

# Food Oral Immunotherapy: A Survey Among US Practicing Allergists Conducted as a AAAAI Leadership Institute Project and Work Group Report



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BACKGROUND: Food oral immunotherapy (OIT) is an active form of treatment for food allergies. Although research in this area has been ongoing for many years, the first US Food and Drug Administration—approved product for peanut allergy treatment became available only in January 2020. Limited data exist on OIT services offered by physicians in the United States. OBJECTIVE: This workgroup report was developed to evaluate OIT practices among allergists practicing in the United States. METHODS: The authors developed an anonymous 15-question survey and was subsequently reviewed and approved by the American Academy of Allergy, Asthma & Immunology Practices, Diagnostics and Therapeutics Committee before distribution to the membership. The American Academy of Allergy, Asthma & Immunology electronically distributed the survey to a random sample of 780 members in November 2021. In addition to questions specific to food OIT, the survey included questions on demographics and professional characteristics of the responders.

experience in OIT originating from research trials in academic versus nonacademic centers. Generally, OIT practices were similar in both settings for the number of foods offered, the performance of oral food challenges before initiating treatment, the number of new patients to whom OIT was offered to per month, and age groups OIT to whom was offered. Almost all of the reported barriers to OIT were similar between settings: staff and time limitations, concerns about safety and anaphylaxis, the need for more education on how to perform, inadequate compensation, and that it was not a significant demand from patients. Clinic space limitations were significantly different and more prominent in academic settings.

CONCLUSIONS: Our survey revealed interesting trends in the

RESULTS: A total of 78 members completed the survey, yielding a 10% response rate. Fifty percent of responders were offering

OIT in their practice. There was a significant difference in

conclusions: Our survey revealed interesting trends in the practice of OIT across the United States, with some significant differences arising when academic and nonacademic settings were compared. © 2023 American Academy of Allergy, Asthma & Immunology (J Allergy Clin Immunol Pract 2023;11:2330-4)

**Key words:** Food oral immunotherapy; Survey; Oral food challenge; Children; Practice; Barriers; Academic; Nonacademic settings

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# **BACKGROUND AND OBJECTIVE**

Food oral immunotherapy (OIT) is an active form of treatment for food allergies with the potential to be disease-modifying. So far, it has been shown that desensitization is achieved by most OIT participants, but disease remission (previously known as sustained unresponsiveness) appears to be less successful and a cure remains elusive. <sup>1-5</sup> Younger age is generally associated with better rates of remission, and some studies showed the ability for *ad libitum* food consumption for a small number of OIT participants. <sup>3,6</sup> Both single and multiple-food

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Abbreviations used

FDA- US Food and Drug Administration

IND-Investigational new drug

IRB-Institutional review board

OFC- Oral food challenge OIT- Oral immunotherapy

OIT have been described.<sup>7-9</sup> Although research in this area has been ongoing for many years, the first US Food and Drug Administration (FDA)-approved product for peanut allergy treatment became available only in January 2020.

Limited data exist on OIT practices among physicians in the United States. This work group report was developed to evaluate OIT practices among allergists in the United States. We were interested in examining how many allergists offer OIT to patients, what foods are offered, and for which age groups. We also set out to evaluate differences in practice between academic and nonacademic centers as well as barriers to providing OIT.

#### **METHODS**

The investigators developed an anonymous 15-question survey to assess current OIT practices across the United States. The survey was reviewed and approved by the American Academy of Allergy, Asthma and Immunology (AAAAI) Practices, Diagnostics, and Therapeutics Committee before distribution to the membership. The AAAAI electronically distributed the survey to a random sample of 780 members in the United States in November 2021. Two reminder e-mails within a 2-week period were sent to members who had not responded to the survey within a prespecified time frame. Fellows in Training were not invited to participate. The survey was available for participation for a total of 6 weeks. The questions were designed in a multiple choice format. Some questions allowed multiple responses. Three questions allowed free writing for an additional response (other). Response to every question was not mandated to complete the survey.

We collected information on the demographics and characteristics of responders (type of practice, area of the country in which the practice was located, age of populations treated, time the responder had been in practice, and prior experience with OIT). Specific questions addressed the different foods offered for OIT, whether single-food or multiple-food OIT was offered, whether oral food challenges (OFCs) were performed before the initiation of OIT, number of patients treated every month, age groups of patients offered OIT, use of an institutional review board (IRB) protocol, use of an investigational new drug (IND) for OIT material, and use of an FDA-approved product. In addition, for practices that did not offer OIT, reasons were explored.

Results were collected via the SurveyMonkey server (Ryan Finley and Chris Finley, San Mateo, California), tabulated by the Information Services Team at the AAAAI, and subsequently analyzed and evaluated by the authors. Data were analyzed using frequency analysis and proportional comparisons were performed using two-sided Fisher exact test at a prespecified  $\alpha$  level of 0.05 for significance.

# **RESULTS**

A total of 78 members completed the survey, yielding a 10% response rate, which was within the expected range of response (10% to 15%) for AAAAI surveys. <sup>10,11</sup> Because response to all

questions was not required to participate in the survey, the number of replies to different questions might have varied; the number of responses received are included for all questions, for clarity.

Among responders, 60.1% identified their primary practice setting as a private practice (44.9% in group practice and 15.4% in solo practice), 24.4% as an academic practice, 10.3% as a multispecialty clinic, and 5.1% as another practice setting (not specified). The geographic distribution of practices included the Southeast (21.8%), the West (16.7%), the Northeast (16.6%), the Mid-South (15.4%), the Mid-Atlantic (12.8%), the Midwest (12.8%) and the Rocky Mountain (3.8%) areas.

Most responders indicated that they care for both children and adults (85.9%); a minority treated only children (7.7%) or only adults (6.4%). Over 60% of responders indicated they had been practicing in allergy/immunology for over 11 years (20.5% for up to 5 years, 15.4% for 6 to 10 years, 19.2% for 11 to 20 years, 25.6% for 21 to 30 years, and 19.2% for more than 30 years). Over half of responders (53.8%) reported having had experience with OIT (41% from clinical practice and 12.8% from research trials), whereas 46.1% of responders reported no experience in OIT (Table I).

Most responders (80.8%) indicated that the patient population was aware of food OIT as a treatment option for food allergies, 6.4% indicated that the patient population was not aware of food OIT, and 12.8% were unsure. Half of responders (n = 39) reported that they were offering food OIT in their practice, 37.2% were not, and 12.9% were not offering OIT currently but were planning to start in the near future. The most common food offered for OIT was peanut (94.1%), followed by tree nuts (47%), sesame (44.1%), egg (41.2%), milk (38.2%), wheat (29.4%), soy (23.5%), and other (23.5%) including legumes, shellfish, and seeds. Most responders (66.7%) reported offering single-food OIT, with 3% offering multiple-food OIT and 30.3% offering both.

Oral food challenges were always performed before starting OIT by 12.1%, most times by 42.4%, sometimes by 30.3%, and rarely by 15.1%. Most responders (68.7%) indicated that they treated one to five new patients every month, whereas 25% treated five to 10 new patients every month, and 6.2% treated more than 10 new patients per month. Oral immunotherapy was offered to patients aged 0 to 3 years by 42.4%, 4 to 11 years by 97%, 12 to 17 years by 97%, and 18 years and older by 42.4%. Most responders (68.7%) used an FDA-approved product for OIT in the practice, whereas 12.5% used an IRB protocol for OIT and 3.1% used an IND. More than one-third (37.5%) reported using none of these. Respondents who did not offer OIT in the practice at the time they completed the survey reported a variety of reasons including staff, space, and time constraints; concerns about safety (allergic reactions, anaphylaxis, and risk for eosinophilic esophagitis) or the risk-benefit ratio; inadequate compensation and insurance coverage issues; lack of education about how to perform it, the effect of the COVID-19 pandemic; and being willing to use only FDA-approved products (Table II).

Comparisons of academic and nonacademic settings showed no difference in terms of areas of practice with the exception of the Southeast (only nonacademic settings participated) and the number of years practicing in allergy/immunology. There was a significant difference in experience in OIT originating from research trials in academic versus nonacademic centers. There

TABLE I. Responders' characteristics

Responders' characteristics	All practices (n = 78)	Academic setting (n = 19)	Nonacademic setting (n = 59)	P
Area of practice	_			
Northeast	13 (16.7%)	5 (26.3%)	8 (13.5%)	.286 NS
Mid-Atlantic	10 (12.8%)	4 (21%)	6 (10.2%)	.248 NS
Southeast	17 (21.8%)	0	17 (28.8%)	.0083
Midwest	10 (12.8%)	3 (15.8%)	7 (11.9%)	.698 NS
Mid-South	12 (15.4%)	3 (15.8%)	9 (15.2%)	1.00 NS
Rocky Mountain	3 (3.8%)	0	3 (5%)	1.00 NS
Western	13 (16.7%)	4 (21%)	9 (15.2%)	.723 NS
Treating children or adults				
Children only	6 (97.7%)	5 (26.3%)	1 (1.7%)	.0028
Adults only	5 (6.4%)	3 (15.8%)	2 (3.4%)	.09 NS
Both	67 (85.9%)	11 (57.9%)	56 (94.9%)	.0003
Years practicing in allergy/immunology				
≤5	16 (20.5%)	6 (31.6%)	10 (16.9%)	.198 NS
6-10	12 (15.4%)	4 (21%)	8 (13.5%)	.472 NS
11-20	15 (19.2%)	6 (31.6%)	9 (15.2%)	.177 NS
21-30	20 (25.6%)	2 (10.5%)	18 (30.5%)	.130 NS
>30	15 (19.2%)	1 (5.3%)	14 (23.7%)	.099 NS
Experience in oral immunotherapy				
Yes, from research trials	10 (12.8%)	6 (31.6%)	4 (6.8%)	.011
Yes, from clinical oral immunotherapy practice	32 (41%)	5 (26.3%)	27 (45.8%)	.182 NS
No	36 (46.1%)	8 (42.1%)	28 (47.4%)	.793 NS

NS, not significant.

were also significant differences in terms of the populations treated, in which more academic centers treated only children and more nonacademic centers treated both children and adults. The OIT practices were similar in both settings for the number of foods offered, the performance of OFCs before treatment was initiated, the number of new patients treated per month, and the age groups to whom OIT was offered. There were significant differences in the use of an IRB (more in academic settings) and of an FDA-approved product (more in academic settings). There was no significant difference in the use of an IND. Almost all reported barriers to OIT were similar in both settings: staff and time limitations, concerns about safety and anaphylaxis, the need for more education on how to perform it, inadequate compensation, and a lack of significant demand from patients. Clinic space limitations were significantly different and more prominent in academic settings (Table III).

## **DISCUSSION**

This evaluation of OIT practices across the United States provided some valuable insights. It appears that food OIT is becoming a popular form of therapy; 50% of responders offered it to their patient populations. This finding is different from a committee report published 8 years ago, when only 13.8% of providers provided OIT as a service. Patients have also become aware of OIT as an available option for food allergy management, because at least eight of 10 survey responders reported that their patient populations were familiar with OIT. It is possible that the availability of the first FDA-approved product for peanut OIT in January 2020 brought this form of therapy to the public's attention. The percentage of allergists using the FDA-approved product in the current survey was 68.8%,

approximately two-thirds of responders. Only a small minority reported using an IRB protocol (12.5%) or an IND (3.1%) for OIT, which was a much smaller number than that seen 8 years ago (34.4% and 26.2%, respectively). This trend may reflect the increased use of the FDA-approved product, an increase in practicing OIT outside the research umbrella (off-label), or both.

According to the responses to this survey, single-food OIT seems to be offered more often than multiple-food OIT, and peanut was by far the most popular allergen for therapy, followed by tree nuts and sesame. The age group most often treated was 4 to 17 years, which may reflect increased patient demand for this age range, or that the FDA-approved product is currently not licensed for children aged younger than 4 years or older than 17 years. Recent studies highlighted the efficacy of peanut OIT in infants and toddlers, <sup>6,13,14</sup> and in our survey, four of 10 practices offered OIT to those young individuals.

The role of an OFC before initiating OIT has been extensively debated. Most research studies included double-blind placebo-controlled food challenge in their protocols,  $^{15-18}$  in contrast to real-world trials that enroll patients based on a positive history of an allergic reaction in combination with positive testing (usually skin testing or specific IgE).  $^{19-22}$  Over two-thirds of responders to this survey indicated that they would use OFCs most times or sometimes, and 12% would use OFCs routinely, which suggests that OFCs are mostly offered to selected patients rather than all. The overall percentage of providers performing OFCs was significantly higher compared with what was reported 8 years ago (84.8 % vs 62.3%; P = .032). This suggests that this trend has changed over time, potentially as a result of OIT becoming more widely and commercially available.

Comparisons of academic and nonacademic settings revealed some significant differences in OIT practice. Experience in OIT mostly originated from research studies in academic centers

TABLE II. Comparison in OIT practices between academic and nonacademic settings

Practices offering OIT (n = 39)	Academic setting $(n = 9)$	Nonacademic setting ( $n = 30$ )
Number of foods offered for OIT		
Single-food OIT	6 (75%)	16 (64%)
Multiple-food OIT	1 (12.5%)	0
Both	1 (12.5%)	9 (36%)
Number of replies: 33	n = 8	n = 25
Perform OFCs		
All of the time/most times	3 (37.5%)	15 (60%)
Sometimes/rarely	5 (62.5%)	10 (40%)
Number of replies: 33	n = 8	n = 25
Number of new patients treated/mo		
1-5	4 (50%)	18 (75%)
5-10	3 (37.5%)	5 (20.8%)
>10	1 (12.5%)	1 (4.16%)
Number of replies: 32	n = 8	n = 24
Age group OIT is offered to, y		
0-3	4 (50%)	10 (40%)
4-11	8 (100%)	24 (96%)
12-17	8 (100%)	24 (96%)
≥18	2 (25%)	12 (48%)
Number of replies: 33	n = 8	n = 25
Use of the following for OIT		
Institutional review board	3 (37.5%)	1 (4.16%)
Investigational new drug	1 (12.5%)	0
US Food and Drug Administration-approved product	8 (100%)	14 (58.3%)
None of the above	0	12 (50%)
Number of replies: 32	n = 8	n = 24

OIT, oral immunotherapy.

TABLE III. Reported barriers to oral immunotherapy practice

Reported barriers to oral immunotherapy	All practice settings (n = 38), n responders (%)	Academic setting (n = 10)	Nonacademic setting (n = 28)	P
Not enough staff	19 (50%)	6 (60%)	13 (46.4%)	.71 NS
My patients are not requesting it	17 (44.7%)	5 (50%)	12 (42.8%)	.72 NS
Time constraints	14 (36.8%)	2 (20%)	12 (42.8%)	.26 NS
Not enough clinic space	13 (34.2%)	6 (60%)	7 (25%)	.06
Concerns about significant allergic reactions/anaphylaxis	12 (31.6%)	1 (10%)	11 (39.3%)	.12 NS
Inadequate compensation	9 (23.7%)	2 (20%)	7 (25%)	1.00 NS
I do not think it provides significant benefit to patients	9 (23.7%)	2 (20%)	7 (25%)	1.00 NS
Need more education on how to perform	8 (21%)	1 (10%)	7 (25%)	.65 NS
I do not think it is safe	5 (13.1%)	1 (10%)	4 (14.3%)	1.00 NS
Other*	12 (31.6%)	0	12 (42.8%)	.01

NS, not significant.

\*Other reported barriers to oral immunotherapy included concerns about eosinophilic esophagitis, concerns about the risk—benefit ratio, insurance coverage, the effect of the COVID-19 pandemic, and awaiting implementation of the US Food and Drug Administration—approved product in the practice.

versus clinical practice in nonacademic settings. This was an expected finding because academic centers tend to be more involved in research studies. The use of an FDA-approved product was significantly higher in academic settings, potentially suggesting faster implementation and a reliance on approved products by allergists in academic practice. It is also possible that academic practices perceive being constrained to

using only FDA-approved products. Clinic space seems to be a significant barrier, and more so in academic settings.

We noted with interest the reported barriers to performing OIT, which included inadequate compensation, staff, time, and clinic space constraints as well as concerns about safety and anaphylaxis. Multiple research trials (including real-world studies) have shown a good safety profile for OIT, although

during the initial up-dosing period adverse reactions are frequent. <sup>23,24</sup> Most of these reactions appear to be mild or moderate; anaphylaxis is uncommon and severe anaphylaxis is rare. In addition, adverse reactions tend to decline during maintenance. <sup>25-27</sup> Concerns about safety for any new treatment are expected, and education is required regarding how to manage known adverse events and mitigate risk.

Over one-third of physicians not performing OIT reported that patients were not requesting this therapy. After years of research studies, it emerged that OIT induces desensitization in most participants, allowing for a substantial increase in the threshold of reactivity, but disease remission is achieved by a small minority and immunologic tolerance (*ad libitum* consumption of the food) remains elusive. This is likely a limitation for patients who are interested in a cure rather than a protective effect toward accidental exposures.

The need for more education about how to perform OIT was also highlighted in this survey as a barrier in both academic and nonacademic settings, revealing an unmet need in physicians' education in this area of therapy. If the aim in our specialty is for OIT to become standard practice offered in all settings, many of these barriers need to be examined in more detail and mitigation strategies should be developed.

Strengths of our work include a representative sample of physicians' practices across the United States, with inclusion of both academic and nonacademic settings. This survey also investigated OIT practices after the availability of the first FDA-approved product for peanut OIT in January 2020. Limitations include a low response rate (which limits the generalizability of the information), self-reported data, and some nonreported data, because answering all questions was not mandatory.

This survey revealed interesting trends in the practice of OIT across the United States. Significant differences arose when we compared academic and nonacademic settings. Further research in this area would be welcome, especially as OIT becomes more widely used and new therapies for food allergies emerge in the near future.

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