INNOVATION PARTNERSHIPS
UNIVERSITY OF MICHIGAN

# Nanoemulsion Vaccine Induces Cross-Protection to Suppress Reactivity to Multiple Food Allergens

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**Inventor**
James Baker Jr.
Jessica O'Konek

**Further information**
Tiefei Dong
tiefeid@umich.edu

**View online**

## OVERVIEW

Intranasal immunotherapy that provides food allergy protection

- Suppresses T helper cell 2 and immunoglobulin E allergic responses
- Can be formulated with multiple allergens to provide allergy protection

## BACKGROUND

Food allergy is an emerging epidemic that now affects up to 15 million people in the US, including 8% of children. Thirty to forty percent of patients with food allergies are sensitized to multiple foods. While allergen-specific immunotherapy has the potential to relieve the burden of fear of reactivity to specific foods, this approach is more difficult for polysensitized individuals. Allergen-specific immunotherapy for food allergy involves the progressive administration of increasing amounts of a specific allergen by one of several routes and has been the primary approach to suppress allergic reactivity. While some studies have demonstrated the ability to desensitize patients with oral immunotherapy (OIT) for up to 5 foods simultaneously (multi-OIT), the amount of each food required to be consumed daily is a burden for some children. Also, this approach does not provide long-term protection following cessation of therapy.

Given these realities, there is interest in the development of therapies for food allergy that work more broadly and are not specific to one allergen. Subcutaneous immunotherapy to food allergens showed promise for protection against IgE-mediated food allergies, however significant adverse reactions limited successful implementation. The primary immunologic mechanism of allergic hypersensitivity is the induction of T helper 2 cell (Th2) polarized cellular

immune responses leading to the production of allergen specific IgE antibodies critical for mast cell activation. While OIT has been proven clinically useful for treating food allergy, it has not induced a long-term redirection of allergen-specific immunity away from a Th2 phenotype. A need exists to develop new strategies that are able to permanently suppress Th2 cellular immune responses or redirect these cellular Th2 responses towards a Th1 phenotype.

## INNOVATION

University of Michigan researchers have discovered that intranasal immunotherapy with allergens formulated in a nanoemulsion (NE) mucosal adjuvant that suppresses Th2/IgE-mediated allergic responses and protects from allergen challenge in murine food allergy models. Protection from oral allergen challenge was achieved despite the persistence of allergen-specific IgE and was associated with strong suppression of both Th2-polarized immune responses, alarmins and type 2 innate lymphoid cells (ILC2). Their discovery demonstrates that anaphylactic reactions to food allergens can be suppressed using allergen-specific immunotherapy without having to eliminate allergen-specific IgE. The inventors discovered that NE can be formulated with multiple allergens and can lead to allergic suppression of all allergens included in the vaccine. Given that long-term protection can be achieved with only a few doses administered at monthly intervals, this approach would significantly reduce the burden on patients with multiple food allergies over daily, allergen-specific immunotherapies.