AAAAI Committee Paper

Allergist-Reported Trends in the Practice of Food Allergen Oral Immunotherapy

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What is already known about this topic? Results of promising preliminary studies indicate that oral immunotherapy (OIT) offers therapeutic potential. Although many thought leaders within the academic community strongly advocate for equipoise, a vocal minority of physicians in nonacademic practice advocate that it is ready for general use.

What does this article add to our knowledge? Minimal information exists regarding current practices for food OIT. This study reveals key differences in beliefs and concerns among those identifying as OIT providers and nonproviders and also differences in academic versus nonacademic OIT programs.

How does this study impact current management guidelines? Significant differences may exist with OIT that occurs in academic versus nonacademic settings. Opinions, motivations, and styles vary regarding regulatory oversight requirements, use of standardized product, and safety. Ongoing assessment is needed to understand these variations.

Food allergen oral immunotherapy (OIT) is an experimental, immune-modifying therapy that may induce clinical desensitization in some patients. OIT is still in early phase clinical research, but some providers may offer OIT as a clinical service. To understand the current practices of allergists who perform OIT, an online survey was sent by e-mail to members of the American Academy of Allergy Asthma & Immunology. Among 442 respondents, 61 reported participating in using OIT (13.8%), including 28 in nonacademic settings. Informed consent for OIT was obtained by 91.3%, institutional review board approval by 47.7% and Investigational New Drug approval by 38.1%. Compared with nonacademic participants, more academic participants used peanut OIT, obtained institutional review board and Investigational New Drug ($P < .0001$ respectively), and challenged patients before entry ($P = .008$). More nonacademic providers billed the patient or insurance for reimbursement ($P < .0001$). Low reported regard for the importance for US Food and Drug Administration approval or a standardized product (increased odds), and a high regard for better safety data (decreased odds) were associated with considering offering OIT as a service. Significant differences exist with OITs that occur in academic versus nonacademic settings. Further assessment is needed regarding the different motivations and practice styles among providers who offer OIT and those who are considering doing so. © 2014 American Academy of Allergy, Asthma & Immunology (J Allergy Clin Immunol Pract 2015;3:33-8)

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Food oral immunotherapy (OIT) is an investigational treatment that can modulate the immune response[1,2] and has been shown in small trials to induce variable hyporesponsiveness to allergen (eg, clinical desensitization).[3-5] However, the interventions and end points used in these and other published trials vary widely, and, to date, most study designs either have not included controls or have used a cross-over design. As a result, neither safety nor efficacy have been definitively established as superior to allergen avoidance, and recent National Institutes of Allergy and Infections Diseases food allergy treatment guidelines specifically recommend against the use of OIT in clinical settings.[6] OIT also is not currently approved by

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Abbreviations used
AAAAI- American Academy of Allergy, Asthma & Immunology
CPT- Current Procedural Terminology
FDA- US Food and Drug Administration
IND- Investigational New Drug
IRB- Institutional review board
OIT- Oral immunotherapy
OR- Odds ratio

the US Food and Drug Administration (FDA), a convention that some allergists in private practice have contested as unnecessary given the potential benefits of OIT.[6-9] The question of equipoise in the practice of OIT continues to be prominently debated, in light of still emerging data that pertain to the safety and efficacy of OIT.[7,10-13] There are limited data that pertain to the actual practice of OIT outside of trials conducted at academic medical centers,[8,11,14] but it is known that OIT is being offered by allergists as well as otolaryngologists and nonallergy specialists in several states, with limited differentiation of these services by patients and some exploratory data suggestive that provider framing is a factor in influencing parent participation in OIT programs.[15]

Additional factors that have been shown to influence participation in using OIT at an academic center include parental anxiety and perception of reaction severity.[16] However, there are no current data that explored provider-level motivations to participate in using OIT, either in an academic or a nonacademic setting; provider opinions regarding OIT; and the question of equipoise as well as understanding the differences that may exist in current practice styles among providers who offer OIT. We, therefore, undertook a study to survey these provider-level attributes among members of the American Academy of Allergy, Asthma & Immunology (AAAAI), to better understand current practice styles and sentiment regarding OIT.

METHODS

A 23-question survey was developed by the investigational team through the AAAAI Adverse Reactions to Foods Committee Subgroup on Oral and Sublingual Immunotherapy. Membership on the subcommittee was open to any interested committee member. Questions were developed to survey current OIT practice styles (including types of patients, patient age, allergens for which OIT was offered, protocol and oversight, and reimbursement options for OIT), opinions on OIT practice styles and current regulatory climate, barriers to entry to the practice of OIT, awareness of other providers who are practicing OIT, and demographic information. Once developed, the survey was posted, for group feedback, on the Basecamp access site for the Adverse Reactions to Foods Committee. Once approved by the subcommittee, the survey was then forwarded to the AAAAI Needs Assessment Committee for approval before distribution through the AAAAI membership e-mail distribution list in January of 2013 to 4370 domestic and international members. A reminder e-mail within a 2-week period was sent to members who did not complete the survey within a specified time frame.

The survey was offered for 4 weeks. No financial incentive for participation was provided. The questions were administered in a multiple-choice format, with some questions that allowed for multiple responses per question, and selected questions that allowed for an open-ended additional response. Response to every question was not mandated. Responses were automatically tabulated through the Survey Monkey server (SurveyMonkey, Palo Alto, CA) and exported to a spreadsheet for data cleaning, variable labeling and/or coding, and uploading into a statistical package. Data were collected and analyzed at the provider level for general descriptive trends by using frequency analysis, and inferential proportional comparisons were assessed by using the 2-sided Fisher exact test at a prespecified alpha level of .05 for significance. Logistic regression was used to build an exploratory model of prespecified factors that may influence provider participation in using OIT. Data were analyzed by using Stata IC, Version 12 (Stata Corp, College Station, Texas). This study was deemed exempt from ongoing review by the University of North Carolina School of Medicine Institutional Review Board.

RESULTS

A total of 442 allergists responded to the survey (a response rate of approximately 10.1% of 4370 invitees). Among responding allergists (n = 440 to this question), 75.9% identified that they were in a private practice (96 in solo practice, 157 in a single specialty group practice, and 81 in a multispecialty group practice), and 24.1% were in an academic practice (106). Geographically, 18.3% reported practicing in the Northeast, 17.4% in the Mid Atlantic area, 10.5% in the Southeast, 17.6% in the Southwest, 17.6% in the Upper Midwest, 18.5% in the Far West, and 0.1% in Canada. Approximately 41.7% indicated that they were aware of either another allergist or another provider (including nonallopathic providers) offering OIT, and 42.6% were aware that another allergist or provider was offering sublingual immunotherapy to food (an alternative approach to oral tolerance also being researched or offered clinically).

A total of 61 providers (13.8%) indicated that they were providing OIT as a service or were studying OIT under a research protocol. Among the allergists who participate in using OIT in some capacity, 68.9% (42/61) reported obtaining informed consent before initiating OIT (including 88% of respondents in academic practice and 95% of those in private practice), 34.4% (21/61) reported having institutional review board approval to conduct OIT, 22.9% (14/61) reported that a data safety monitoring board oversaw their administration of OIT, 26.2% (16/61) reported obtaining an Investigational New Drug to administer OIT, and 18% (11/61) reported they had none of these aforementioned oversights in place. The location (venue) of where dose escalations occurred and the frequency at which dose escalations occurred are detailed in Figure 1. Forty-six respondents provided information regarding compensation for OIT, with 23.9% reporting research or grant funding, 43.5% reporting insurance reimbursement, 13% reporting that the patient paid out of pocket, and 19.6% reported offering the service *pro bono*. When asked to rank the relative importance of OIT as a means of developing a new revenue stream, however, 9.7% indicated that this was a "most important" or "very important" consideration, and that there was no significant difference in this trend when comparing academic and private practice. Specific differences with the administration of OIT between allergists who identified themselves as academic versus those who identified themselves as nonacademic are detailed in Table I.

Among the 381 providers not participating in using OIT currently, 74.3% indicated that they are awaiting FDA approval

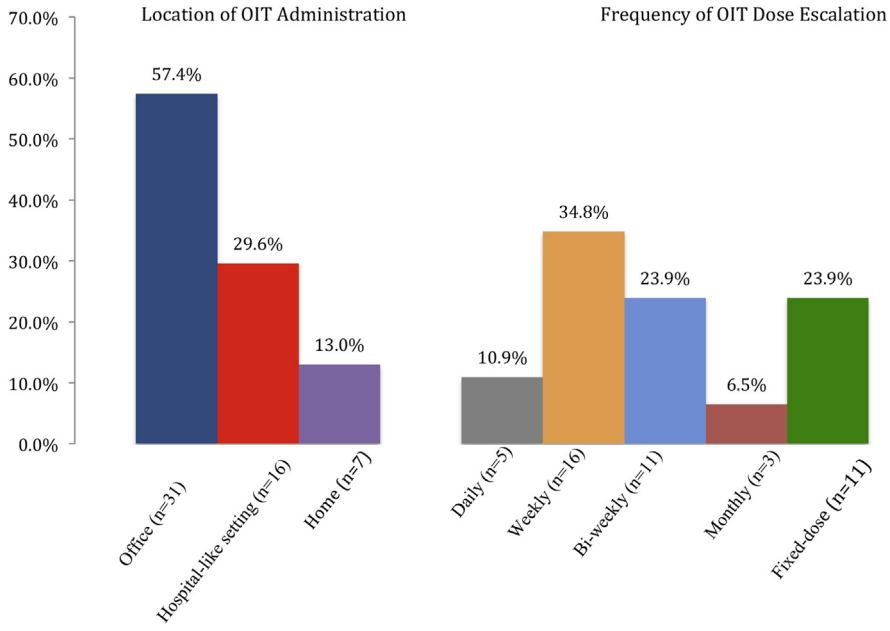

FIGURE 1. Reported locations of OIT administration and frequency of OIT dose escalations. The *left-sided graph* compares the reported venue or location in which the OIT is administered; the *right-sided graph* represents the reported range of the frequency of OIT dose escalation.

TABLE I. Specific trends related to the administration of OIT based on practice type

Trend (total no. for trend)	Academic practice, % (no.)	Nonacademic practice, % (no.)	*P**
Offering OIT (n = 61)	54.1 (33)	45.9 (28)	<.001
OIT protocol IRB approved (n = 21)	85.7 (18)	14.3 (3)	<.001
Informed consent obtained (n = 42)	47.6 (20)	52.4 (22)	.61
IND obtained for material (n = 16)	93.8 (15)	6.3 (1)	<.001
Challenge before entry (n = 38)	52.6 (20)	47.3 (18)	.008
Bill insurance or patient for service (n = 26)	0	100 (26)	<.001
Offer OIT to peanut (n = 32)	43.7 (14)	56.3 (18)	.19
Offer OIT to milk (n = 31)	29 (9)	71 (22)	.007
Offer OIT to egg (n = 30)	30 (9)	70 (21)	.03
Commercial food product used for OIT (n = 25)	24 (6)	76 (19)	.02

IND, Investigational New Drug, *IRB*, institutional review board.
*All comparisons were made by using the 2-sided Fisher exact test in a cross tabulation, which represents the relative percentages for the trend as stratified by practice type.

before offering this therapy, 21.2% indicated they are considering offering OIT but not yet doing so, and 4.5% indicated they did not have the resources at present to offer OIT but were interested in doing so. Among this group, several questions regarding motivation to offer OIT were investigated. Regarding the importance of specific reasons as to why these providers were not participating in using OIT at present, FDA approval was thought to be extremely important or important in 88.3% (326 responded to this item), better established safety data were thought to be extremely important or important to 90.9% (318 responded to this item), insurance coverage of the service was thought to be extremely important or important to 70.9% (310 responded to this item), and long-term data that support the efficacy of the procedure was thought to be extremely important or important to 85.1% (316 responded to this item). When asked to rate the relative importance of factors that would specifically motivate these providers to offer OIT in the future, 90.5% indicated FDA approval; 91.9%, a standardized product; 86%, a Current Procedural Terminology (CPT) billing code; 93.9%, additional data that pertained to the safety of OIT; 92.5%, data that indicated that OIT can produce long-term tolerance; and 88.5%, indicated that a practice parameter or evidence-based guideline was thought to be extremely important or important factors. Described in Table II is a logistic regression model that details factors that influence the odds of considering OIT at present versus waiting for FDA approval for OIT, which revealed significant positive associations with a lack of belief in the importance for FDA approval of OIT or the need for a standardized OIT product. A similar regression model was attempted to determine the association among providers participating in using OIT between practice type and the same variables in the model in Table I, but 5 of the 6 included variables were perfect predictors of practice type, and no regression could be generated.

TABLE II. Factors predictive of providers who are considering offering OIT or wanting to offer OIT but lack the resources to do so

Predictive factors identified	OR (95% CI)	P
Knowledge of a nearby practice offering OIT	1.76 (0.89-3.47)	.1
Academic practice	0.91 (0.4-2.08)	.83
Region		
Northeast (reference)	1	
Mid Atlantic	2.57 (0.83-7.97)	.1
Southeast	1.01 (0.25-4.08)	.98
Southwest	0.65 (0.19-2.24)	.5
Upper Midwest	2.11 (0.76-5.89)	.15
Far West	3.08 (1.09-8.64)	.03
Belief that*		
FDA approval for OIT is neutral/not important	20.52 (5.64-74.6)	<.001
A standardized product for OIT is neutral/not important	6.26 (1.89-20.73)	.003
A CPT code for OIT is neutral/not important	1.36 (0.55-3.35)	.51
Better safety data for OIT are neutral/not important	0.19 (0.03-1.09)	.06
Proof that OIT can establish tolerance is neutral/not important	1.63 (0.44-6.04)	.47
Having more support staff to conduct OIT is neutral/not important	1.37 (0.72-2.64)	.34
Having clinical guidelines for OIT is neutral/not important	0.77 (0.26-2.26)	.63

OR, Odds ratio.
*Neutral/not important represents a combined range of opinion compared with very important/important.

DISCUSSION

There is intense interest about OIT, given the growing problem of food allergy, promising preliminary data, and the lack of any existing interventional treatment for food allergy. Although OIT is not currently an FDA-approved therapy, more than 40% of respondents could identify at least 1 provider in their area who was currently administering OIT or offering sublingual immunotherapy as a food allergy therapy (a similar therapeutic approach to oral tolerance that also is being researched and offered in clinical practice by some providers). At present, sentiment among AAAAI members who completed this survey is clear and indicates several points: (a) the vast majority of providers neither participate in using OIT as a research project nor offer OIT as a clinical treatment service, although there is a sizable component that is considering doing so (in particular, OIT as a clinical service); (b) the issue of OIT not being an FDA-approved therapy is rather significant and is, at present, a barrier to many providers; and (c) present knowledge gaps that support further safety of OIT, its long-term efficacy, and ultimate outcomes produced (a transient outcome such as desensitization vs a lasting outcome, eg, tolerance), and lack of both a standardized OIT product and consensus parameter for how to administer OIT are very important to providers currently not offering OIT.

A small segment of respondents to this survey indicated they are currently participating in using OIT. Academic providers who were studying OIT under research protocols slightly outnumbered providers in practice who were offering OIT. Although nearly all providers who offer OIT obtained informed consent, those in practice did not readily obtain other types of oversight, whereas they were significantly more commonly obtained among academic researchers. These include obtaining Investigational New Drug approval from the FDA to use food as a therapeutic substance, having institutional review board approval, or having a research protocol for OIT with a safety monitoring board. How this affects the administration of OIT is not well understood, nor is whether the individual with food allergy or the family receiving the therapy is aware that such differences in oversight exist.[15] Those providers in private practice who are administering OIT have contested the importance of many of these oversights, given that they advocate performing OIT as a service and not for research, where these oversights would be required and expected.[11] However, those in academic practice have advocated strongly that such safeguards are exceptionally important.[7] This argument is one of exceptional importance but is beyond the scope of this survey. With respect to the type of therapy offered, there were no differences in the proportion of academic or private practices studying and/or administering peanut OIT, but significantly more private practices were using OIT to milk and egg. Among respondents, those in practice were significantly more likely to report that they charge the patient directly or bill insurance for this service than did those in academic settings. However, there were no reported differences by type of practice in the reported relative importance of using OIT as a new revenue stream. There is no CPT code at present for food OIT, and it is unknown if insurance plans regularly reimburse for this procedure among those who provide OIT as a clinical service.

Within our sample, among providers not participating in using OIT, there were a few factors that were predictive of those either strongly considering it or those who would offer OIT if they had sufficient staff. These included reporting neutrality or a lack of importance for OIT requiring FDA approval, neutrality or lack of importance that OIT protocols use a standardized food product, and neutrality or lack of importance that OIT have better present safety data. Proof of long-term efficacy (such as clinical tolerance); having clinical guidelines, having other providers in the area offering the procedure, and having a billing code, and, most importantly, the type of practice were not significant. Although type of practice was not a significant influence in this model, provider behavior does appear to significantly change based on the type of practice once the provider does engage in using OIT, according to the trends detected in Table I, and the fact that practice type was nearly perfectly predicted in an attempt to construct a regression model from those variables. This study was not designed, intended, or powered to understand the influencing differences between academic and private practice styles that pertain to administering OIT and was only designed to identify if any differences exist. However, in this sample, we identified potential major differences based on practice type, which would be of interest to examine further in a future study.

Limitations of this study include a limited response rate, exclusive distribution to providers on the AAAAI e-mail distribution list (which was limited to a nonclustered, single-staged, nonstratified sampling frame from the active AAAAI membership list and, therefore, allowed data collection only at the provider level), use of self-reported provider data, use of an Internet-based survey that allowed providers to not answer every question, and that only a small number of responding providers (approximately 13.8%) were engaged in using OIT. Self-reported measures, by

provider or by patients, are subject to questions of validity and recall bias, although the validity argument may be more appropriate to patient-reported attributes of a disease and not to provider-reported practices. Question-to-question dropout on selected responses, a consequence of not forcing participants to answer every question also likely created relative issues of imbalance for selected individual items, although the nature of this study was purely exploratory and hypothesis generating, not hypothesis confirming. To more specifically address the issue of the low response rate, per discussion with the AAAAI administrative team that oversees membership surveys similar to this project, our response rate is in line with past member surveys. We acknowledge that small response rates may result in reporting bias and limit the generalizability of these data to the membership as a whole.

As stated, we caution that this study was exploratory, for needs assessment of a controversial and emerging therapy. There was no intent to specifically compare dosing style, target dose, or specific therapeutic goal, and was intended only to categorize the range and variations of currently reported OIT practices. Complex analysis of the propensity for the average AAAAI member to respond or not respond to a survey was not available to account for the effect of participation bias or nonresponse bias. Similarly, subpopulation weighting was unable to be performed given the use of a single strata and sampling unit, which also may have helped. We also consider that OIT may just be a topic of limited interest to all but a small segment of the membership and that a response rate of 10% o 15% may actually be inclusive of all interested members of this topic. Our intent is not to suggest that these findings are applicable to the membership as a whole but rather to position these findings as a measure of needs assessment and a current understanding of OIT by some segment of the AAAAI membership.

We would like to highlight the issue of FDA approval as an important finding of the survey. Any item intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease is a drug or a biologic and, therefore, is subject to the pertinent FDA regulations. FDA has previously ruled that allergenic material (eg, peanut flour) used to treat food allergy as with OIT meets the definition of a drug.[17] Hence, academic researchers study the use of OIT under Investigational New Drug guidelines, and at least 1 company is conducting OIT research with intent to develop 1 or more products to submit for approval through the New Drug Application process upon eventual completion of successful phase II and III trials (http://www.allergenresearch.com/). A large number of respondents expressed that FDA approval of OIT was an important step in considering providing this as a service.

Although we intended the survey question to inquire about FDA approval of an OIT drug as described above, we cannot be certain that the respondents did not interpret the question to mean FDA approval in a broader sense (ie, as a procedure), which is outside the FDA's jurisdiction. Readily available allergenic foods, such as peanut-containing candy or liquid milk, could be used as treatment material during OIT, and FDA does not regulate medical practice.[17] Regardless of the interpretation of the question, we believe that the results of this survey demonstrate a strong desire on the part of many of the responding practitioners for formal evaluation, regulation, and standardization of OIT by a governmental source. Similarly, many respondents expressed strong wishes for standardized protocols and practice guidelines to harmonize the implementation of OIT across sites. Thus, it is unclear at this time if or how OIT would gain approval by FDA or be regulated, but participants expressed a strong desire for the development of additional structures and safeguards by federal and professional agencies before changing their practice.

In conclusion, to our knowledge this study presents the first allergist-reported opinions about OIT and details data regarding the practice of OIT in the United States. As OIT emerges as a potential therapy, backed by multicentered research sponsored by the National Institutes of Health, it also is currently being used as a marketed therapy in private practice. Very limited information is known about the differences in practice styles, which makes this information unique and timely. Although the majority of allergists do not offer OIT, among those who do, oversight and type of reimbursement differed significantly between those studying OIT at academic centers versus those in practice who offer OIT in their offices. Among allergists who do not currently participate in using OIT, there is a strong desire for FDA approval, a standardized product, a CPT billing code, additional data that pertain to the safety of OIT, data that indicate that OIT can produce long-term tolerance, and some sort of practice parameter or evidence-based guideline for OIT. However, factors most associated with consideration to initiate OIT as opposed to waiting for OIT to be FDA approved included belief that FDA approval, enhanced safety data, and a CPT code for the procedure were not important. Although we have identified some preliminary traits associated with providers who currently administer OIT as well as traits that may predict which future providers are more likely to start doing so soon, continued study to identify additional traits is needed.

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