A practical focus on peanut oral immunotherapy

Tricia Lee, M.D.,[1,2] Codi Horton, C.P.N.P.,[1] Chelsea Leef, D.N.P.,[1] and Brian P. Vickery, M.D.[1,2]

ABSTRACT

A new era of active treatment for food allergy has arrived because patients with peanut allergy are increasingly able to access options for oral immunotherapy (OIT). This milestone is a culmination of years of clinical research and represents a major inflection point for the field because it will have dramatic impacts on allergy practice. In this review, we provide a brief review of the literature as well as practical guidance with concern for the use of U.S. Food and Drug Administration approved peanut OIT as well as shelf-bought products.

(J Food Allergy 4:112–119, 2022; doi: 10.2500/jfa.2022.4.220027)

Peanut oral immunotherapy (POIT) is increasingly being practiced by allergists for clinical management of peanut allergy, and now with a U.S. Food and Drug Administration (FDA) approved product, Palforzia (previously AR101) (Aimmune, Brisbane, CA), it is more readily available to allergists. The recently published POIT data can be used to set realistic expectations of this treatment as well as guide implementation into allergy practices. Numerous publications have shown the benefits of POIT, primarily in raising the threshold of reactivity with desensitization (Table 1).[1–4] The largest POIT study to date is a randomized placebo controlled clinical trial that evaluated AR101.[1] The majority of participants (67%), 4 to 17 years of age, in the AR101 active-drug group tolerated the 600-mg dose of peanut protein without dose-limiting symptoms compared with 4% in the placebo group.[1] The participants who received active therapy with AR101 had less-severe symptoms during peanut exposure at the exit challenge.[1]

From the [1]Children's Healthcare of Atlanta, Atlanta, Georgia; and [2]Department of Pediatrics and Division of Allergy/Immunology, Emory University School of Medicine, Atlanta, Georgia

BP Vickery reports grants from Abbott, grants and personal fees from Aimmune, grants from Alladapt, personal fees from AllerGenis, personal fees from Aravax, grants and personal fees from DBV, grants and personal fees from FARE, grants from Genentech, stock options from Moonlight Therapeutics, personal fees from Reacta Biosciences, grants and personal fees from Regeneron, grants from Siolta, outside the submitted work

The remaining authors have no conflicts to report

No external funding sources reported

Address correspondence to Brian Vickery, M.D., Children's Healthcare of Atlanta, 1400 Tullie Rd., Atlanta, GA 30329

E-mail address: brian.p.vickery@emory.edu

*This manuscript is part of the **Journal of Food Allergy** collection of published works referred to as the "Oral Immunotherapy Manual." The contents of this work reflects the opinion(s) of the author(s) and is not intended to replace published guidelines or the clinician's medical advice in the doctor-patient relationship*

In addition, there are retrospective studies that used shelf-bought peanut products in a real-world setting, including the cohort of Wasserman *et al.*,[2] of whom 79% were desensitized to 3000 mg, and the cohort of Guarnieri *et al.*,[3] of whom, 83% were desensitized to > 1000 mg. Whereas recent POIT studies prove desensitization is achievable for the majority of patients, fewer attain sustained unresponsiveness (SU), except in select populations. The first randomized trial, by Vickery *et al.*,[4] of preschool patients found that POIT was able to desensitize 81% of preschoolers, with 78% achieving SU. Furthermore, POIT, in combination with the probiotic *Lactobacillus rhamnosus*, was shown to be successful in attaining SU.[5] This concept of adjunct treatments to POIT has also included familiar biologics, *e.g.*, omalizumab and dupilumab, although there is a lack of data to support increased SU with these biologics.[6]

When incorporating POIT into a busy clinical practice, designating a team of health-care providers who are primarily responsible for managing the POIT program is useful.[7] Preparing the office to prescribe Palforzia requires Risk Evaluation and Mitigation Strategy (REMS) enrollment for the health-care setting and the provider.[8] The REMS agreement details safety information: appointing an authorized representative, educating healthcare staff, providing equipment to treat anaphylaxis, having an in-clinic REMS certified provider deliver the doses to the patient, and having a proper system for documenting the in-clinic administration of Palforzia. The patient facing REMS outlines important details: proper counseling and monitoring during each office visit, carrying an epinephrine autoinjector, reporting anaphylaxis, and maintaining a peanut-free diet.[8] The REMS agreements for the health-care setting, provider, and each individual patient must be submitted and approved before initiation of Palforzia because these agreements are subject to audits.

For shelf-bought regular food POIT, it is up to the individual practice to implement standard operating protocols, as presented by Jones *et al.*[9] in "Practical

Table 1 **Recent POIT experience in the United States**

Study, y	Sample Size of Treatment Groups, *n*; Median Age	Product (brand)	Initial Dose of Peanut Protein, mg	No. Updoses (duration, mo)	Maintenance Daily Dose of Peanut Protein (duration)	Results for Treatment Groups	AEs in Treatment Groups	Conclusion
Guarnieri *et al.*,[3] 2021	174; 6.6 y (age range, 0.5–17.4 y)	Peanut powder (PB2), then peanut butter	0.1	15 (5.4)	2332 mg for older children and 1166 mg for toddlers (41 wk)	89% were desensitized; 29% consumed peanut *ad libitum*	31% had allergic reactions during in-clinic updosing visits and 55% during home updosing phase, most were grade 1/3; most common were GI, then skin during in-clinic reactions and oral symptoms during home reactions; 17% of participants discontinued, mostly due to aversion or GI symptoms; 9 doses of epinephrine were given; 18 ED visits with 28% triggered by exercise	Clinical POIT has similar outcomes to research protocols to include adolescents and individuals with markedly elevated baseline peanut sIgE
Afinogenova *et* al.,[24] 2020	783; 9.7 y (age range, 3.5–48.3 y)	Peanut flour (Byrd Mill) then peanuts, peanut M&Ms (Mars, McLean, VA), peanut butter M&Ms (Mars, McLean, VA), Reese's cups (Hershey, Hershey, PA), or PB2	0.1	18 (7.7)	750–4500 (104 wk)	89% were desensitized	Buildup AE: 84% had GI and 47% had cutaneous; 110 systemic reactions, with 47 requiring epinephrine; 11% of participants discontinued; for maintenance AE: 27% had GI AE and 15% had cutaneous AEs; 191 systemic reactions with 94 requiring epinephrine; 3% were discontinued	POIT in private practice is possible
Chinthrajah et al.,[12] 2019	95; 10.5 y	Peanut flour (Byrd Mill)	0.5	22 (10–14)*	4 g (42 wk) and then either 300 or 0 mg (52 wk)	84% were desensitized; 13 wk after dropping from 4 g to 0 mg, 35% tolerated 4 g; 52 wk after dropping from 4 g to 300 mg, 37% tolerated 4 g	AEs: most were grade 1 out of 3 in year 1#; most common were GI, then skin; 19% needed epinephrine in Y1; 14 participants discontinued; there were 2 SAEs: 1 participant diagnosed with EoE from the peanut-0 group, 1 participant with anaphylaxis after exercise in the peanut-300 group	Can desensitize most to 4 g of peanut protein but discontinuation or reduction increases the likelihood of regaining clinical reactivity

Table 1 **Continued**

Study, y	Sample Size of Treatment Groups, *n*; Median Age	Product (brand)	Initial Dose of Peanut Protein, mg	No. Updoses (duration, mo)	Maintenance Daily Dose of Peanut Protein (duration)	Results for Treatment Groups	AEs in Treatment Groups	Conclusion
Wasserman et al.,[2] 2019	270; 8.1 y (age range, 4–18 y)	Peanut flour, then peanuts, butter, M&Ms (Mars, McLean, VA), Bamba, Reese's pieces (Hershey, Hershey, PA)	0.00205	21 (6.5)*	3000 mg (156 wk)	79% were desensitized; 14% achieved SU	65% AEs; 100 reactions received epinephrine during updosing; 28 reactions received epinephrine during maintenance; 38 patients experienced ELORS with 5 discontinuing; 39% withdrew	POIT in private practice is possible, although epinephrine-treated reactions and ELORS may occur
Palisade Group et al.,[1] 2018	372; age range, 4–17 y	AR101- peanut flour	0.5	11 (6)	300 mg (24 wk)	77% tolerated 300 mg, 67% tolerated 600 mg, and 50% tolerated 1000 mg; during the exit challenge, 25% had moderate max severity of symptoms and 5% had mild max severity of symptoms	99% AEs, most moderate severity; most common was abdominal pain, then vomiting; most were during updosing; 14% received epinephrine; 22% of participants discontinued, with 43 due to AEs to include 1 EoE and 7 systemic allergic reactions; 8 SAEs: 2 systemic allergic reactions during updosing, which led to 1 discontinuation, 2 asthma exacerbations during updosing, which led to 1 discontinuation, 1 anaphylactic reaction during maintenance, which led to 1 discontinuation	AR101 results in higher doses tolerated and lower symptom severity
Vickery *et al.*,[4] 2017	37; 28.5 mo (age range, 9–36 mo)	Defatted peanut flour (Golden Peanut Co)	0.1	20 (10.5)*	300 or 3000 mg (median, 74 wk)	85% were desensitized to 300 mg, 76% were desensitized to 3000 mg; 78% achieved SU	95% AEs, 85% mild; 1 patient received epinephrine; most common was GI tract, then upper airway; 5 participants discontinued, with 4 from the high-dose arm and 1 due to EoE; 0 SAEs	Early peanut OIT is safe and effective

POIT = Peanut oral immunotherapy; AE = adverse event; GI = gastrointestinal; ED = eliciting dose; sIgE = specific immunoglobulin E; SAE = severe adverse event; EoE = Eosinophilic Esophagitis; OIT = oral immunotherapy; SU = sustained unresponsiveness; ELORS = EoE-like OIT-related syndrome.
**Assuming tolerates a complete initial dose escalation schedule.*
#Y1: 95% peanut-0 and 91% peanut-300; Y3: 2% peanut-0 and 20% peanut-300.

Table 2 **Palforzia eligibility criteria**

Inclusion Criteria	And One of the Following	Exclusion Criteria
Ages 4–17 y	SPT ≥ 3 mm Peanut IgE ≥ 0.35 kU_A/L OFC with documented reaction to peanut A history of IgE-mediated reaction to peanut	Eosinophilic esophagitis Severe or uncontrolled asthma Severe anaphylaxis or anaphylactic shock within the past 2 mo

SPT= Skin-prick test; IgE = immunoglobulin E; OFC = oral food challenge.

aspects of OIT, the importance of an optimal office setup; physical space and staffing." Furthermore, an informed consent form may be used to include risks and benefits as well as the patient's responsibilities.[10] After a patient has shown interest in POIT, a dedicated POIT consult visit can take place, as discussed by Greiwe in "Optimal patient selection for OIT."[11] There are some data to support using patient characteristics to assist in predicting which patients will be most successful on POIT with the least risk for reactions.

Table 3 **Example dosing schedules**

Visit No.	High Dose, mg peanut protein*	Low Dose, mg peanut protein#
1	0.5–6	0.1–6
2	6	6
3	12	12
4	25	25
5	50	50
6	75	75
7	100	100
8	125	125
9	156	156
10	195	195
11	245	245
12	306	306
13	383	383
14	479	479
15	599	599
16	749	749
17	936	936
18	1170	
19	1463	
20	1869	
21	2286	
22	2858	
23	3573	
24	4000	

**From Ref. 16.*
#From Ref. 4.

Younger age and lower specific immunoglobulin E levels (peanut and Ara h 2 immunoglobulin E) have been associated with better outcomes, which equates to more likely being desensitized, and/or fewer adverse events.[1,3,4,12] Using shared decision-making tools is useful, as emphasized by Greenhawt *et al.*[13] in "Patient/parent counselling and consent in the shared decision-making process for OIT." Although age-appropriate shared decision-making tools are not currently available, there are books that are geared toward young children.[14,15]

The cost of POIT is variable and will depend on the patient's insurance coverage and the type of POIT chosen by the family. It should be noted that costs of treatment go beyond the product itself and may also include copays for visits; the purchase of equipment, such as scales and/or measuring spoons; compounding pharmacy fees; the opportunity costs of missed work or school; and other costs. Shelf-bought peanut products will generally be paid for out of pocket, although low cost and as inexpensive as a few dollars per year. The announced list price of Palforzia is approximately $9840 per year ($820 per month), but insurance coverage is currently possible for most private-pay insurers, which can lower cost to the patient (as low as $20/month based on the plan, although annual caps may apply and each family's cost will be different).[16]

At the POIT consult visit, the prescription and enrollment initiation forms should be completed so that these forms, along with supporting documentation with regard to the child's eligibility criteria (Table 2), are submitted directly to the patient's insurance. Alternatively documents can be submitted through the Palforzia Pathway (Aimmune, Brisbane, CA), through which the patient is directly contacted if he or she qualifies for copay assistance. It is common for a prior authorization to then be required. After obtaining approval, the patient will be contacted by the specialty pharmacy, whose staff will discuss copayment costs and directly ship Palforzia to the patient either at home or to the physician's office.

The different POIT studies have used varying forms of peanut powder or flour, with Byrd Mill (Byrd Mill

Table 4 **Example product schedules**

Visit No.	Palforzia Capsule or Sachet (peanut protein, mg)*#	PB2, mg (peanut protein, mg)§	Bamba piece(s) (peanut protein, mg)§
1	One 0.5-mg capsule to six 1-mg capsules (0.5 to 6)	0.24–14.4 (0.1–6)	1/8 (10)
2	Three 1-mg capsules (3)	28.8 (12)	1/4 (20)
3	Six 1-mg capsules (6)	60 (25)	1/2 (40)
4	Two 1-mg capsules + one 10-mg capsule (12)	120 (50)	1 (80)
5	One 20-mg capsule (20)	180 (75)	1.5 (120)
6	Two 20-mg capsules (40)	240 (100)	2 (160)
7	Four 20-mg capsules (80)	300 (125)	3 (240)
8	One 20-mg capsule + one 100-mg capsule (120)	374.4 (156)	4 (320)
9	Three 20-mg capsules + one 100-mg capsule (160)	468 (195)	
10	Two 100-mg capsules (200)	588 (245)	
11	Two 20-mg capsules + two 100-mg capsules (240)	720 (300)	
12	One 300-mg sachet (300)		

**Palforzia information: from Ref. 8.*
#Capsules are to be opened and emptied into food and mixed well; do not swallow capsule.
§From Ref. 10.

Company, Ashland, VA) brand being the most commonly used and easy to purchase online.[7,12] Golden Peanut (Golden Peanut Company, Alpharetta, GA) brand peanut flour was found to have relative amounts of the major peanut allergens among different lots that remained stable over 12 months[17]; however, Filep *et al.*[18] found marked differences in specific peanut allergen profiles with peanut flour extracts, ranging from 1187 to 5270 μg/mL of Ara h 2. The Canadian Society of Allergy and Clinical Immunology recently published preparation and dosing recommendations for shelf-bought peanut products, including Bamba (Osem Group, Holon, Israel) and PB2 (PB2 Foods, Tifton, GA).[10] Palforzia is a standardized, highly characterized product, which is derived from a 12% defatted roasted peanut flour premeasured and packaged in capsules and sachets, which are intended to be opened and sprinkled into a semisolid food.[8] One obvious advantage to using Palforzia is the ease in delivering small doses of allergen when patients are just beginning dosing and not yet desensitized; because adverse events are most common early in treatment, control of these early doses is critical.

Because of the difficulty in accurately measuring small amounts of peanut powder, it is a technical challenge to consistently deliver the first few doses of

Table 5 **Peanut maintenance doses with food equivalents of 300 mg**

Product	Label	300 mg Equivalent
Peanut butter	2 tbsp = 7 g of protein	1/4 tsp
Peanuts	1 oz = 7 g of protein	1.5 peanuts
Peanut flour, 12% fat*	1/4 cup = 12 g of protein	1/3 tsp
Reese's Miniature Peanut Butter Cups, individually wrapped (brand only)	5 pieces = 4 g of protein	1/2 Miniature cup
Peanut M&M (brand only)	1.5 oz = 4 g of protein	2 Peanut M&Ms
Reese's Pieces candy (brand only)	40 g = 4 g of protein	4 Reese's Pieces

**Flours may be defatted differently, which affects protein concentrations.*

Table 6 **Practical application of successful peanut OIT dosing**

Strategies	Pitfalls
Involve the patient in selecting the food vehicle into which to mix the OIT dose	Do not punish the patient if he or she is having difficulty learning to take his or her dose
Provide the patient with developmentally appropriate choices (*i.e.,* what color spoon or bowl)	Avoid mixing the OIT dose into more food than you need
Consider masking the dose with savory or sweet foods (ice cream, chocolate syrup)	
Follow the dose with a liquid that has a strong taste profile (soda, orange juice)	
Make it a predictable part of the daily routine	
Consider presenting pre-scooped bites to the patient to complete his or her dose if developmentally appropriate	
Start with small bites then increase with success	
Provide specific praise to the patient when he or she is doing well	
Provide a small daily reward	

OIT = Oral immunotherapy.

POIT. Many clinics turn to compounding pharmacies or produce their own liquid preparations in which peanut protein is mixed with a volume of fluid to create a concentrated product. This is then used to accomplish the initial updosing visits when patients receive doses of ≤1 mg, but these products are generally not considered extracts or solutions and may not consistently deliver doses. These also must be kept refrigerated and remade regularly because stability is not assured. It is usually not until patients have completed several updosing visits before they can begin to reliably measure and use shelf-bought peanut products. Much more detail about product selection, preparation, and protocols, can be found elsewhere and is beyond the scope of this review.[10] Decisions on product use will depend on the practice model, patient preference, access, and cost.

The POIT studies have different updosing schedules and ultimate maintenance doses, so the optimal dosing regimen for each individual has yet to be determined. Palforzia starts with an in-office, provider-monitored initial dose escalation, which lasts ~4 hours.[8] After the initial dose escalation visit, the patient returns to the office for each updose, which occurs every 2 weeks. Each updose visit includes 60 minutes of monitoring in the office. The day after the updose visit, the patient takes that dose at home daily until the next in-office updose visit. For Palforzia, there are 11 updose visits. The maintenance dose is reached in ~6 months; however, if there are any issues with the updoses, either in the office or at home, the buildup phase may be longer. These in-office doses can come from Palforzia's Office Dose Kit, which is designed for flexibility in dose adjustment as needed. If using shelf-bought regular food, the general principles of the schedule are similar to Palforzia in that a small amount is started and then gradually increased at each updose visit, which generally occurs every 2 weeks.[7,10]

Although Palforzia's dosing schedule is supported by the highest quality level of evidence with a standardized and easily reproducible schedule, there are alternative schedules (Tables 3 and 4). Kukkonen *et al.*[19] were safely able to give some updoses at home, although this is not standard practice. Blumchen *et al.*[20] used a longer buildup phase over 13 months and yielded a similar clinically meaningful desensitization. Regardless of specific dosing schedule used, there may be adaptations and flexibility to fit the patient's needs. Ultimately, the patient reaches a maintenance dose (Table 5), which has varied in the literature, ranging from 125 mg[4] to 4000 mg,[21] with similar outcome rates for desensitization. The maintenance dose is continued daily and indefinitely because decreasing the dose has been shown to increase the likelihood of reacting to previously tolerated higher thresholds,[12] and non-daily dosing was associated with greater frequency and severity of adverse events.[22]

The ingestion tends to be successful when patients bring a food vehicle of choice, such as applesauce or pudding, and entertainment, *e.g.,* books or games, to occupy their time while waiting during in-office visits. In our experience, home dosing can be successful by focusing on age-appropriate strategies (Table 6). Taste aversion is a concern as well as dose fatigue. We suggest offering a variety of options with different consistencies, both

Table 7 **Food vehicles to mix with the oral immunotherapy dose**

Sweet	Savory
Applesauce	Butters (sunflower seed, soy, *etc.*)
Bake into muffins, bread, pancakes, waffles, *etc.*	Cheese (cottage, ricotta, under the cheese on a pizza, *etc.*)
Caramel	Cooked into casserole
Extracts (cinnamon, peppermint)	Condiments (ketchup, mustard, *etc.*)
Freeze into popsicle	Dips (hummus, guacamole, *etc.*) with chips or crackers
Icing or frosting (middle of cookie)	Mashed potatoes
Jelly, jam, or marmalade	Pureed vegetables
Marshmallow	Refried beans
Milkshake or ice cream	Rice porridge
Oatmeal	Salad dressing
Pudding or custard (chocolate, lemon, *etc.*)	Sauces (tomato, pesto, alfredo, gravy)
Pureed fruits	Scrambled eggs, omelet, or egg salad
Smoothie	Soups
Syrup	Tofu
Whipped cream	Tuna salad or fish burger
Yogurt	Tofu

savory and sweet options (Table 7), and follow the dose with a liquid that has a strong taste profile. Caution should be advised that nuts should not be swallowed whole and chewing is necessary. While on maintenance therapy, patients should be seen for regular scheduled follow ups, which, in real-world studies, has been every 6 months. At these follow-ups, a health-care provider should discuss the interval history as well as any hardship with the long-term commitment of POIT, as discussed by Wasserman in "Long term management: assessment of OIT success including integration of oral sustained unresponsiveness challenges."[23] Some practices have retested patients at these follow-up visits and considered SU challenges.[2]

CONCLUSION

POIT can be integrated into busy clinical allergy practices with guidance from the combination of data from randomized controlled trials and real-world studies. Many of the processes needed to implement POIT are already incorporated into allergy practices, such as food challenges, informed consents, prior authorizations, and monitoring and/or treating for allergic reactions. With continued research, more treatment options will follow, so allergy offices will need to adjust practices to be able to provide these new treatments.

CLINICAL PEARLS

- Multiple options exist for patients seeking peanut OIT, and each has advantages and drawbacks. A systematic shared decision-making process is best to help each family identify whether treatment is indicated and which approach.
- Palforzia is the first and only medication to be approved by the FDA with a food allergy indication. Its use is governed by a REMS program mandated by the FDA.
- Multiple studies have shown that peanut OIT is effective in inducing desensitization, which is considered to be a transient shift in threshold reactivity. Other outcomes, such as SU or remission, remain poorly characterized and much remains to be learned about the optimal dosing strategies and ideal patient selection to achieve these different outcomes.

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