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Goldilocks zone: Allergists' perceptions of family anxiety and investment in food allergy oral immunotherapy

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ABSTRACT

Background: Oral immunotherapy (OIT) is an increasingly popular but still contentious treatment option for food allergies. Because most patients receiving OIT are children, families' involvement in treatment is an important part of the discussion of the appropriateness of this treatment option for individual patients.
Objective: To explore how US-based allergists judge whether OIT is a good fit for specific patients and their families.
Methods: Providers were recruited through direct solicitation by email to participate in an in-depth interview about their perceptions of the risks and benefits of current and future food allergy treatment options, including OIT.
Results: A total of 60 interviews were conducted with academic and community providers from 34 states. The primary finding was that as part of the shared decision-making process for OIT, providers actively assessed families' levels of anxiety and investment in this treatment option. They were seeking levels of both that were "just right" and found families with both too low and too high levels of anxiety and investment as a poor fit for OIT.
Conclusion: Providers used assessments of family anxiety and investment as mechanisms to optimize the benefits and minimize the risk of harm to their patients from OIT and to streamline staffing burdens in their practices.

Introduction

Oral immunotherapy (OIT) has become increasingly available to patients as more allergists see it as an effective food allergy treatment.[1,2] OIT involves systematic desensitization to a food allergen by exposing patients to larger doses of that allergen until a "maintenance" phase is reached.[3] A single OIT product is approved by the US Food and Drug Administration (FDA)—peanut (*Arachis hypogaea*) allergen powder-dnfp (PTAH)[4]—but allergists also use commercially available foods as "off-label" OIT.[5,6] Although some reports indicate that OIT has allowed patients to eat their allergens ad libitum, the more common goal of treatment is "bite-proof protection": reducing patients' risk of severe reaction (or any reaction at all) from an accidental exposure.[7,8] However, OIT remains controversial because of its inherent risk to patients of anaphylaxis.[9-12]

Even among its proponents, OIT is not perceived as appropriate for all patients. First, OIT has clinical contraindications, including uncontrolled asthma and eosinophilic esophagitis.[13] Second, OIT is an intensive treatment that requires a substantial number of office visits for updosing as well as adherence to various daily restrictions to minimize the chance of anaphylaxis.[14] As a result, shared decision-making is critical to ensure that families understand the risks, benefits, and treatment burdens of OIT and that treatment aligns with their goals.[15-18] However, despite the laudable goal of empowering families to choose or decline OIT, many providers remain concerned about the risks of OIT to their patients.[19-21]

We conducted a qualitative study of US-based providers to assess their perceptions of current and future food allergy treatments, of which OIT was a central focus. This article reports on our findings regarding how providers actively assess families' fit for OIT. In particular, we reveal how the shared decision-making process enables providers to evaluate whether families fall in the desirable "Goldilocks zone" of the right amount of anxiety about food allergy, on one hand, and neither too much nor too little investment in treatment, on the other.

Methods

We conducted 60 semistructured interviews between January and October 2023 with physicians specializing in food allergy. The study's objective was to investigate providers' views about the risks and benefits of current and future food allergy treatments from OIT and other forms of immunotherapy (ie, sublingual and epicutaneous) to biologics (eg, omalizumab). Our study received approval from the biomedical institutional review board at the University of North Carolina at Chapel Hill.

For recruitment across the United States, we created a list of potential participants based on providers' association with food allergy treatment or research clinics, web searches in specific regions, or referrals from other participants. In all cases, we identified

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individuals who had experience in treating food allergy based on information available on the web and/or had a research interest in food allergy. Typically, academic providers had both, but we also selected academic providers whose research was not focused on food allergy (eg, asthma and atopic dermatitis). We aimed to have geographic diversity, an equal number of providers from academic and community practices, and gender balance (ie, among those who identified as a "man" or "woman") in our sample, so we attended to all 3 elements during recruitment.[22] Contacting providers via email, we attached an institutional review board–approved information sheet with study details. No compensation for participation was offered. Those who agreed to participate gave verbal consent before the interview, which was conducted by phone or Zoom, audio-recorded, and transcribed. All identifying information was removed from transcripts to protect participants' confidentiality.

To analyze our results, we extracted quasi-quantitative details about providers' practices, including details about treatments they offered on- or off-label. We also developed a codebook to assist with thematic analysis based on a priori domains included in our interview guide and a posteriori themes that emerged from the interviews. Our coding approach followed the principles of flexible coding, which simultaneously prioritizes big-picture findings and detailed themes using a combination of memo writing and systematic coding.[23] All transcripts were coded using Dedoose software. Further analysis for this article was done by focusing on all data coded with "ideal/difficult patients for OIT" and by categorizing the ways in which providers talked about their process of determining whether patients and their families were appropriate candidates for OIT. Once we had identified the major themes of levels of anxiety and investment in OIT, we further categorized our findings into "too much," "too little," and "just right," which prompted our comparison to Goldilocks. The final step of our analysis was to identify quotes that would best illustrate our findings. We identify providers quoted below by participant identification number, which indicates whether they were academic providers (APs) or community providers (CPs).

Results

Participant Characteristics

Our final sample included 60 physicians, of whom 32 (53.3%) worked in a community practice and 28 (46.7%) worked in an academic setting. Our sample was drawn from 34 US states and included more men than women (57% and 42%, respectively). Most participants were non-Hispanic White (60%) or Asian (28%), and the plurality were in their 40s (42%). Detailed demographic characteristics of our sample are in Table 1. In total, we contacted 173 potential interviewees. There were 66 individuals who agreed to participate, but 6 did not reply to further follow-up and were not included in the study. Only 10 individuals explicitly declined participation, and the others never replied. Our response rate was 34.7%. We had a higher response rate among academic providers (49% vs 28%) and among men (40% vs 30%).

Table 1
Self-Reported Participant Characteristics

Demographics	N (%)
Practice Setting	
Academic	28 (46.7)
Community	32 (53.3)
Gender	
Men	34 (56.7)
Women	25 (41.7)
Not reported	1 (1.7)
Race/Ethnicity	
Asian	17 (28.3)
Black or African American	1 (1.7)
Hispanic	2 (3.3)
Non-Hispanic White	36 (60.0)
Not reported	4 (6.7)
Age	
30s	10 (16.7)
40s	25 (41.7)
50s	13 (21.7)
60s	7 (11.7)
70s and older	5 (8.3)

Oral Immunotherapy Practices

There were 51 providers (85%) who had incorporated OIT into their practice. The percentage of academic and community providers offering OIT was essentially the same (85.7% and 84.4%, respectively), and all providers who offered any OIT treated peanut allergy. Only 10 providers (16.7%) offered only FDA-approved PTAH to their patients; 22 (36.7%) offered PTAH and used commercially available foods in their OIT programs; and 19 (31.7%) exclusively used commercially available foods. It is also noteworthy that 8 providers (3 academic and 5 community) had never started a patient on PTAH despite claiming to offer it to patients. It was more common for academic providers to offer both PTAH and commercially available foods for OIT (46.4%), whereas more community providers offered OIT only with commercially available foods (37.5%) (Table 2). In addition, approximately half of all providers also offered OIT to treat milk, egg, and tree nut allergies (52%, 53%, and 48%, respectively) and 4 providers (6.7%) claimed to treat any food allergy with OIT. All providers who offered OIT for non-peanut allergies used commercially available foods as there are no FDA-approved OIT products for these foods.

Oral Immunotherapy Shared Decision-Making

Regardless of the type of OIT offered, providers emphasized the importance of shared decision-making for treatment. For example, one provider stated,

> It's very much a shared decision-making approach. I want to make sure everybody understands risks, benefits, daily regimen, and expected outcomes. We do not promote it as a cure. We promote it as potentially lifelong, if not years long, therapy. . . . And we really want to make sure that families are on board so they understand what's involved, promote an open line of communication with our office, and talk about it being a long-term partnership. (AP25)

Providers also noted that the decision to pursue OIT should not be made hastily and should involve the whole family, not just the caregiver attending the appointment:

> I'm very careful at the beginning of the process to go through a real shared-decision model where we never try to make the decision to do it in one day. . . . We always say, "You got to go home, and both parents have to agree." (CP03)

A common refrain among providers was that patients and their families really needed to understand the risks and burdens of OIT in all their "gory detail" (AP17).

Providers also viewed shared decision-making as a 2-way street in which patient and family goals must necessarily align with treatment, but providers could also assess whether the patient and family were a good fit for OIT: "It's about 50 minutes to an hour that we spend with them to go over everything and to get an idea of how well they've thought about the process" (AP17). In other words, the decision is not the family's alone, or in the words of one provider: "We highly select the patients that we put on oral immunotherapy" (CP03). Although the health status of the child is paramount (eg, degree of asthma control and other risk factors), providers were referring here to social and behavioral assessments of the families. Or, as one provider declared,

Table 2
OIT Offering by Practice Setting

Type of OIT, n (%)	Academic providers (n = 28)	Community providers (n = 32)	All providers (N = 60)
None offered	4 (14.3)	5 (15.6)	9 (15.0)
Offers PTAH only	4 (14.3)	6 (18.8)[a]	10 (16.7)
Offers PTAH and off-label OIT	13 (46.4)[b]	9 (28.1)[b]	22 (36.7)
Offers off-label OIT only	7 (25.0)	12 (37.5)	19 (31.7)

Abbreviations: OIT, oral immunotherapy; PTAH, peanut (*Arachis hypogaea*) allergen powder-dnfp.
[a]Two of these providers had offered PTAH to patients but had not yet prescribed it.
[b]Three of these providers had offered PTAH to patients but had not yet prescribed it.

> They think they're coming in to interview us, and they don't realize that they're being interviewed by every person that walks in the room. The nurses go back into the back room and like, "Those guys would be good." We have a ... back-channel rating system. ... Each person who interacts with them rates them. (CP18)

Thus, providers are not merely informing families about OIT risks and benefits, they are also actively making decisions about which patients are appropriate candidates for treatment.

Oral Immunotherapy Goldilocks Zone

Providers often spoke about "ideal" or "difficult" patients for OIT. Rather than focusing on the children to be treated, providers were more apt to evaluate the family as a whole, or even just the caregivers, when determining which children should start OIT. Providers' perspective on patients' good fit for OIT often hinged on families falling in a Goldilocks zone of just the right amount of (1) anxiety about their child's food allergy and the risks of treatment and (2) investment in the desensitization program, described not just as commitment but also as a clear understanding of how OIT works and adherence to the protocol. As the subsequent sections illustrate, this Goldilocks zone served both to make OIT as beneficial and safe as possible for the child and to reduce the clinical burden on providers and their staff.

Level of Family Anxiety

For patients to benefit from OIT, most providers indicated that families ought to have a heightened level of anxiety about the child's food allergy, but too much anxiety would undermine treatment. Although the goal of OIT is to protect patients from accidental allergen exposure, many providers considered OIT to be primarily beneficial as an "anti-anxiety" treatment to improve families' quality of life. Shared decision-making allowed providers to gauge how anxiety about food allergy affected families' quality of life and how it might affect the success of OIT.

OIT providers were adamant that treatment can be particularly effective for reducing family anxiety, especially mothers'. One provider opined that the most ideal OIT patients have mothers who "worry excessively about the child dying and having bad things [happen]" (CP11). When anxiety affects quality of life, especially through what providers characterized as caregivers' unnecessary restrictions on children's activities, OIT could reduce that anxiety enough to achieve a more "normal" life:

> [S]ome parents have deep anxiety about food allergy, and avoidance then leads them to do profound lifestyle alterations that can be very socially and emotionally detrimental for the whole family. ... [T]hose are the patients that probably would benefit the most from OIT. (CP30)

Providers argued that successful OIT results in children dining in restaurants or eating foods with precautionary labels:

> I've had kids that would have never eaten out ... at any restaurant because they were so scared. And then after OIT, they eat at these places. It gives them the confidence to do that. ... And some that were like, "I don't even want to go to college because I'm so scared," and [after OIT,] they're willing to go and live on campus. So, it can be very empowering. (CP22)

Thus, providers perceived OIT making a profound difference in the quality of life of anxious children and caregivers.

However, for families with "too little" anxiety, providers often determined that the benefits of OIT are not worth the burdens because treatment is unlikely to improve their quality of life. For example, one provider asserted, "Not everybody has anxiety. Not everybody is very affected. No, there are some people who are very much, 'I'm fine with it. ... I'm living my life. ... If I have a reaction, I'll treat it.' Well, you're fine [without treatment] then" (AP18).

Although anxiety is a crucial element to making OIT worthwhile, providers noted that families with too much anxiety are also poor candidates for treatment. One factor informing this view is that OIT is contraindicated when families are too afraid to administer epinephrine:

> We do exclude patients for reasons of safety, ... [such as when] a family has an anxiety level that's so high that we're worried that they wouldn't be efficiently treating reactions should they occur. That is, we don't want to increase the risk of reactions by feeding them the food that they're allergic to if we're not convinced that they're capable of rapidly responding to the reactions should they occur. (CP18)

Another critical element of why too much anxiety is problematic is that OIT can exacerbate the patients' fear of either the food itself or of anaphylaxis, which could do more harm than good. According to one provider, "What's happening is that they're stewing in anxiety, worried every day that their OIT dose is going to kill them. You're compounding the problem and making it worse for these people" (CP01).

Beyond preventing harm to the child, providers also indicated that overly anxious caregivers become burdensome on their practice:

> [T]he anxiety from the parents and the family matters a huge deal as well. The kids might be completely nonchalant and they don't care at all, but I'm going to get a call every other day from this mom because she has her own debilitating anxiety. If I read that in the room, I'm not going to start the kid on it. ... I'm trying to read the subtle verbal and nonverbal cues on anxiety just to see if this is a good fit or not. (CP01)

In the case of such "helicopter parents," providers or their staff must field too many questions just to reassure them their child is safe: "Sometimes we get a really nervous parent who's just constantly calling us or emailing us and being like, 'I dosed my child in the morning, and now she has a rash' ... and so that's tough also" (CP32).

When evaluating families for OIT, however, some providers acknowledged that it was not easy to judge who was in the Goldilocks zone of anxiety:

> It's interesting, you look at data on quality of life, and some of these recent papers over the last few years say that OIT actually improves quality of life, and I think that's true. . . . [However,] it can go both ways, and sometimes I don't really have a good handle on who it's going to help and who it's going to hurt in terms of anxiety. (CP01)

This is why additional factors can help providers determine who is the best fit for OIT.

Level of Family Investment

Providers also indicated that they used shared decision-making to assess whether families would be appropriately invested in OIT. Because of the burdens associated with OIT protocols and the risks of anaphylaxis, providers wanted assurance that families would be fully adherent to the rules and restrictions necessary for patient safety:

> Oral immunotherapy is a pretty labor-intensive thing. You have to have enough flexibility in your work schedule and your life schedule that you come every two weeks and then you sit here and you wait for an hour after you dose to make sure you don't react, and that's a lot of time. You also have to have enough structure in the life that they can take a dose at home and follow all the necessary precautions like no exercise, no hot showers, et cetera. (AP06)

More than any other family member, providers typically wanted the child's mother to be completely invested in OIT because, as one provider put it, "I feel it's the mom who's making this commitment. She has to do it every day" (CP26). Another provider questioned mothers' investment if they expected their child to manage treatment on their own: "This is an everyday thing that even though their child seems like they should be old enough to take their own medications, that there is still adult oversight. . . . That's what I mean by the right family" (AP21).

Even if a child's mother is completely invested in OIT, there remains a risk of too little investment from the whole family. Providers were clear that the patients, depending on their age, and all primary caregivers must be committed to treatment for its success. Regarding patients, a provider avowed, "I'm not going to choose to make the child do something that they don't have any desire to do just because the parent would like that" (CP17). Most providers typically focused on teenagers' investment in OIT because teens might hide doses or otherwise put themselves at risk. Regarding other caregivers, providers routinely noted that too little investment was common among divorced or separated parents:

> We've had a few patients where, well, mom and dad are divorced and they have totally different opinions about the process, and then the child is going to dad's house and dad is not consistent, and then bad things happen that way. (CP12)

Investment in the process is not just commitment but also a clear understanding of how OIT works and adherence to the protocol. The right family is, therefore, knowledgeable about how to administer the OIT doses daily and control the child's environment. For providers, too little commitment can also manifest as caregivers' lack of trust in the process. As one provider declared,

> They have to accept the whole program. If they question every decision we make, my nurses . . . don't have time for each of these phone calls to be 45 minutes. They can't have moms and dads questioning everything we do. They have to demonstrate that if we say, "Jump," they say, "How high?" . . . Pushback [means] they're not ready." (CP18)

As with anxiety, providers perceive that insufficient investment could jeopardize the child's safety and increase the burden on clinical staff.

Providers also problematized families who were too invested in OIT, particularly those in denial about potential harm to their child. As one provider described, "Once parents get committed to it, they're the ones who are really pushing for it, even when the child is having a lot of setbacks" (CP12). Overinvestment in OIT can be particularly dangerous when caregivers fail to disclose their child's adverse reactions and are, according to one provider, in "noncompliance with our rules of communication" (AP16). The need to stop treatment is a difficult conversation to have with parents that can result in "some tears . . . and anger and stuff, and they may go elsewhere . . . and get therapy" (AP17). Even more unsettling is the possibility that families could continue treatment on their own, which is a potential danger of OIT using commercially available food:

> We have to hope that they stop because we tell them that doing this without medical supervision is extremely, extremely unsafe . . . but that is a concern, that they're just going to continue to do it. Because they know your protocols, they've got the measuring spoons, they could continue to up-dose at home. (AP17)

In this way, the overinvested family has difficulty recognizing when OIT is not in their child's best interest and does not want to stop after all the time, effort, and hope they have invested in pursuing treatment.

Discussion

Providers make decisions about whether patients are good candidates for OIT based on certain medical guidelines (eg, proper diagnosis and comorbidities),[24] but as our findings demonstrate, they also use shared decision-making to assess nonmedical factors that affect patients' fit with treatment. In particular, both academic and community providers narrate a kind of Goldilocks zone of anxiety and investment in which patients and their family members must fall.

Patient and caregiver anxiety has been cited as driving demand for OIT.[25] Studies have also revealed that OIT may be especially beneficial in treating caregivers' anxiety and improving their quality of life rather than their children's.[10,26-28] Our findings indicate that providers deem there to be a "right" level of anxiety before OIT to improve patients' and families' quality of life—specifically by reducing anxiety to the point in which they can appropriately loosen dietary and activity restrictions. On one hand, if a family is not burdened by restrictions before therapy, then the benefits of OIT are less certain. On the other, if OIT exacerbates anxiety through the daily consumption of a food allergen, then this could further harm the patient and/or their caregivers.

The OIT literature has also focused on treatment burdens on patients and their families, often emphasizing the importance of adherence to the treatment regimen for OIT to be safe.[24,29,30] Indeed, the involved and lengthy nature of OIT requires a high level of coordination between providers, caregivers, and patients. Our study has revealed how providers' clinical decision-making is colored by their desire to protect their patients through choosing the optimum level of family investment to carry out this complicated dance. Beyond time and competence to follow OIT protocols, providers discussed the necessity of securing buy-in from pediatric patients and agreement among all primary caregivers. Separated or divorced families were described as particularly problematic because of the complexity of multiple caregivers being on board and the high potential for disagreement about treatment. Although too little investment was the more common concern among providers, they also noted that some families became too invested in treatment, downplaying or not reporting patients' adverse reactions or refusing to stop OIT when it caused more harm than good.

Most of providers' criteria for evaluating families' levels of anxiety and investment were centered on ensuring that OIT is beneficial and

safe for their patients. By being cautious when determining who are the right patients for OIT, providers may be managing their own anxiety about offering a treatment that increases patients' risk of anaphylaxis. On one hand, providers should be making decisions that are in their patients' best interests, but on the other, their process of assessing families' levels of anxiety and investment in OIT can be biased, raising questions about the ethics of this practice. More research is needed to determine whether and how such treatment decisions could exacerbate existing health disparities in food allergy treatment. Although providers may understand well the burdens and risks of OIT, their assessments of family anxiety and investment will often rely on assumptions not evidence.

We also found that these treatment criteria could ease some burdens of OIT on the providers and their staff. Our study found that providers sought families that would trust them and the process and communicate effectively (its own Goldilocks zone of neither too little nor too much) about their concerns. Although the literature has focused more on the burdens of OIT to patients and their families, as noted previously, there is clear evidence that OIT also introduces logistical problems for clinics.[31-34] Indeed, studies have revealed that personnel and reimbursement burdens have been important barriers to integrating OIT into clinical practice.[35,36] Thus, providers wanting to protect themselves or their staff from families' excessive phone calls, texts, or emails about OIT is a legitimate concern when their practices may already be stretched thin.

Despite the preponderance of data supporting these findings, there are limitations to our study. First, our interviews provide data on providers' perceptions, not practices. Thus, it is impossible to gauge how these criteria are mobilized in specific patient encounters, including the relative weight in treatment decisions that providers put on assessments of families' anxiety and investment. In addition, although many providers treated adults with food allergies, we prioritized the collection of data around pediatric patients and their families. Providers may use different criteria when offering OIT to adult patients. Finally, our sampling methodology focused on recruiting participants who had substantial experience managing and treating food allergies, which may have inadvertently increased the percentage of providers in both academic and community settings that offered OIT to their patients. Although it is reassuring that community and academic providers were quite similar in their practices and perspectives, qualitative research is ill equipped to generate a representative sample of all providers who see patients with food allergy. Despite these limitations, our sample consisted of providers located throughout the United States with a range of experience with OIT, indicating that our findings apply to diverse practice settings, including community and academic clinics and practices that use FDA-approved PTAH and off-label OIT.

In this article, we focused on the non-evidence–based criteria that allergists used to describe ideal candidates for food OIT. Discussions of shared decision-making in the literature have largely focused on the critical importance of properly informing patients and their families about OIT so they can determine whether treatment aligns with their goals and values.[15-17] Our findings underscore that the shared decision-making process may have an equally important function for providers: helping to assess whether a family is indeed a good fit for treatment based on the nonmedical factors of anxiety levels and investment in the process. Although part of their evaluation of families was to minimize the burden on their clinical practice, providers were primarily engaged in this process to optimize their patients' chance of benefiting from OIT and to minimize their risk.

Disclosures

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