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Community and academic allergists' perspectives on integrating biologics into food allergy care

A qualitative study

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ABSTRACT

Background: Biologics are an important area of research and development, including for treatment of food allergy (FA). However, how allergists perceive the risks and benefits of biologics to treat FA remains largely unknown.

Objective: To explore how US-based allergists perceive the use of biologics in FA treatment.

Methods: Using a combination of purposive and snowball sampling, providers were recruited through direct solicitation by email to participate in a telephone or Zoom interview about their perceptions of the risks and benefits of current and future FA treatment options. Interviews were transcribed, deidentified, and coded to conduct a thematic analysis.

Results: We conducted 60 interviews with providers from 34 states working either in community practice (53.3%) or academic medical centers (46.7%). Our sample was primarily non-Hispanic White (60.0%) and men (56.7%). The plurality was in their 40s (41.7%). Our findings clustered in the following 4 main themes: (1) perceived benefits of biologics, (2) ideal use of biologics, (3) concerns about biologics, and (4) biologics as the perceived future of FA. Community and academic providers had largely similar views, but academic providers more often emphasized the benefits of biologics, and community providers were, on the whole, more supportive of using biologics as an adjunct to oral immunotherapy rather than as monotherapy.

Conclusion: This study indicates that providers hold mixed views about the use of biologics to treat FA. However, most were enthusiastic about prescribing biologics for FA while also being highly concerned about the cost to patients and the health care system.

Introduction

Biologics have become an important area of research and development, including for the treatment of food allergy (FA).[1,2] In February 2024, omalizumab became the first biologic to receive approval by the US Food and Drug Administration (FDA) for the treatment of FA.[3] Given its broad approval for use in patients 1 year and older, the field of FA may be at a turning point in how the care of patients with FA, especially those with multiple FAs, is managed. Although the approval of omalizumab for FA has been anticipated, the debate about which patients should be offered this treatment and how it should be offered continues.[4,5]

FA affects an estimated 10% of the US population.[6] Moreover, one study found that 40% of children with FA have allergy to multiple foods.[7] Beyond FA prevalence, the burden of disease is high with substantial negative effects on patients' and their families' quality of life.[8-10] The current medical approach to managing FA is largely to counsel avoidance and to prescribe an epinephrine autoinjector.[11] Before the approval of omalizumab, the only FDA-approved FA treatment was a peanut oral immunotherapy (OIT) product (peanut [*Arachis hypogaea*] allergen powder-dnfp).[12] However, OIT has become increasingly common using commercially available foods, with many allergists offering patients these "off-label" products.[13,14]

Unlike OIT which attempts to desensitize patients to their allergens through exposure therapy, the use of biologics for FA rests on a different treatment paradigm.[1] In the case of omalizumab, the drug is an anti-IgE antibody that works to interrupt the immune response that occurs when patients consume their food allergens.[15] The phase III clinical trial supporting omalizumab's FDA approval indicated that treatment with the drug raised participants' reaction threshold for multiple foods, allowing them to safely consume greater amounts of their allergen during oral food challenge (ie, ≥600 mg of peanut protein or ≥1000 mg of 2 other food allergens) compared with placebo.[16]

Despite the strong data supporting omalizumab's safety and efficacy, the question of when and how omalizumab should be used remains.[4] One publication written after FDA approval identified 4 patient groups that might be most appropriate for omalizumab therapy: (1) those at the highest risk of a severe or fatal reaction; (2)

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those who are traveling or face other high-risk situations; (3) those who are highly anxious about a potential reaction and consequently have poor quality of life; and (4) those wishing to begin OIT and are at greater risk of adverse reactions from OIT.[5]

Given omalizumab's broad approval for any patient more than 1 year of age with as few as 1 FA, there is a need to understand how providers perceive the role of biologics in treating FA. In this article, we draw on a qualitative study conducted before the approval of omalizumab for FA to report on allergists' views about the benefits and risks of prescribing biologics for their patients with FA.

Methods

US-based physicians were recruited to participate in a semistructured interview about their perceptions of the risks and benefits of current and future FA treatment options. The study was conducted between January and October 2023. We identified providers through a combination of purposive sampling (eg, self-identified FA experts, providers with a record of involvement in OIT and/or clinical trials, and practice websites that identified FA as a primary area of interest and/or experience) and snowball sampling (ie, recommendations from providers already interviewed). We aimed for diversity in our sample by recruiting providers from all genders (ie, identify as a "man," "woman," or some other category), racial and ethnic groups, and ages. Recruitment was closed after saturation was reached, when no new themes emerged from the interviews. The study was approved by the Biomedical Institutional Review Board at the University of North Carolina at Chapel Hill.

Providers were emailed a study information sheet and gave verbal consent to participate. Interviews were conducted through telephone or Zoom, per the participants' preference. The interview guide was developed deductively based on the study's aims (ie, to understand providers' views of the benefits and risks of current and future FA treatments) (eAppendix 1). The guide was reviewed and iterated after each of the first 5 interviews to ensure that questions captured intended areas of concern and no major themes were missing. As is typical of semistructured interviewing,[17] interviewers followed the pre-established guide, but questions were adapted (eg, added, skipped, and reformulated) during the interview to reflect participants' experiences. At the end of the interview, participants verbally self-reported the following basic demographic information: gender, ethnicity, race, and age bracket (eAppendix 1).

Interviews were conducted by 2 experienced PhD-level qualitative researchers (JAF and ME). All interviews were recorded and transcribed, and to preserve participants' confidentiality, identifying information was removed from the transcripts. Following the methods of "abductive"[18] and "flexible"[19] coding to support thematic analysis, we developed a codebook to capture relevant study themes based on our primary areas of interest (eg, providers' perceptions of treatment risks and benefits) and on unexpected themes that emerged (eg, overdiagnosis of FA and types of ethical dilemmas). The 2 original interviewers coded all transcripts in Dedoose and wrote "memos" to summarize themes of interest.[20] For our focus on biologics in particular, we closely read all the coded excerpts related to biologics to do a ground-up analysis of the subthemes regarding how providers were thinking about the use of these drugs to treat FA. The interviewers met weekly to discuss coding and adjudicate disagreements that had emerged. During coding, data from the transcripts were extracted, when possible, about providers' current practices, such as whether they had ever conducted FA clinical trials, offered OIT, or prescribed biologics to their patients for other approved conditions with an intent of treating FA. Demographic data and providers' involvement in FA clinical trials were calculated as percentages to describe the sample. Finally, we identified quotes to illustrate the themes and subthemes. Participant identifications used below indicate whether the provider was an academic provider (AP) or a community provider (CP). The generic names of drugs are used unless we are quoting verbatim participants who used products' brand names.

Results

We enrolled 60 US-based physicians from 34 states working either in community or academic settings. We emailed 173 providers; 10 explicitly declined participation, and 6 others replied to express initial interest but did not reply to further follow-up. A total of 60 individuals participated, making our response rate 34.7%. Our final sample included 32 CPs (53.3%) and 28 APs (46.7%). Approximately half of the participants (n = 31, 53.4%) had personal experience with FA clinical trials, most (n = 24, 77.4%) being the APs (Table 1). Despite focusing on diversity in recruitment, our sample was primarily non-Hispanic White men in their 40s (Table 2). Most providers (85%) regardless of practice setting offered OIT to their patients. Furthermore, approximately half (n = 31; 51.7%) prescribed peanut (*A hypogaea*) allergen powder-dnfp and two-thirds (n = 40) offered patients OIT using commercially available foods. We had a higher response rate among APs (49% vs 28%) and among men (40% vs 30%). We cannot assess how our sample compared with the broader recruitment pool based on self-reported race, OIT offering, or clinical trial involvement because we did not have a static recruitment pool due to purposive sampling.

Although all the providers regularly prescribed biologics, 8 (13.3%) reported that they had specifically prescribed a biologic (typically omalizumab or dupilumab) off-label to treat FA. Of these providers, 7 worked in a community practice and only 1 worked in an academic setting. Other providers had prescribed biologics to their patients with FA for approved conditions (eg, asthma, urticaria, and atopic dermatitis) without the primary goal of addressing FA.

The study's qualitative findings clustered into the following 4 primary themes: (1) benefits of biologics, (2) ideal use of biologics, (3) concerns about biologics, and (4) biologics as the future of FA. Within these larger themes, nuanced subthemes emerged from our data analysis. The subsequent sections use illustrative quotes to reveal how providers' views of biologics were multifaceted.

Theme 1: Benefits of Biologics

Our analysis revealed that providers viewed several types of benefits of prescribing biologics, including addressing a treatment need, treating comorbid allergic conditions and multiple FAs, and managing patients' and families' anxieties (Table 3).

Additional Treatment Option

Providers who were enthusiastic about biologics often described them as another tool in the FA treatment toolkit. For them, biologics were important drugs because they have the potential to expand treatment to more patients with FA. For example, some providers perceived biologics as excellent therapies for adolescents and young adults because they were both a high-risk group when it comes to FA

Table 1
FA Clinical Trial Experience by Practice Setting

Provider Type	n (%)
Academic physicians	
No FA trials	4 (14.3)
FA trials	24 (85.7)
Community physicians	
No FA trials	23 (71.9)
FA trials	7 (21.9)
Unknown	2 (6.3)

Abbreviation: FA, food allergy.

Table 2
Self-Reported Participant Characteristics

Demographics	n (%)
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	5 (8.3)

more generally and usually poor candidates for OIT when it comes to existing treatment options.

> *Additionally, I think the best use of [biologics] would be in that high-risk age group, that 18 to 24-year-old age group, that "I'm invincible" age group, the kids [who] are in college. (...) That feels like we could do something to help protect you if you don't want to do OIT. (CP32)*

Comorbidities

FA often coexists with other conditions such as eczema or asthma. In justifying why biologics would be useful to treat FA, some providers emphasized how they could control multiple conditions with 1 treatment.

> *[W]e know so many people with food allergies who have other allergic issues, so that would be amazing if somebody has asthma, eczema, and food allergies and they get dupilumab, one medication to treat both. Or somebody with chronic hives and asthma and food allergy, okay, fine, they get omalizumab. (AP21)*

Multiple Food Allergies

Biologics were also perceived to be especially beneficial to patients with multiple FAs. Because OIT typically desensitizes patients to 1 allergen at a time, many providers thought that this treatment option was overly burdensome or impossible for patients with multiple FAs. In contrast, they expressed enthusiasm for how biologics could simultaneously increase the threshold for multiple allergens, providing a more practical therapy for those patients.

> *[T]he biggest challenge with food allergy is that there's so many foods. (...) [Y]ou know, you solve one and then you have the next one. What about egg? And what about cashew? What about shrimp? But what about sesame? You need the same effort [for each]. (...) Maybe we'll be using Xolair. (AP13)*

Anxiety

When considering the benefits of biologics, providers also focused on how drug treatment could play a role in alleviating the anxiety of patients with FA. Specifically, biologics were thought to improve the quality of life of families with FA by decreasing anxiety about potential accidental exposures.

> *To me, that's the benefit of treatment, alleviating that concern that we all have when we send our kids out the door, but the food allergy parents have an added worry. (AP11)*

Theme 2: Ideal Use of Biologics

Providers had nuanced views of 2 primary approaches to using biologics for FA: as an adjunct to OIT or as a monotherapy (Table 4). Some providers were more dogmatic about following only 1 approach, whereas others expressed more flexibility, with an emphasis on meeting the needs of each patient.

Adjunct to Oral Immunotherapy

The providers advocating for biologics as an adjunct to OIT believed that OIT was the best FA treatment option. They nonetheless saw advantages to biologics when biologics could expand OIT treatment to patients who cannot start or remain on OIT for various reasons. For example, biologics could be used as an adjunct to OIT for foods that were perceived as higher risk.

> *I think [biologics] have a role in potentially difficult OIT that's difficult to tolerate (...) like milk and egg, doing OIT for those two, it's a little difficult. (CP05)*

Table 3
Perceived Benefits of Biologics—Subthemes and Additional Quotes

Theme	Subtheme	Quotes
a. Additional treatment option	General	*I think having biologics available also broadens [the number of people we can treat with food allergies]. And I'm excited to have that opportunity for biological therapies for food allergy patients. (CP11)* *I think it's most exciting for especially the adolescents who are going off to college, where they've been helicoptered [by their parents] their entire life. (AP10)*
b. Comorbidities	General	*Yeah, and I think a lot of these, that food allergy rarely shows up alone, so particularly for kids who have multiple allergic comorbidities, if we find that any of these agents truly can help food allergy, that'll help with the selection of treatments that may be prescribed for other primary indications. (AP23)* *I can't wait to be able to use [biologics]. I love them, especially because a lot of the kiddos that are food allergic have other atopic conditions, like seasonal allergies, asthma, eczema. (...) So I am a big fan of biologics, not just because it assists me in building up [OIT], it also reduces adverse events and it helps with these other comorbid conditions that they already have. (AP04)*
c. Multiple FA	General	*Because there are just people who don't want to do things on a daily basis, and people with multiple allergies. How many things can you eat on a daily basis for oral immunotherapy? 10 foods, that's starting to get some meal replacement probably, depending on how much one eats. And then patches, how many patches can you stick on a person? Maybe a lot, I don't know. But at some point for the people who truly have multiple food allergies, it's going to get hard with these allergen-specific therapies. Having a non-food specific treatment I think would be amazing. (AP21)*
d. Anxiety	Accidental exposure	*Yeah, typically it's like, "Listen, this isn't a cure for their food allergy. (...) I just want you to know that while they're receiving this therapy, their threshold has probably changed, and they would likely need to eat more of their allergen to cause a reaction, especially a severe reaction." So I offer that more from peace of mind for low risk exposures. (...) So it's more like so many families place unnecessary restrictions on themselves. They never let their child go to an ice cream parlor because they're worried about cross contact, or [they're worried to] eat [foods with] precautionary labeling or eat at a restaurant that uses peanut oil or stuff like that. So if they're already at low risk before the biologic, and then once they're on the biologic, I just say, "Great news. This is everything that you've always wanted." (AP25)*

Table 4
Perceived Ideal Use of Biologics—Subthemes and Additional Quotes

Theme	Subtheme	Quotes
a. Adjunct therapy	Enabling high-risk patients to start OIT	*[T]he biggest thing (...) that has been somewhat beneficial for as I've started on younger and younger kids is the really young kids that have severe eczema and also food allergies that want to consider OIT. Starting some of the patients on Dupixent has improved their skin drastically to the point where we're able to do OIT. (CP07)* *Getting back to the whole safety perspective, if a patient comes in and they're a poorly controlled asthmatic that wants to do OIT, I'm like, "Well, this is a full stop from starting OIT because you're a poorly controlled asthmatic." (...) And if it's less so an allergy driven and more asthma driven saying, "Here are options, you are likely someone that would benefit from a biologic. And even more so if you're going to be starting oral immunotherapy, it will probably give you some amount of protectiveness and increased efficacy there as well," when going through treatment options for the asthma or, I guess, eczema. (CP07)*
	Faster and safer desensitization	*I think [using biologics] is the right way to build up faster, to have fewer side effects, just have better outcome. (CP12)* *Now, every now and then there will be the patient who has severe, severe allergy. And even before I start OIT, I'll get them approved for Xolair because I know they're going to need it. Patients who anaphylax to like, I don't know, their food touched a baked egg, you know, like that sort of thing. And a lot of those patients, I'm like, "Well, your levels are crazy high, you anaphylax to such teeny, teeny, tiny doses. I think that this would greatly improve your safety." (CP22)*
	Failed OIT	*Usually I reserve a biologic for somebody who's kind of failed regular OIT, because I don't want to add an additional medication into their system when I don't have to. It's costly. There's time and effort that it takes to get it approved. (...) But for those patients, it's been incredibly helpful. I've had some patients where we were stuck on 2 ml's of cashew milk for months, and then you start OIT with Xolair, and they finish (...) the entire OIT within six months. So it is incredibly helpful. It increases safety, much fewer allergic reactions. Patients have fewer symptoms as a whole. I feel like patients feel reassured on it as well. (CP22)*
b. Monotherapy	Easier, safer, and more practical than OIT	*I do think that if omalizumab is approved [for food allergy], I really won't have to do [OIT] nearly as much, oral immunotherapy, because we'll have, I think, probably a safer option. (CP10)* *Safety standpoint, your risk of anaphylaxis [from omalizumab], at least based on all their pooled data, is 0.1 to 0.2%. (...) The nice thing about that, the practicality is that you've got to get your first three doses, supposedly, at the doctor's office and then you can give the dose at home. But you don't have to eat anything. It's not a daily therapy, so the practicality of it, once you get past the shot part of it, is very easy. And it treats multiple foods at once, that's the advantage of it. And it's going to work in four to six months, faster than any other therapy out there. So it's going to be faster, it's going to be just as safe. (AP17)* *Because every day, or three to four times a week, my poor patients have to take something that they think is going to kill them [with OIT]. It gives them little itching in their mouth. The families, the parents have to run around, "Take this, take this, take this." 85% of them hate the taste, and it's like torture every single day. If I can give them a shot once a month, I'm like, "Yes, yes, yes, I'm going to give you a shot once a month." (AP03)*
	Decreased risk of accidental exposure	*But I think the families where it's most helpful and the ones that (...) know really minimal amounts have caused serious go-to-the-ED, epi-needing reactions. But yeah, I think [it would be good] for other people who could be lesser sensitized but maybe just more prone for whatever reason to accidental exposure reaction. (CP09)* *I have one woman who she's, I think, 17, and she has a wheat allergy. She's totally gluten-free, but we realized that sometimes gluten-free doesn't mean wheat free, and that they can actually put other things back in and just take the gluten out. Which is just so, so disgusting. So for her, I actually did put her on Xolair [off label]. (...) But she's done tremendously well. And I think that for her family when she went to Europe and went on some kind of school trip, and [she] was able to just go and be and do. (...) For her, it's been life changing. (CP15)*
	Multiple food allergies	*I think that kids that are allergic to things that are just so common contaminants like wheat and soy, those kids I think have an incredibly hard time. I think for the people that are truly multi-food allergic where their calorie content is limited, or they're literally in situations where they cannot eat anything otherwise, I think that it would be really great. (...) I think those are probably the two biggest categories, would be either foods that are just common contaminants or additives, or multi food-allergic kids. (CP15)* *So we had some kids in fellowship that have so many food allergies and were having so many episodes of anaphylaxis that you're like, "This kid's risk is astronomical. If I could do anything to reduce the risk in these kids, I would." So we had a couple people that were on [omalizumab], and it made the reactions sometimes not as severe. It doesn't bind all the IgE, so it's not a hundred percent, but it makes sense from an immunology perspective and for these multiple risk kids, I just think it's a great option to be able to use. (CP19)*

Abbreviation: OIT, oral immunotherapy.

Or, these providers thought biologics could decrease the risk of OIT for patients with comorbidities such as eczema or asthma.

> *I was just talking about those high-risk kids that I would sort of say 'no' to before. But we will say 'yes' to those kids in the context of putting them on Xolair during the dose-escalation phase. (CP09)*

Some OIT providers saw biologics as facilitating faster and safer desensitization by decreasing anaphylaxis risk and adverse effects during up-dosing. One provider even noted that this approach could potentially cure patients:

> *[I]n clinical practice, we use it as an adjunct to OIT. (...) [I]f they're getting the biologic, it'll offer protection. We can probably push the [OIT] dose much higher and build up faster and potentially cure people if we can actually get them to a higher maintenance dose than what they would tolerate without it. (AP25)*

Similarly, these providers thought biologics could benefit patients who "failed regular OIT" because of treatment adverse effects by allowing them to continue OIT when otherwise they would have to stop (Table 4).

Monotherapy

In contrast, in almost all cases in which monotherapy was discussed, providers viewed biologics as a better treatment approach than OIT. One such perspective focused on how biologics monotherapy is easier, safer, and potentially more effective than OIT.

> *It's going to get you at least the same benefit [as OIT], hopefully, conceptually, increasing your threshold dose. But the ask, the lift, the commitment is much less, and the safety profile is probably better. (AP08)*

Biologics monotherapy was mentioned as a particularly good option for decreasing FA risks for patients who have frequent accidental exposures, especially if they do not want to do OIT, or for patients exposed to their allergens in circumstances they cannot control.

Table 5
Perceived Concerns About Biologics—Subthemes and Additional Quotes

Theme	Subtheme	Quotes
a. Insufficient evidence	General	*I think the jury's out as to whether they're going to be really helpful. I'm guessing they may not. (AP15)* *I don't think we have a lot of data yet to say that this is worth adding to the picture of treating a kid with food allergy. It's too early to say. I wouldn't advise. (CP23)*
	Lack of evidence to support efficacy	*I think the data speaks for itself. Xolair has been used for at least a decade and a half. It had some very negative outcomes in '06 and '08. (...) I was impressed that it allowed for some level of exposure, but it was not consistent. And the rebound effect was pronounced when the patients came off of Xolair. It seemed that their threshold to react was lowered, but we didn't know what that meant. (...) And the answer is simple: If whatever is happening in immunotherapy, if it does not achieve ultimately a level of safety, convenience, and long-term success, people don't want to do it. It's just that simple. And Xolair has not shown that. Dupixent has certainly not shown that. (CP04)*
	Mixed clinical experience	*For some, I see skin testing go down in the challenge, but I always tell them, if you were to come off of dupilumab, I don't know. [In] those patients, when they're on dupilumab and I see skin tests go down, is it the dupilumab? Is it natural outgrowth of a food allergy? We challenge as long as they tolerate it. I say keep it in the diet and then hopefully, even if they stop the dupilumab, if they're consistently eating it, they'll have sustained tolerance. But it's all anecdotal at this point. Some patients who are on dupilumab, their food allergy profiles don't budge. So I don't know. It's not predictable to me. (AP24)* *But I have to wonder, a few weeks ago, this kid [who had one of my scariest cases of anaphylaxis] was on dupilumab and they needed two doses of epinephrine, and I debated sending them to the short stay unit for their baked milk challenge. And this is one that they had anaphylaxis to when they were one year old, and now they're six years old, and they're on dupilumab. So it is now, for that family, it's even more of a, wow, they're on a biologic and they still, with half a bite of a muffin, it'll still happen. (AP10)*
	Lack of evidence to support use	*I've seen that Dupixent lowers the IgEs like no other biologic. I mean, the IgEs go from 1,000 to 50s like 30s really quickly. (...) Is there a right time to introduce OIT or even food in there? That remains a very-. I don't know what the answer to that question is. And even if you introduce, let's say, dairy or egg or something like that and then do OIT, what does that look like? Meaning, will that induce protection? Will they have to stay on it for the rest of their life, like OIT? (...) Do you follow an immunological marker? Do you follow a clinical marker? And what is your clinical marker? What isn't your clinical marker? These are very complex questions, and I don't know how one would design a study around it. (CP14)* *The other question with the biologics is do they need to be on it forever, or can we put them on it for a short period of time and desensitize someone to the food they're allergic to, and then take them off of the biologic and they can maintain desensitization? (AP26)* *Again, how would you know it's actually working [as a monotherapy] unless you actually do a [food] challenge too? (...) But how are we calibrating or calculating that as a monotherapy for food allergy? (...) And with asthma or eczema we do have data to monitor to say what's going on, is the biologic really helping? I would say as a monotherapy, it would make sense if there was a follow-up to say what is it actually doing? (CP24)*
	Long-term safety unknown	*I mean there are some questionable long-term, potentially, side effects to Xolair and who knows about Dupixent, it's not been out long enough. (CP16)* *Even though these medications, biologics, they have a great safety profile, we still don't know what's going to happen 5 years, 10 years, 15, 20 years down the road when they get the treatment for the benefit of using with OIT. So there are a lot of unknowns still. (AP14)* *[O]ur immune systems developed these pathways for a reason. (...) Is there a risk down the stream? It's possible. So which, again, gets back to, as you can probably see, where I tend to be not a strong proponent of recommending any of these things. (AP01)*
b. Patient/parent resistance	Mode of administration	*The practicality is [that] you just got to get over that you're giving your child a shot, so that's the biggest downside. (...) It's not going to be for everyone, because not everyone's going to want to give their kid a shot. (AP17)*
	Drug risks	*There's a lot of fear about biologics. I think everybody thinks it's like Humira, and there's just so many stories out there in general about biologics that I think there's just a lot of fear about putting their child on a biologic. And I do think the tumor risk also, that does bring up some fear in patients as well. (...) A lot of parents, it's interesting, food OIT, they feel like is natural because you're giving them the food. It's not something foreign. But this is a medication that you're adding on. And I have a lot of resistance. The parents, they don't want to put their kids on medications a lot. And so the idea of putting them on a biologic is something that is really against what they want to do. (CP22)*
	Long-term use	*I think it would be very rare that there would be a situation where someone would take the biologic once a month for the food allergy. (...) [U]sually the [allergen] exposure is very sporadic and even if they have an accidental exposure once a year, I don't think that would be very motivating to take a biologic every month indefinitely. (CP02)* *If you look at Dupixent, how well it's done. The difference in (...) Dupixent and Xolair is that families feel and see a difference immediately, almost, in Dupixent. The skin is better, they get sleeping better, they aren't using steroids as much, so they feel it. With Xolair, you're not going to feel it if you're food allergic, unless you're eating the food. So it's almost like to make patients want it, they're going have to start eating the food on it, I think. (AP11)*
c. Potential for overuse/ overtreatment	General	*What I worry about is that this will become a blanket for everybody. (...) So I worry that these biologics are going to be probably overused, instead of just good cautionary guidance and whatnot for patients. (CP15)* *I get it if it's something like milk and wheat and anaphylaxis and a quality-of-life issue. But for something like shrimp, I know that there may be different familial cultural contexts with this and everyone would need to approach it differently, but I'm less inclined to jump on board and push OIT or biologics or anything else for something that is a little more of an obscure type allergen, like seafood or walnuts or something along those lines. But if it's something very hard to avoid, like milk or wheat or, increasingly, sesame seed or legumes. (AP10)*
	Unnecessary adjunct	*Biologics are an expensive treatment in search of a disease to treat. So once you come up with one, you got to go find some diseases that you can use to sell it for. That's how the drug companies do it anyway. As an adjunct to oral desensitization, it's so safe anyway, why do you need it? Unless you want to get desensitized in 1 week instead of 11 weeks or something. But if that's the purpose, then I suppose it's worthwhile. (...) But in terms of making it so that it's more likely to be successful, we already have a greater than 90% success rate. I don't know that it's really necessary as an adjunct. I'm not worried about anaphylaxis during OIT. (AP07)* *[I]n regards to the peanut, 90% of people can do peanut OIT with no issues. So in my head, why put a $30,000 a year medicine on something that 90% of people don't need? So that's why I don't see that utility [in prescribing a biologic]. (CP05)* *I guess a side risk is to realize that if money is behind this, and (...) my concern is that it'll give a false impression that doing OIT without a biologic is worrisome or dangerous, which it's not, especially depending on the food. (...) And then once those thought leaders, who are often on the pharmaceutical part of payroll, start saying, "This is the way you do it," then other people will start doing that. (...) I'm like, "So now people are like, 'Oh, the leaders say that's the standard,' where you're going to tell people to spend $30,000 for a reaction that never occurs," and people will follow that, where the logic and the money doesn't make sense. (...) So my concern is that depending on who starts promoting using biologics, there might be a skewed view. That's what it is. And overutilization, I would say overutilization. (CP05)*

(*continued*)

Table 5 (*Continued*)

Theme	Subtheme	Quotes
d. Cost	General	*I just feel that that is a huge cost and burden on the health care system potentially, as well as just a unclear benefit across the board. (. . .) But I do just struggle with the sense of putting someone on a expensive lifelong medicine, that without knowing confidently that it's going to make a huge difference in terms of outcomes. (AP01)*
	Disparities	*I think with any conversation in medicine, it's just the logistics of our really broken health care system because I think cost is something, whether it's epinephrine, whether it's specialty visits. I mean, just every day if I could make the medical decision that I felt was best for my patient without having to navigate all of that, and all of that ends up being a real barrier for a lot of treatments. And I think that's going to hold true, certainly, for the biologics. And we're seeing such a burden of food allergy in disadvantaged populations, and they're the ones who won't be able to access the treatments. So there's that huge disparity that it's like writing on the wall that's going to happen, and so I do worry about that. (AP23)*
	Relative to OIT	*Now again, you have obviously less anaphylaxis [with biologics], but you also have a treatment modality that will cost between 30- and $60,000 a year in perpetuity. My [OIT] treatment costs nothing in perpetuity. After a year you have no cost, forever. So that's a big difference. Something you have to consider. Again, and as a concern about the world health care costs, you have to consider some of those things. (CP11)*
	Relative to avoidance	*I mean, I assume that they're still having to avoid whatever it is. It's not just like, "Hey, take this biologic, and you can eat what you want." And so to me that's pretty expensive as opposed to just carrying an EpiPen. (CP17)* *It's going to come down to cost-benefit. Because essentially your treatment for food allergies is avoidance and carrying an EpiPen, which are pretty darn good treatments. But to do Xolair, unless the cost of Xolair comes way down, I don't think it's going to pan out, just if you look at a societal cost-benefit when you look at all that. In a perfect world, utopian world, heck yeah, let's go for it, but we don't need to talk about [utopian worlds]. (CP29)*
	Ethical issue	*For me, it's just the cost is an issue, the social cost of some biologics. I think that's an ethical issue. (AP22)*

Abbreviation: OIT, oral immunotherapy.

> *I think someone who works, let's say, in the food industry, where they're exposed to the food and they just really can't avoid it, (...) maybe someone like that could justify taking the biologic all the time. (CP02)*

Biologics monotherapy was also noted as potentially the most appropriate treatment route for patients with multi-FAs.

> *These poor kids with peanut, tree nut, dairy, egg, wheat, soy, and sesame. It's just really hard to manage those kids. (...) And some of these kids, they're just incredibly sensitized where they are having really serious reactions to really small amounts, cross contamination, et cetera. So, we will put patients off-label on Xolair just as monotherapy or what I call risk reduction therapy, and it works great. (CP09)*

Theme 3: Concerns About Biologics

Providers identified several concerns associated with using biologics for FA, including insufficient evidence to guide clinical practice, patient/parent resistance, potential for overuse and overtreatment, and cost. This section illustrates how each of these concerns contained multiple subthemes, reflecting providers' diverse perspectives on the potential drawbacks to using biologics to treat FA (Table 5).

Insufficient Evidence

A primary concern among providers about biologics was their belief that evidence remained insufficient for FA treatment. Given our study's timing before omalizumab's approval for FA, some providers doubted available data about biologics' efficacy in treating FA.

> *I'm underwhelmed with that data so far. I've been at the poster sessions. I think the biologic data is mediocre at best. I don't think it gives anywhere the efficacy that OIT does. (CP11)*

In addition, clinical experiences prescribing biologics sometimes provided mixed anecdotal evidence of their efficacy.

> *I've had one of my scariest anaphylaxis ever while they were on their dupilumab for a baked milk challenge. And I've also had kids who passed other food challenges, and I'm like, "Okay. Well, you passed. Not sure if it's a dupi side effect or you passed on your own." (AP10)*

Even when providers did not question biologics' efficacy in treating FA, some pointed to the lack of evidence for *how* to use biologics. For example, providers noted a lack of guidelines to determine whether a biologic as a monotherapy is working (Table 5) or when to stop treatment, particularly when used as an adjunct to OIT.

> *I worry about it because it does help you get through OIT, but then it's like, well, do you have to stay on it? Sort of like Ozempic. Once you go on and you lose your weight, what happens when you stop it? You gain your weight back, so then you're sort of stuck on it. (CP32)*

A final subtheme for lack of evidence was providers' concerns about biologics' safety. Although they trusted the overall safety profiles of drugs such as omalizumab or dupilumab, some worried about how long-term use of biologics could affect children's immune systems.

> *Are you putting a child on this for how many years to come? Also, what is that doing to their immune system for many years to come? We don't necessarily know the answer to that, so it gives me pause. (CP30)*

Patient/Parent Resistance

Even among providers who were enthusiastic about the use of biologics for FA, some anticipated pediatric patients' and parents' resistance to the treatment. One concern was the mode of administration, noting that regular injections would be difficult for parents and children (Table 5). Providers also anticipated parent resistance because of biologics' perceived risks.

> *I think there's always a little parental resistance with biologics. This seems like a scary foreign substance. Xolair still has a box warning on it, so I think there is a little bit of overcoming that. (CP09)*

A final source of resistance noted by providers could stem from biologics being a long-term, and potentially indefinite, therapy.

> *[T]here could be families that are just desperate for it, but then when you say, "This is going to be a shot that's every two weeks, or every three weeks, indefinitely, and when you're off the shot it's not going to change the underlying issue," I think it's going to be interesting to see what happens. (CP32)*

Potential for Overuse/Overtreatment

Another substantial concern discussed by providers was the potential for biologics' overuse, particularly in terms of a more general overtreatment of FA.

> *I could see some people having that be a major part of their practice. Like everybody with food allergy is going to get started on Xolair, and I just feel that that would be sad. (AP01)*

A specific concern that OIT providers voiced about overtreatment was that a biologic was largely unnecessary to safely and effectively increase patients' tolerance through OIT.

> *I think that's overtreatment to do a biologic, unless the biologic itself can take care of the peanut allergy. (. . .) I don't think the biologics right now that I'm aware of are really that necessary or useful. (CP23)*

Cost

Cost was also a major focus of providers' concern about biologics' use to treat FA. One source of their apprehension was the cost burden to the health care system overall.

> *I think there's some value there, but the cost is just so high. I just don't know how we, as a society, support $60,000 a year for Xolair to prevent severe allergic reactions. (AP22)*

Providers also expressed concern about the cost of biologics exacerbating existing health disparities, such that not all patients would benefit.

> *[B]iologics are effective for food allergy. That's the benefit. The risk is that they're unaffordable for almost everyone. So, going down the route of using biologics for the treatment of food allergy will worsen the disparities in care that already exist for patients with food allergy. (CP06)*

Comparisons with OIT came up again in relation to cost.

> *Let's just say Xolair gets approved just for peanut allergy, I'm like, "You could have just done OIT for $1,000 for the whole thing as opposed to charging $30,000 annually." (...) And these are not fictional numbers. (...) [A] biologic will be $30,000 a year forever. (CP05)*

Even more stark were providers' comparisons between the cost of biologics and avoidance.

> *I can't imagine how we can afford to pay (. . .) 50- to $60,000 a year in system costs, for really something that should be just managed by avoidance. So, I really don't know that I'm in favor of that approach for the pharmacoeconomics of it. (CP30)*

Notably, some providers framed cost not just as a practical consideration but also an ethical one, either because of health disparities and health care system costs or because of patients' poor management of FA.

> *I would love to get [my nephew] on a biologic because of the amount of reactions he has. (...) He's 24, and he has very severe milk allergy. (. . .) He is not (. . .) the most careful human being and uses epinephrine a lot as a result. What is the ethical question there too? Do we put somebody on a very expensive biologic because they can't stop drinking milk or avoiding dairy? (CP28)*

Theme 4: Biologics as the Future of Food Allergy

Biologics were the most cited product when we asked providers about the future of FA treatment. Most were enthusiastic about biologics, one (CP24) even calling it a "turning point" in FA treatment. The convenience of a shot compared with doing OIT was seen to make biologics superior as a short-term or temporary solution for situations such as travel.

> *Predict 10, 20 years in the future. I think I'll have biologics, which may be really useful. "Hey, I'm going on vacation. I'm not so sure how well things are there where I'm going on vacation; I'll take my biologics for the next three months to keep myself safe on vacation." I can see people using biologics that way. (AP06)*

Even those providers who had a more negative view described biologics as an inevitable development.

> *I think biologics are (...) where things are going to be going, too, because I think that's something that can be monetized. (...) And so my prediction is that whether that be some kind of monoclonal antibody or Xolair, or something of that nature, that I envision that that's probably going to be the future [of food allergy]. (AP01)*

The providers with negative views about biologics as the inevitable future voiced dread about their own future management of patients.

> *I feel very jaded by it. I think what's going to happen is that once (...) Xolair is approved for food allergy with OIT, I think I'm going to be very frustrated and disappointed that all this money is going to be spent on something that should just be avoided. And then if patients can afford it, then I'll probably offer it to them. (CP30)*

Differences Between Academic and Community Providers

Overall, CPs and APs held similar views of biologics' benefits, and they shared concerns about their use in FA treatment. However, APs spoke more extensively (ie, in more detail and for larger portions of the transcripts) about the benefits of biologics for the treatment of FA than did CPs. Another difference between the groups was that it was primarily CPs who advocated most forcefully for the use of biologics as an adjunct to OIT.

Discussion

As part of our study of allergists' perceptions of current and future FA treatments, we asked about the use of biologics as a treatment option. Most providers were quite positive, even enthusiastic, about the possibility of prescribing biologics for patients with FA. The benefits they perceived included having a new tool for FA treatment, especially for adolescents and young adults, patients with allergic comorbidities, and those with multiple FAs, while also diminishing patient and parent anxiety about accidental exposure. Treating anxiety, especially that of parents, rather than FA directly has been a controversial point in the field, yet quality-of-life challenges are often perceived as the biggest burden for patients with FA and their families.[21] At the same time, there was disagreement about whether biologics would best be used as an adjunct to OIT or as a monotherapy. The providers who advocated for adjunctive therapy noted that biologics would be helpful for allowing high-risk patients to start OIT or for helping patients continue OIT who would otherwise "fail" because of adverse reactions. Biologics were also found to desensitize patients on OIT faster and safer, a perspective supported by the literature.[22-26] In contrast, providers who thought biologics would be best used as

an FA monotherapy perceived this treatment route as easier, safer, and more practical than OIT. In addition, providers saw biologics monotherapy as particularly well suited for patients with multiple FAs or as a risk-reduction therapy to decrease patients' reactions in cases of accidental exposure.

The APs seemed to have more experience with and knowledge about the use of biologics to treat FA. This difference may be because more APs were involved in FA clinical trials evaluating biologics and, therefore, had different clinical and research experiences with biologics. As a result, many had professional interests in seeing biologics succeed in the FA treatment space. In contrast, more CPs advocated for biologics' use as an adjunct to OIT rather than monotherapy. Although most CPs and APs offered OIT (78% and 86%, respectively), many CPs seemed to have been doing so longer than APs. Because of their longer-standing involvement in OIT, CPs had stronger professional interests in continuing to offer OIT, particularly when they perceived it to be highly efficacious in protecting patients from accidental exposure and/or allowing patients to liberalize their diets.

Taken together, providers' perceptions about appropriate patient groups for biologics mirrored the recent literature.[5] However, our findings also underscore providers' concerns about biologics. One such concern focused on insufficient evidence about biologics' use and safety. It is important to note that interviews were conducted before omalizumab's approval for FA and publication of the Omalizumab as Monotherapy and as Adjunct Therapy to Multi-Allergen OIT in Food Allergic Participants (OUtMATCH) trial results.[16] FDA approval and the trial results could address providers' concerns about omalizumab's efficacy. However, their concerns about the lack of evidence for how to use biologics in terms of which patients and for how long, including concerns about long-term safety for young children with developing immune systems, remain unaddressed. The one provider's comparison of biologics to the weight-loss drug semaglutide highlights the potentially problematic nature of a temporary, rather than disease-modifying FA treatment, contextualizing concerns about biologics within larger critiques of pharmaceuticals as expensive—and profit-generating—lifestyle drugs.[27,28] This comparison also speaks to participants' 2 other major concerns about biologics: the potential for overtreatment and high cost, the latter of which was posed as both an ethical issue and a health care system problem. Alongside overtreatment risk and massive costs to the health care system, biologics may also exacerbate health inequities. The high cost of biologics could mean that some patients with FA who could benefit from treatment may not receive it, whereas others with the best health insurance plans, including some people with unconfirmed FA, will have access to treatment.

Omalizumab's FDA-approved product label makes most of the providers' concerns all the more salient because of its broad indication for patients as young as 1 year old and with as few as 1 FA.[3] That said, one potential obstacle to overuse is payers, who may restrict access to treatment. Another obstacle, as noted by providers, is patients' and parents' resistance to treatment because of children's fear of injections that may require as many as 4 shots every 2 weeks[16] and parents' anxiety about biologics as a class of drugs. To date, there have been no published studies about parents' and children's perceptions of biologics to treat FA, only OIT and epicutaneous immunotherapy.[29] This is a much-needed area of research.

The concerns discussed often did not diminish providers' overall enthusiasm for biologics. Indeed, when describing the future of FA, many envisioned biologics as the dominant treatment approach. The providers who were less enthusiastic expressed an inevitability about how they, too, would have to offer these drugs to their patients despite their concerns, because biologics would become standard of care and expected by patients. Importantly, despite these providers' concerns, they did not discuss ways they, or allergy professionals as a whole, could curb the risk of overtreatment, of unnecessary use of biologics as an adjunct to OIT, or of potential health disparities when they spoke about the future as one in which they will prescribe biologics for FA. Providers might implicitly assume that these downsides will also be an inevitable part of the future therapeutic landscape. This inevitability may stem from providers and patients wanting—and in some cases, eagerly awaiting—more treatment options for FA.

Our study has several limitations. First, it was conducted before omalizumab's approval for FA, so providers were primarily reflecting on their own clinical or research experiences and their exposure to information about biologics in the published literature and conferences. Very few providers (13.3%) admitted to prescribing biologics off-label specifically for FA, but many had patients on omalizumab or dupilumab for other conditions. Second, with 85% of providers in our study offering OIT, our sample may have a higher rate of OIT than the national average. However, although those who advocated for biologics as an adjunct to OIT were OIT providers, there were also OIT providers who thought biologics would best be used as an FA monotherapy. Third, our purposive and snowball sampling methods identified providers who are visibly in the field of FA treatment. This may mean that their views are not representative of the broader population of US allergists. We also had a better response rate among APs than CPs. However, we limited our sample of APs and interviewed more CPs (28 vs 32). Men were also more likely to participate, but no differences stood out in how men vs women providers discussed biologics in FA. Finally, because qualitative research is largely exploratory in nature, it is best at identifying themes and providing fine-grained detail rather than providing evidence of what providers' practices are in managing their patients with FA. Nonetheless, we were able to solicit rich data about these providers' perspectives on an emergent treatment for FA.

In conclusion, this qualitative study provides a snapshot on how allergists perceived the use of biologics to treat FA. Our findings revealed the overall enthusiasm expressed by CPs and APs about biologics and their perception that biologics are the future of FA treatment. Now that omalizumab has been approved for FA, the future could be said to have arrived. Future studies should evaluate how providers actually incorporate omalizumab, or other biologics, into their practice and how patients and their families perceive the benefits and risks of these FA treatments.

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Supplementary Dataa

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eAppendix 1. Semistructured Interview Guide

(Note: Specific questions about biologics are in red font)

- What is your clinical approach to managing children's food allergies?
- How do you determine what course of treatment, if any, you offer or recommend for different children?
- What are some treatment approaches used by other allergists that you have decided **not** to offer your patients?
- We know that in clinical trials, investigators used food challenges as part of enrollment in studies, but it seems that clinical practices vary in whether and when they do food challenges. When, if ever, does your clinic use food challenges?
- What is (or should be) the role of avoidance in managing food allergies?
- Do you offer any type of oral immunotherapy (OIT) to your patients? What kind of OIT?
- How has US Food and Drug Administration (FDA) approval of Palforzia affected how you treat children with peanut allergies?
- What are the advantages of prescribing an FDA-approved OIT therapy such as Palforzia?
- What are the disadvantages of prescribing Palforzia?
- As you know, Palforzia is currently the only FDA-approved OIT and it is just for peanut allergy, so there are no FDA approved products for other food allergies. We are really interested in how clinics incorporate non-FDA approved OIT into their practice.
- What are the advantages of providing these other OIT treatments to patients?
- What are the disadvantages of providing these other OIT therapies to patients?
- What do you think the role of the FDA should be in regulating food-based OIT?
- How do you think offering immunotherapies that are not FDA approved affect the profession?
- As I am sure you are aware, there is a lot of research and development now on using biologics to treat food allergies, either as a monotherapy or as an adjunctive therapy.
- In your opinion, when should biologics be used to treat food allergies?
- What are the benefits of prescribing off-label treatments of FDA-approved biologics for food allergies?
- What are the risks of prescribing off-label treatments of FDA-approved biologics for food allergies?
- How do you think the off-label use of biologics affect the profession?
- What other food allergy therapies have you heard about that are currently in development?
- How do parents typically respond to the food allergy treatment options they have for their kids?
- How do you explain to parents the benefits of OIT?
- How do you explain to parents the risks of OIT?
- How do you explain to kids the benefits of OIT?
- How do you explain to kids the risks of OIT?
- How do you explain to parents the benefits of biologics for treating food allergies?
- What do you tell parents about the risks of biologics for treating food allergies?
- What ethical dilemmas do you face when interacting with families about their children's food allergy treatment options? [How do you handle these dilemmas?]
- Do you or have you conducted any food allergy clinical trials?
- How do you think the current availability of Palforzia and other OIT affect clinical trials?
- How does participating in clinical research benefit patients?
- What risks do patients face from clinical research that they would not face in clinical care?
- What expectations about clinical trials do parents typically have?
- What expectations about clinical trials do kids typically have?
- How have your views of OIT changed over time?
- What types of treatments would you like to see for food allergies in the future?
- That is all my questions, but what else should I have asked about managing food allergies and food allergy treatments? What am I missing?
- Who else do you think we should talk to?

Before we conclude the interview, I would like to collect some demographic information from you:

1. **What is your gender?**
   - ○ Genderfluid
   - ○ Man
   - ○ Woman
   - ○ Prefer not to report

2. **Are you of Hispanic or Latino origin?**
   - ○ No
   - ○ Yes
   - ○ Prefer not to report

3. **Which of the following describe you?** *(You can pick multiple categories)*
   - ○ American Indian or Alaska Native
   - ○ Asian
   - ○ Black or African American
   - ○ Native Hawaiian or Other Pacific Islander

- White
- Prefer not to report

4. **Which of the follow age brackets are you in?**
   - 18-29
   - 30-39
   - 40-49
   - 50-59
   - 60-69
   - 70-79
   - 80-89
   - 90 or older
   - Prefer not to report