food allergy.

What this means, then, is there is a potential for the overdiagnosis of food allergy.

"I frequently see patients in my clinical practice who have food intolerance, but have previously had inadequate or inappropriate evaluation and been told they have a 'food allergy'," said Riedl. "This causes a great deal of unnecessary anxiety and concern for the patient."

Previous studies have tried to determine whether the skin-prick or blood test is superior over the other, but in reviewing the evidence, Chafen and her colleagues found "no statistical superiority in either test." They also found generally inconclusive results from 10 previous studies in which the tests were combined, in an effort to improve diagnostic accuracy.

"I was very surprised," said Chafen. "I'm a general internist and I thought diagnostic strategies were more-studied."

In terms of treatment, Chafen said expert opinion is that an elimination diet — having the patient stop consuming the food that causes the allergic reaction — is the most common. Although the approach is a common-sense one ("If a patient breaks out in hives repeatedly after drinking milk, it's your instinct as a physician to say, 'Don't drink milk,'" Chafen said), the researchers found the treatment hasn't been well-



## studied.

It would be unethical to conduct controlled studies of elimination diets for patients with serious, life-threatening allergic reactions, but as pointed out in the paper, there are few studies of this approach on patients with relatively minor symptoms.

"In these instances, the benefits of an elimination diet are uncertain based on published evidence and potential benefits need to be weighed against the potential nutritional risks of such a diet, particularly in children," the researchers wrote.

Chafen and her colleagues also found that immunotherapy, a treatment in which the body's immune system is altered by administering increasing doses of the allergen over time, appeared to be effective at eliminating symptoms in the short term. Immunotherapy isn't a licensed method for allergy treatment, but the researchers urged more study on its long-term effect and safety.

In all, the researchers concluded, the <u>food-allergy</u> field is in need of uniformity in the criteria for what constitutes an allergy and a set of evidence-based guidelines upon which to make this diagnosis. NIAID, which put together an expert panel and has reviewed the group's analysis, is planning to finalize such guidelines later this summer.

As for Chafen, who sees patients with potential food allergies, these findings have encouraged her to rely more on specialists to help clinch a diagnosis. "People need to be seen by someone with a deep understanding of diagnostic tests and criteria," she said. "The distinction between food intolerance and <u>food allergy</u> is really important."

The study was funded by NIAID. Other Stanford authors on the study are Dena Bravata, MD, a PCOR affiliate; and Vandana Sundaram, MPH,



assistant director of research for CHP/PCOR. Paul Shekelle, MD, PhD, with the RAND Corp.'s Southern California Evidence-Based Practice Center and the West Los Angeles VA Medical Center, is the senior author.

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