Oral Immunotherapy
(Gown Perspective)

AAIFNC 2019 Symposium

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Disclosures

During the past 2 years, I **have/had** an affiliation (financial or otherwise) with a commercial organization that may have a direct or indirect connection to the content of my presentation(s).

Financial Interest/Affiliation	Name of Company(s)
Grant/research support	Aimmune Therapeutics DBV Technologies
Membership on an advisory panel, standing committee, or board of directors	Medical Advisory Board for the Food Allergy & Anaphylaxis Connection Team (FAACT); Clinical Advisory Board for Food Allergy Research & Education (FARE); Medical Advisory Council for the National Peanut Board
Other financial or material interest	Royalties: UpToDate; Speaker: Nutricia, Abbott; Consultant: INSYS Therapeutics, Intrommune Therapeutics, DBV Technologies, AllerGenis, DOTS Technology, Aravax

Objective

- Equip you with the appropriate tools to guide patients & their families in making the best decision for them with respect to treatment for food allergy.

Choosing Treatment vs. Avoidance

- Caregivers are faced with many decisions
  - --May focus on the perceived benefit vs. accidental death
  - --May prefer to avoid therapy that becomes burdensome
  - --May prefer to avoid costly therapy, or not care about cost
  - --May have realistic or unrealistic expectations
  - --May feel doing “something” is better than avoidance
- Have to define their expectations and goals
- We can’t judge or prescribe—we are guides
- But, we must inform what would work best
  - --If that is even possible!

Goals of Food Immunotherapy

1. ***Desensitization***: a reversible state typically induced by short-term exposure to allergen; once administration of allergen is discontinued, the previous level of clinical reactivity returns.

2. ***Sustained unresponsiveness***: ability to consume the allergen after stopping active treatment; documented by passing a food challenge off therapy for an amount of time (? how long).

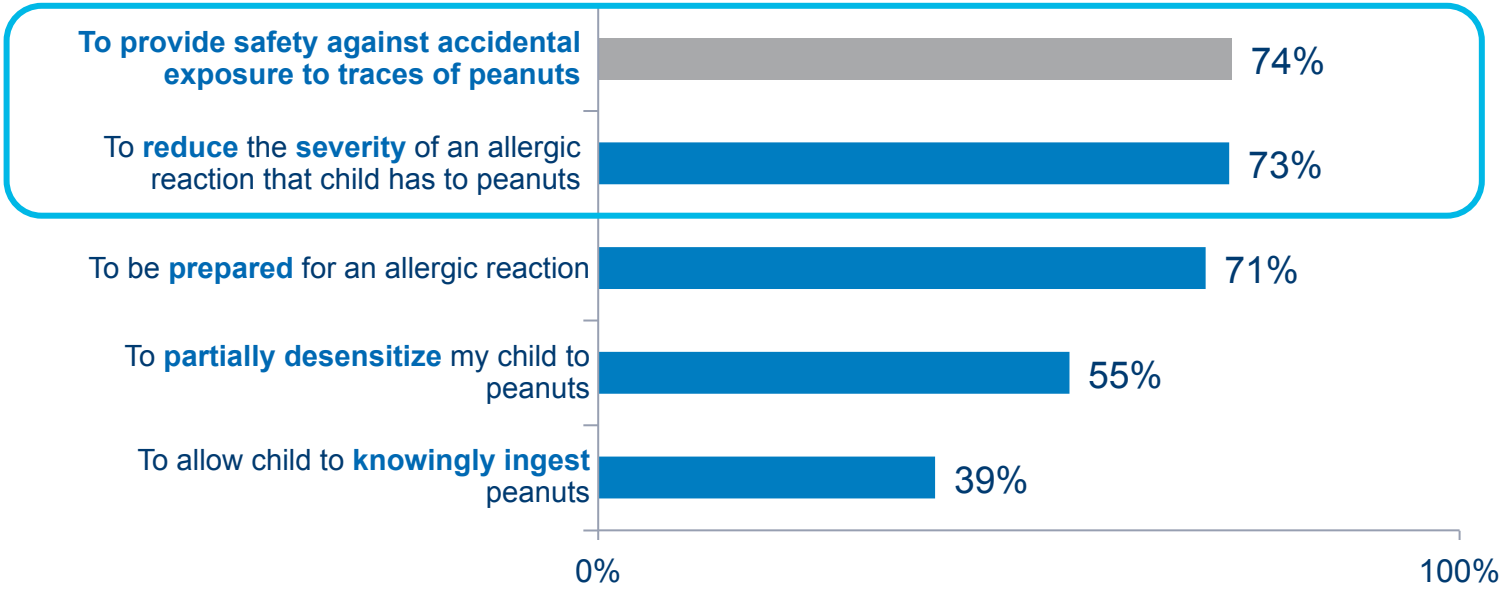
3. ***Tolerance***: relatively long-lasting effects of immunotherapy, presumably due to effects on B cell and T cell responsiveness, that persist even after the treatment is discontinued (although tolerance may not always be permanent).

Goals of Food Immunotherapy Vary

1. Differ by medical provider
2. Differ by patient and/or parent
3. Differ by food

Protection Against Reactions Due to Accidental Exposure to Peanuts Is a Top Priority for Parents

Objectives of Treatment
(N=360)



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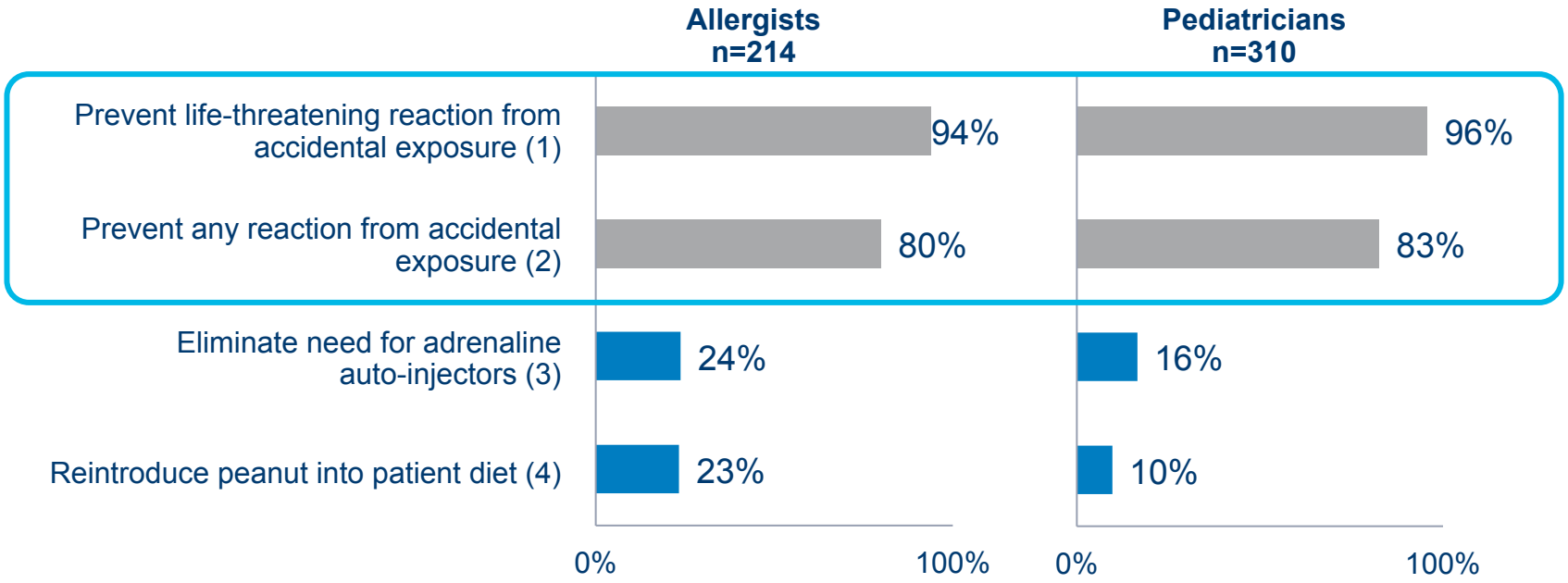
Survey question: If there were treatment options available for peanut allergy, what is your level of agreement with the following statements as being the objective of treatment?

*Based on primary market research with 360 caregivers of children 4–11 years of age with peanut allergy in the United States. DBV Technologies. Data on file. 2016.

Primary Treatment Goal of Physicians Is Protection Against Reactions Due to Accidental Exposure

Physicians' Primary Treatment Goals*



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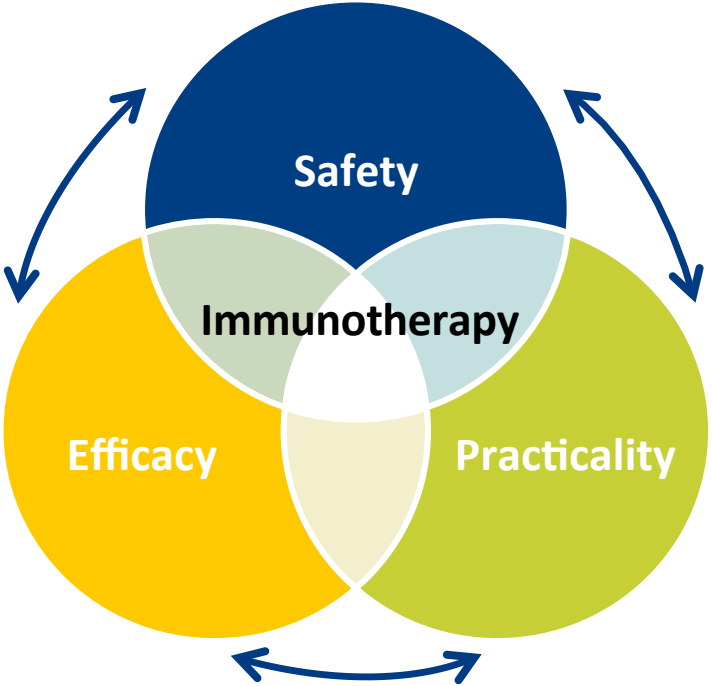
Survey question: What are your primary treatment goals for your patients?
*Based on primary market research among 214 Allergists and 310 Paediatricians in the United States. DBV Technologies. Data on file. 2016.

Immunotherapy Strategies Aim to Balance Efficacy, Safety, and Practicality



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FDA Advisory Committee Meeting. January 21, 2016 Transcript. https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/BloodVaccinesandOtherBiologics/Allergenic ProductsAdvisoryCommittee/UCM484938.pdf. Accessed February 8, 2018.

https://www.foodallergy.org/research-programs/overview. Accessed February 8, 2018.

Efficacy

- Many achieve some degree of desensitization
  --Reaction threshold increases for most but not all
  --There is a subset that develops sustained unresponsiveness
- Meta-analysis by Nurmatov et al.:
  --showed substantial benefit in terms of desensitization with OIT: risk ratio [RR] = 0.16, 95% CI 0.10, 0.26
  --however, only benefit in children, not in adults
  --only suggested, but did not confirm, sustained unresponsiveness: RR 0.29, 95% CI 0.08, 1.13
- Fairly equal effects seen with milk, egg, peanut

Nurmatov U et al. Allergy 2017

Peanut Oral Immunotherapy (OIT): Efficacy Overview

- Desensitization induced in majority of patients who are able to tolerate therapy
- Magnitude varies widely based on study design and protocol

Reference	Design	N	Age (y)	Maintenance Dose (mg)	Duration	Primary Outcome
Jones 2009	Open-label	29	1–16	1800	36 mo	**93% passed 3.9 g OFC**
Blumchen 2010	Randomized, open-label	23	3–14	500	7 d rush, 8 wk maintenance	**64% reached maintenance of 500 mg peanut**
Varshney 2011	Randomized, placebo-controlled	19	3–11	2000	48 wk	**84% passed 5000 mg OFC**
Anagnostou 2011	Open-label	22	4–18	800	32 wk	**64% tolerated 6.6 g OFC**
Anagnostou 2014	Randomized, controlled	39	7–16	800	26 wk	**62% tolerated 1400 mg challenge**
Vickery 2014	Open-label	24	1–16	<4000	Up to 5 y	**50% SU to 5000 mg OFC after 4-wk avoidance**
Narisety 2014	Randomized, placebo-controlled	16	7–13	2000	12 mo	**OIT > SLIT in OFC threshold, low rate of SU**
Vickery 2017	Randomized, placebo-controlled	40	9–36 mo	300 vs 3000	Up to 3 y	**85% in 300 mg and 76% in 3000 mg achieved SU after 4-wk avoidance**
PALISADE AR101 - Aimmune	Randomized, placebo-controlled	372 active	4-17	300	12 mo	**76% 443 mg cumulative 67% 1043 mg cumulative 50% 2043 mg cumulative**

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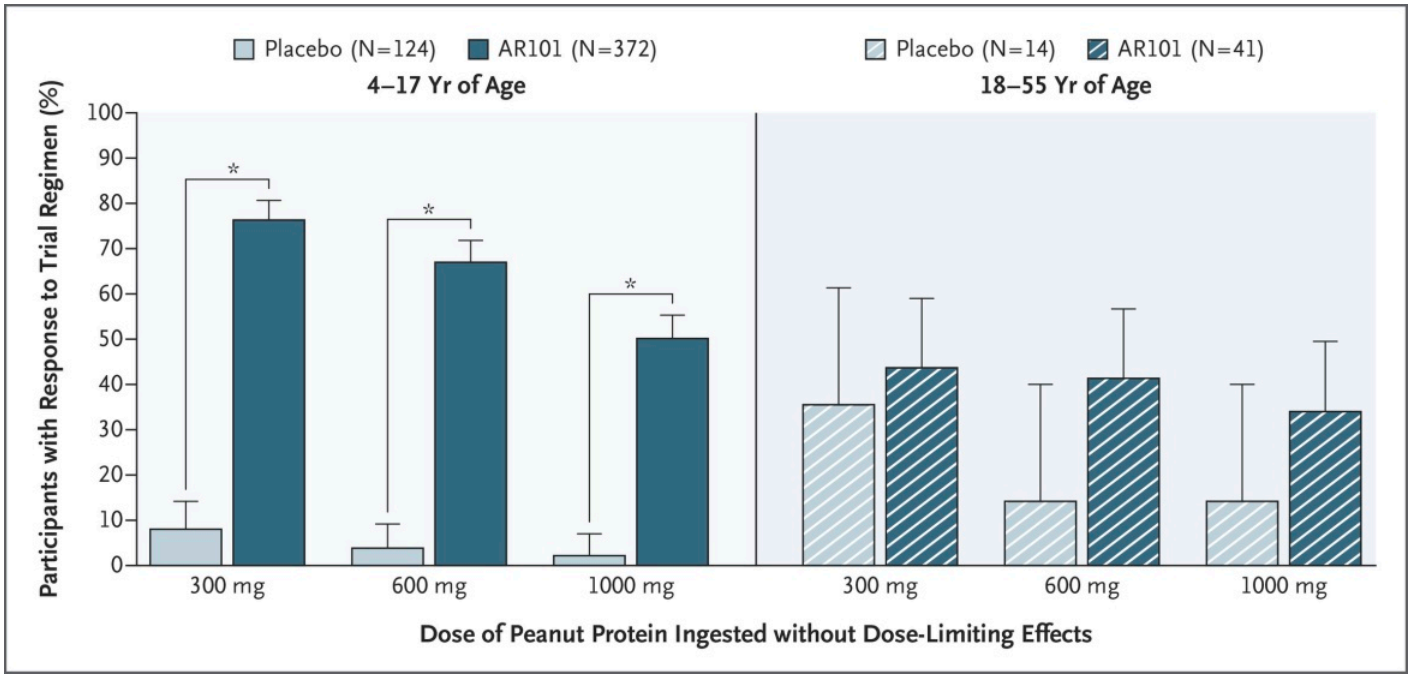
Wood RA. *J Allergy Clin Immunol.* 2016;137:973-982.
Vickery BP, et al. *J Allergy Clin Immunol.* 2017;139:173-181
Jones SM, et al. AAAAI 2018. Abstract L6

PALISADE Phase 3 Trial



Primary Endpoint:
Tolerate exit DBPCFC at 600-mg dose
(1043 mg cumulative)

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- *P < .00001 vs placebo.
- Vickery et al. NEJM 2018.

The Safety Profile of OIT

Nurmatov U et al. meta-analysis: caveat – different formats in reporting reactions between trials

Local reactions (minor oropharyngeal/gastrointestinal or perioral rash):

- Risk of local reactions was higher in those receiving OIT (RR of ***not*** experiencing a reaction in controls = 2.08, 95% CI 1.43, 3.02)

Systemic reactions:

- Risk of experiencing a systemic reaction was higher in those receiving OIT (RR of ***not*** experiencing a reaction in controls = 1.16, 95% CI 1.03, 1.30)

Allergic reactions are more common among OIT participants than in those continuing avoidance

Nurmatov U et al. Allergy 2017

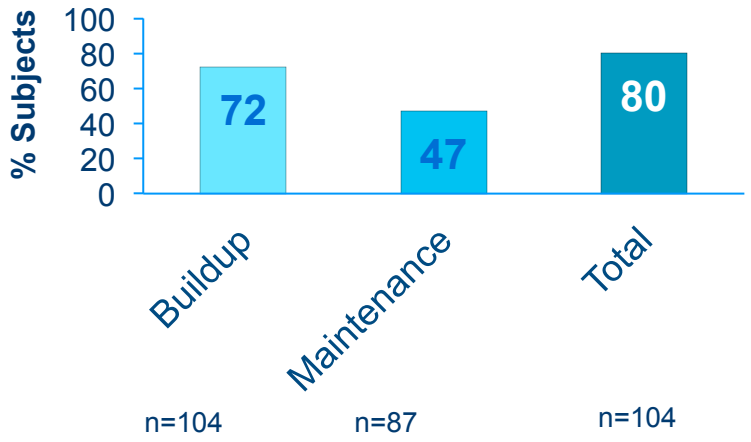
Peanut OIT: Safety Overview

- Adverse events (AEs) are common[1-4]
- Greatest risk of allergic symptoms occurs during initial escalation[1-4]
- Risk of serious AEs[4]

Virkud et al, 2017[5]

- Retrospective, pooled safety analysis of 3 peanut OIT studies
- 104 children 0–13 years of age
- 85% of AEs were mild; >90% occurred at home
- 42% experience systemic AEs (49% GI-related)
- 12% treated with epinephrine
- 20% withdrew from treatment, half due to GI issues (2 diagnosed with EoE=1.9% of total population)

Rates of Likely Treatment-Related AEs by Study Phase[5]



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1. MacGinnitie et al. *Curr Allerg Asth Rep.* 2017;17:1-7. **2.** Burbank AJ, Burks W. *Expert Rev Gastroenterol Hepatol.* 2015;9:1147-1159. **3.** Lucendo AJ, et al. *Ann Allergy Asthma Immunol.* 2014;113:624-629. **4.** Wood RA. *J Allergy Clin Immunol.* 2016;137:973-982. **5.** Virkud YV, et al. *J Allergy Clin Immunol.* 2017;139:882-888.

Adverse Events Affecting More Than 5% of the Participants 4 to 17 Years of Age in Either Group, According to Trial Phase

SAFETY DATA:

- 10 patients experienced SAEs
  - 9 in AR101 group (2.4%)
  - 1 in placebo group (0.8%)
  - 9 SAEs in AR 101 group
    - 5 were mild to moderate
    - 4 were severe
      - 2 related to treatment: anaphylaxis and wheezing on first treatment day

Vickery et al. NEJM 2018.

Table 2. Adverse Events Affecting More Than 5% of the Participants 4 to 17 Years of Age in Either Group, According to Trial Phase.*

Event	Initial Dose-Escalation Phase		Increasing-Dose Phase		Maintenance Phase		Overall	
	AR101 (N=372)	Placebo (N=124)	AR101 (N=366)	Placebo (N=123)	AR101 (N=310)	Placebo (N=118)	AR101 (N=372)	Placebo (N=124)
	number of participants with event (percent)							
≥1 Adverse event	189 (50.8)	36 (29.0)	353 (96.4)	108 (87.8)	270 (87.1)	94 (79.7)	367 (98.7)	118 (95.2)
Abdominal pain	83 (22.3)	8 (6.5)	156 (42.6)	25 (20.3)	46 (14.8)	7 (5.9)	194 (52.2)	30 (24.2)
Vomiting	15 (4.0)	0	127 (34.7)	22 (17.9)	50 (16.1)	14 (11.9)	154 (41.4)	30 (24.2)
Upper abdominal pain	9 (2.4)	3 (2.4)	136 (37.2)	17 (13.8)	41 (13.2)	9 (7.6)	152 (40.9)	26 (21.0)
Oral pruritus	36 (9.7)	8 (6.5)	131 (35.8)	15 (12.2)	39 (12.6)	5 (4.2)	151 (40.6)	20 (16.1)
Nausea	31 (8.3)	1 (0.8)	128 (35.0)	22 (17.9)	45 (14.5)	8 (6.8)	146 (39.2)	29 (23.4)
Oral paresthesia	4 (1.1)	2 (1.6)	57 (15.6)	5 (4.1)	23 (7.4)	2 (1.7)	65 (17.5)	8 (6.5)
Lip swelling	2 (0.5)	0	25 (6.8)	3 (2.4)	13 (4.2)	2 (1.7)	38 (10.2)	5 (4.0)
Cough	10 (2.7)	0	117 (32.0)	30 (24.4)	61 (19.7)	22 (18.6)	152 (40.9)	42 (33.9)
Throat irritation	28 (7.5)	5 (4.0)	131 (35.8)	26 (21.1)	43 (13.9)	11 (9.3)	152 (40.9)	34 (27.4)
Rhinorrhea	6 (1.6)	1 (0.8)	82 (22.4)	25 (20.3)	46 (14.8)	9 (7.6)	113 (30.4)	28 (22.6)
Sneezing	16 (4.3)	3 (2.4)	76 (20.8)	15 (12.2)	33 (10.6)	5 (4.2)	98 (26.3)	18 (14.5)
Throat tightness	14 (3.8)	3 (2.4)	70 (19.1)	6 (4.9)	20 (6.5)	0	86 (23.1)	8 (6.5)
Dyspnea	2 (0.5)	1 (0.8)	32 (8.7)	3 (2.4)	17 (5.5)	1 (0.8)	44 (11.8)	5 (4.0)
Dysphonia	1 (0.3)	0	19 (5.2)	2 (1.6)	8 (2.6)	1 (0.8)	25 (6.7)	2 (1.6)
Pruritus	25 (6.7)	8 (6.5)	117 (32.0)	25 (20.3)	45 (14.5)	14 (11.9)	153 (41.1)	34 (27.4)
Urticaria	16 (4.3)	3 (2.4)	115 (31.4)	23 (18.7)	63 (20.3)	17 (14.4)	143 (38.4)	30 (24.2)
Rash	12 (3.2)	1 (0.8)	61 (16.7)	15 (12.2)	24 (7.7)	7 (5.9)	81 (21.8)	18 (14.5)
Chest discomfort	2 (0.5)	0	19 (5.2)	1 (0.8)	8 (2.6)	0	24 (6.5)	1 (0.8)
Systemic allergic reaction†	1 (0.3)	0	31 (8.5)	2 (1.6)	27 (8.7)	2 (1.7)	53 (14.2)	4 (3.2)
Ear pruritus	3 (0.8)	0	23 (6.3)	0	7 (2.3)	0	25 (6.7)	0

* The data in the maintenance-phase and overall columns exclude symptoms that were recorded during the exit double-blind, placebo-controlled food challenge.
† Events of systemic allergic reaction included one case of severe anaphylaxis in the active-drug group during the maintenance phase.

Safety

Real-World Experience with Peanut Oral Immunotherapy: Lessons Learned From 270 Patients

Richard L. Wasserman, MD, PhD[a,b], Angela R. Hague, PA-C[a], Deanna M. Pence, RRT[a], Robert W. Sugerman, MD[a,b], Stacy K. Silvers, MD[b,c], Joanna G. Rolen, PA-C[a], and Morley Herbert, PhD[d] *Dallas and Austin, Texas*

Target maintenance dose: 3000 mg

100 ETRs occurred in 63/270 patients (23%) during buildup

- **37 in the office**

TABLE III. Dropouts

Primary reason	Escalation	Maintenance
Total N/total treated (%)	48/270 (18%)	25/214 (12%)
Reactions among dropouts	11/48 (23%)	7/25 (28%)
ETRs, N/total dropouts	8/48 (17%)	3/25 (12%)
Non-ETR/non-ELORS reactions, N/N dropouts	3/48 (6%)	4/25 (16%)
ELORS, N/N dropouts	21/48 (44%)	1/25 (4%)

ETR: epinephrine-treated reactions
ELORS: eosinophilic esophagitis-like oral immunotherapy-related syndrome: episodic vomiting 2 hrs post dosing

Wasserman RL et al. JACI In Practice 2019

Patient Selection: Who is the Right Patient?

- Age:
  - At what age can a patient tell us reliably how they are feeling?
  - May vary by food: therapies generally work better at younger age; give time to naturally outgrow milk/egg/wheat?

- Discussion with family **AND** patient ahead of time regarding risk of reactions to therapy, possible side effects, and expected outcome

- Goals of therapy/endpoint: need to be made clear ahead of time
  - Is goal to decrease risk of reaction due to accidental exposure?
  - Is goal to be able to add the food back to the diet eventually?

Sampson HA JACI: In Pract 2013
Greenhawt M et al. Ann Allergy Asthma Immuno 2018;121: 575-9
Rodriguez Del Rio P et al. JACI 2018
Blumchen K, Eiwegger T. Allergy 2018

Patient Selection: Who is the Right Patient?

- What severity of past allergic reaction to the food will practitioners be comfortable treating patients?
  - All grades of anaphylaxis?

- Severe asthma?
  - Some studies exclude certain doses of inhaled steroids (>500 mcg) and or ICS/LABA doses
  - But what if well controlled on higher dose medications?

Sampson HA JACI: In Pract 2013
Greenhawt M et al. Ann Allergy Asthma Immuno 2018;121: 575-9
Rodriguez Del Rio P et al. JACI 2018 (epub)
Blumchen K, Eiwegger T. Allergy 2018

Dosing

- What should be the targeted maintenance dose?
  - Maintenance dosing for peanut for FDA-approval: 300mg
  - If trying to incorporate fully into diet – higher?

- What is the ideal frequency of maintenance dosing?
  - Daily, for how long?
  - Could every other day or weekly be used after some time period?

- What is the optimal duration of dosing?
  - Years?
  - Indefinite?

Wood RA. JACI. 2016;137:973-982.
Vickery BP, et al. JACI. 2017;139:173-181
Blumchen K, Eiwegger T. Allergy 2018

Dosing: Practicality Issues

- When to give:
  - Not on empty stomach
  - 2-3 hour post-dose physical activity or hot bath/shower restriction
  - Not given within 2 hours of bedtime
  - URI, fever, gastroenteritis, asthma exacerbation: withhold dose or decrease dose (e.g., 50%)

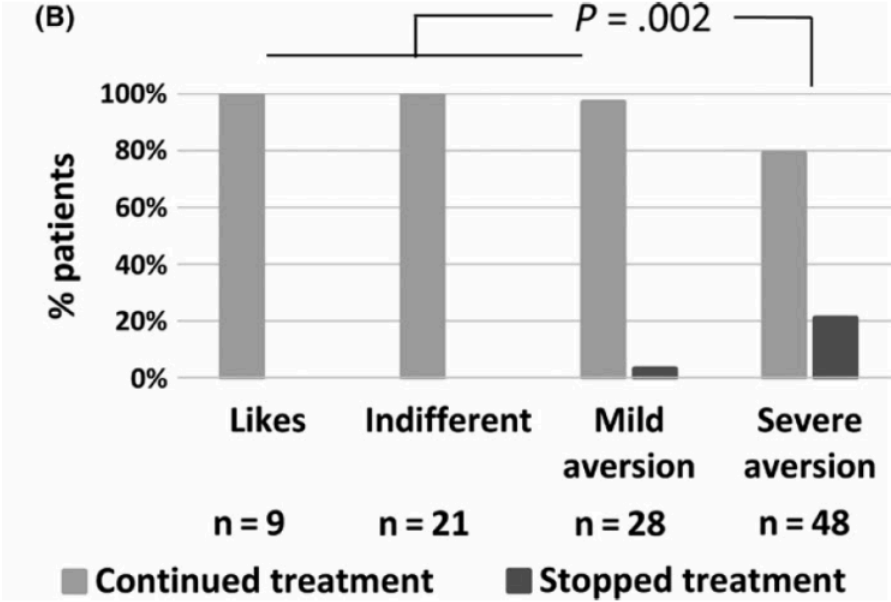
- Missed doses during up-dosing (considered higher risk than maintenance):
  - Miss 2 days in a row: give last dose at home
  - Miss 3-4 days in a row: current dose under medical supervision
  - Miss 5-7 days in a row: 50% of last dose under medical supervision

Wood RA. JACI. 2016;137:973-982

Dosing: Practicality Issues

Food aversion:

- Fourteen patients (12.6%) discontinued treatment after reaching full desensitization. Cessation of treatment was not due to adverse reactions during maintenance, as reported by others, but primarily due to an aversion to peanuts.



Nachshon L et al. Pediatr Allergy Immunol. 2018;29: 519–526

Single Food or Multiple Foods?

- What are the patient and parents priorities/goals with respect to the specific food allergies? Which foods?
- What is the ability of the patient to consume the number **AND** amounts of food(s) per day?
- Can you use cross-reactivity of certain tree nuts, for example?
  - Use cashew for OIT and then challenge pistachio as well
  - Similar protection to pecan with walnut OIT

Begin P et al. Allergy Asthma Clin Immunol 2014
Otani IM et al. Allergy Asthma Clin Immunol 2014

OIT Plus Adjunctive Therapies

- Generally done to enhance the safety and efficacy: accelerate buildup phase and minimize side effects
  - Omalizumab
  - Dupilumab
  - Interferon-gamma
  - Nanoparticles
  - Food Allergy Herbal Formula-2
  - Probiotics
- What is the safety of using the adjunctive therapies themselves?
- What will be the cost of some of the adjunctive therapies?

Virkud YV et al. Clin Rev Allergy Immunol 2018;55: 172-89

Academic vs Office Practice

- Longstanding debate: in pro/cons and in the literature
- An FDA-approved OIT product for peanut is likely coming in 2020

- Regardless of how you may feel, **BOTH** academic and office practices must:
  - Be prepared for an increase in night and weekend phone calls
  - Be prepared to treat/manage potentially severe reactions in and out of workplace
  - Be prepared for the impact of therapy on workflow
  - Provide increased education for office staff – medical providers, nurses, MA's – and educate patients and parents about potential side effects and management of different reactions

Wood RA. JACI. 2016;137:973-982
Wasserman RL et al. JACI In Practice 2019
Wasserman RL et al. JACI In Pract 2014;2: 91-6
Wasserman RL et al. JACI 2011;127: 290-1

OFCs: How, When, Where?

- A 2009 AAAAI survey showed that while 84% of surveyed allergists indicated they perform OFCs, fewer than 5.5% responded they performed more than 10 per month.

- In a 2017 follow-up survey, 93% perform OFCs, but still only 15% perform more than 10 per month.
  - 25% of respondents reported lack of comfort with the procedure
  - 40% will not perform infant OFCs even for early peanut introduction

Pongracic, JA e t al. J Allergy Clin Immunol. 2012; 129: 564–566
Griewe J et al. Workgroup Report: Oral Food Challenge Practices Among Allergists in the US, 2017. Poster presented at 2019 AAAAI Meeting

OFCs: Where, How?

- Since these OFCs could be considered higher risk, should only those practices that have sufficient experience performing food challenges offer OIT?
- Are there ways to partner with academic centers for OFCs or can there be regional referral centers for OIT in areas where these OFCs may not be done?

- For clinical use of food immunotherapy, DBPCFCs are not necessary, nor are the strict OFC stopping rules for when an OFC is considered positive.

- If we know by study results how much protein most patients can consume after 12 months of therapy, do you have to perform OFCs to higher protein amounts to prove it's working?

Wood RA. JACI. 2016;137:973-982
Wasserman RL et al. Ann Allergy Asthma Immunol 2018;121: 272-5
Jones SM, et al. AAAAI 2018. Abstract L6.

OFCs: When?

- Do some patients need an OFC prior to starting therapy?
  - If food never been eaten (i.e., positive tests only)?
  - If food never eaten, but the skin test large and/or sIgE levels high (how much)?
  - If food never eaten and skin test small or sIgE low?
  - What if clinical reaction, but has been a number of years since eaten (>2, >5)?

- Should there be an OFC after 1 year, 2 year or longer of therapy?
- Will insurance require an OFC to prove the therapy is working in order to continue to use it?
- When should you perform OFCs for sustained unresponsiveness?

Wood RA. JACI. 2016;137:973-982
Wasserman RL et al. Ann Allergy Asthma Immunol 2018;121: 272-5

FDA-approved Products Only?

- OIT to milk, egg, peanut, tree nuts, and wheat have been done with commercially available products for years.[1,2]
- If using these products, sourcing and preparing foods will require some staff time and training.

- With a peanut OIT product likely being FDA approved in 2019, what will the FDA or our academic societies state regarding the use of other products?
- Since OIT does not utilize a medical device or a medication (drug), should OIT fall under FDA purview?
  - Can they regulate these?

- Can we, or our patients and families, continue to wait 3-5 years for each other food OIT product to be FDA approved?

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Wood RA J Investig Allergol Clin Immunol 2017;27: 151-9
Wasserman RL et al. JACI In Practice 2019
Wasserman RL et al. JACI In Pract 2014;2: 91-6
Wasserman RL et al. JACI 2011;127: 290-1

Price and Cost-Effectiveness

- How much will the FDA-approved products cost?
- Will insurances cover their use:
  - For all patients?
  - Some?
  - Certain specific patients?
- Will these therapies be cost-effective?

SUMMARY: What We Know and Still Don't Know

1. We know OIT works to induce desensitization in most of the ~80% of patients who do not stop OIT due to side effects.

2. We know OIT can induce sustained unresponsiveness in some. We do **NOT** know if OIT (or other therapies) induces "tolerance". Thus, we do **NOT** know
   - The necessary length of treatment to reach tolerance
   - When tolerance occurs
   - Which patients will develop tolerance
   - If tolerance induced by food immunotherapy is the same as naturally outgrowing a food allergy
   - How often and in what amounts the former allergen needs to be consumed to maintain tolerance
   - If patients who develop tolerance still need to carry an epinephrine autoinjector and anaphylaxis plan?

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Wood RA. JACI. 2016;137:973-982
Rodriguez Del Rio P et al. JACI 2018
Scurlock A Clin Rev Allergy Immunol 2018;55: 139-52

SUMMARY: What We Know and Still Don't Know

3. We know that ongoing avoidance of a food(s) should be considered as a reasonable option for patients and families. But we do **NOT** know
   - How the risks of ongoing avoidance compare to the short-term risks (e.g., anaphylaxis) or the long-term risks (e.g., EoE) of doing OIT (or risks from other therapies)

4. We do **NOT** know much about the logistics of doing OIT outside of academic practice
   - How will clinical use differ from clinical trials
   - How do private practitioners perform it now in their office − can we learn from them?
   - Who will perform the OFCs as part of these treatments
   - Are there ways to partner in patient care between academic and private practices

Wood RA. JACI. 2016;137:973-982
Rodriguez Del Rio P et al. JACI 2018
Scurlock A Clin Rev Allergy Immunol 2018;55: 139-52

SUMMARY: What We Don't Know

5. We do **NOT** know how OIT (or other therapies) affects patient-reported outcomes in large clinical trials (e.g., anxiety, QoL). Most studies to date (small numbers of patients) have looked at caregiver health-related QoL.

6. We do **NOT** know what other approaches will be available?
   - EPIT / SLIT / SCIT / Vaccine
   - OIT + Omalizumab, dupilumab, other biologics

7. We do **NOT** have precision medicine in food allergy treatment: How to pick the right approach for the right patient, including avoidance.

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