BURGHARDT FOOD ALLERGY Center

OHSU

Food Allergies & Immunotherapy

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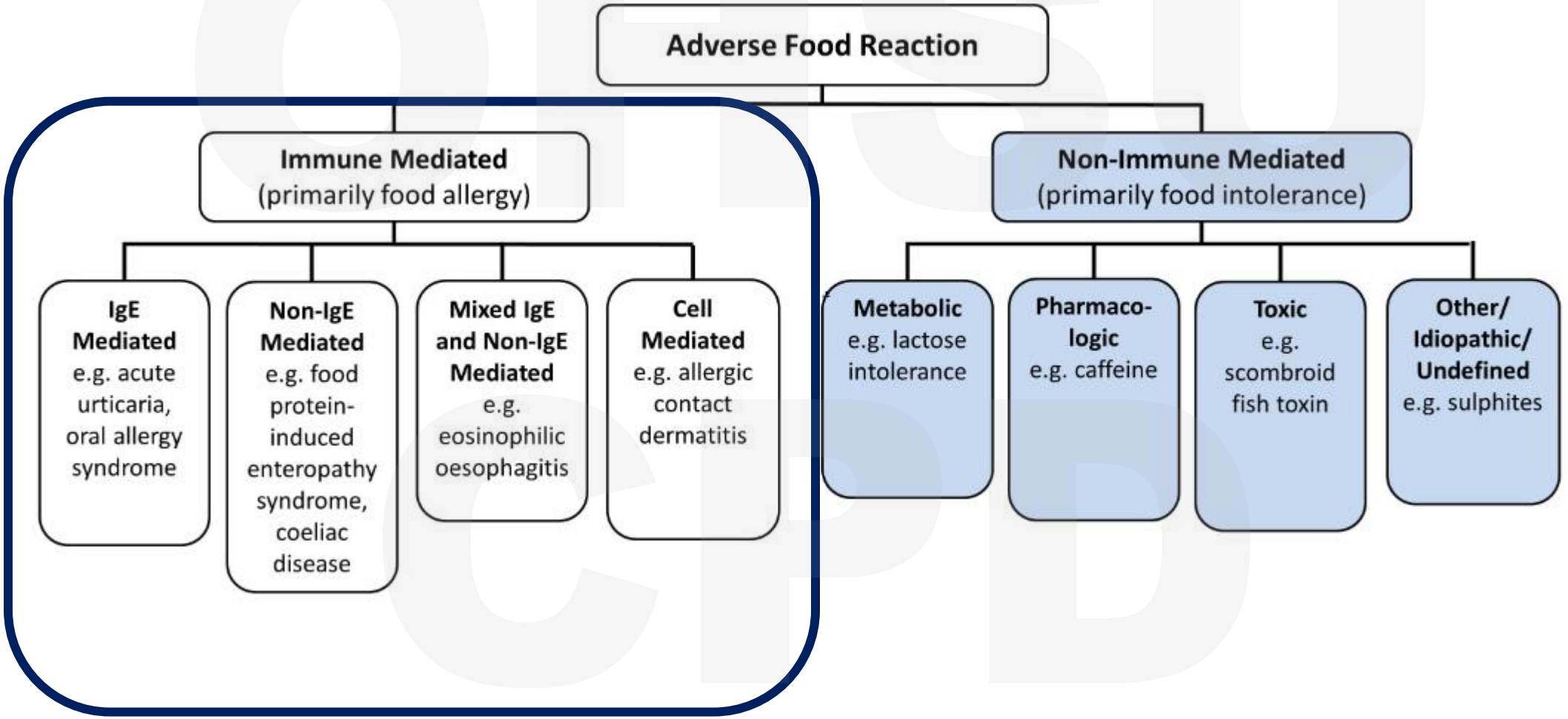
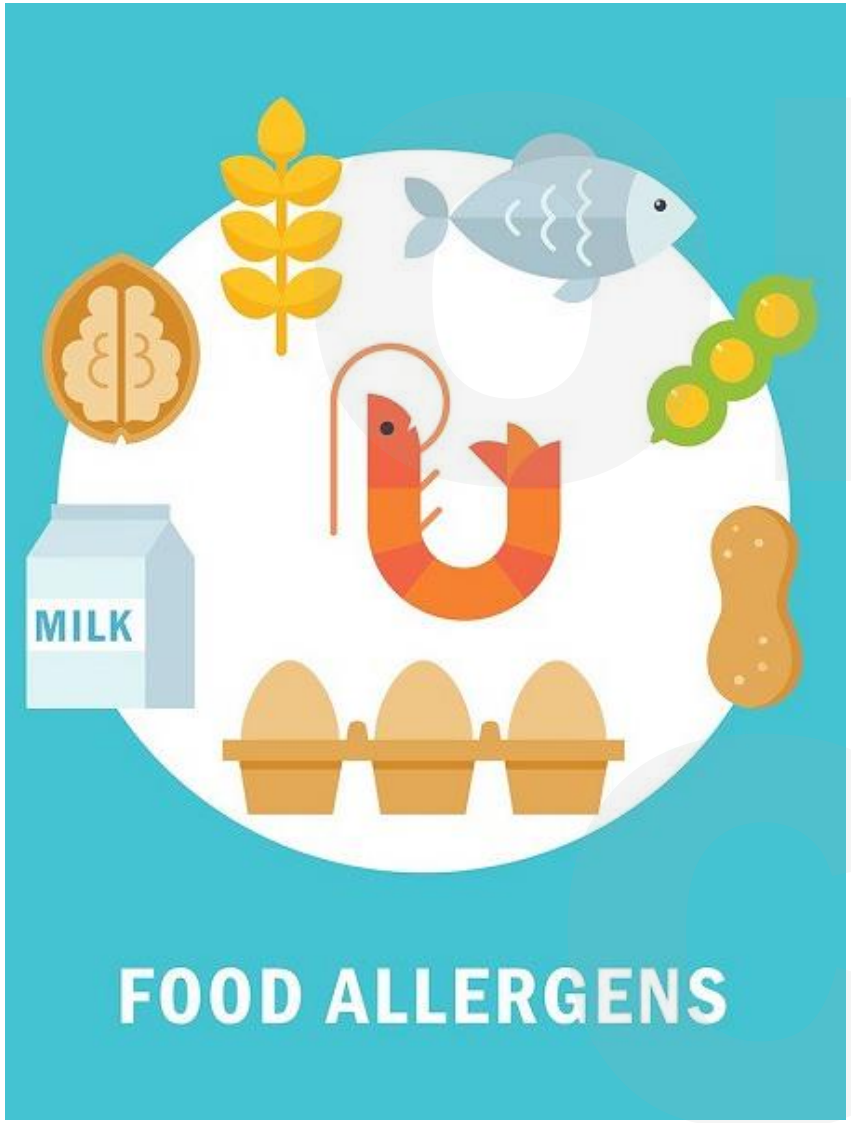
Disclosures: None

Objectives

- Provide brief overview of food allergy burden
- Diagnosing food allergy in clinic
- Outline treatment options including oral immunotherapy, sublingual immunotherapy, epicutaneous immunotherapy, and omalizumab
- Compare efficacy and safety of different treatment options
- Discuss implementation of treatment options in clinical practice
- Review future directions including other treatments currently being studied



https://www.allergy.org.au/patients/food-other-adverse-reactions/food-intolerance



Food Allergy Burden

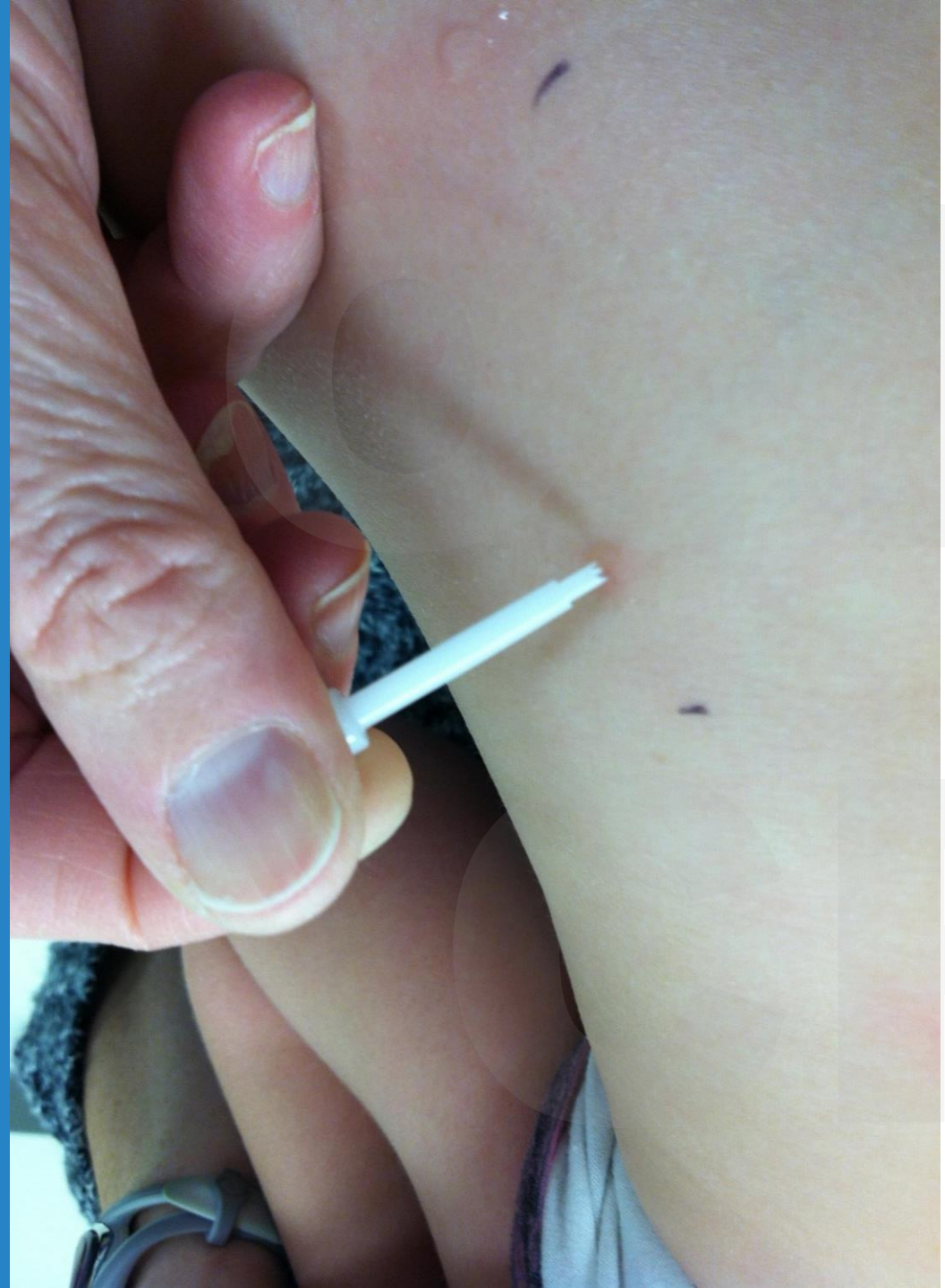
- Approximately 10% of the United States is impacted by food allergy
- For decades the mainstay of treatment was avoidance of the food and management of anaphylactic reactions; however, there are new therapies available and being studied
- No “cure” currently
- There is a significant impairment in quality of life, in addition to life-threatening reactions
- There is a large financial and psychosocial burden

Food Allergy Diagnosis

USING SPT, SERUM IGE, AND COMPONENT RESOLVED DIAGNOSTICS

Clinical History is **Key** in Diagnosing Food Allergies

- 11-month-old presents for ED follow up after being seen for facial hives and lip swelling approximately 15 minutes after eating strawberries
- 9-month-old with eczema gets a red rash with bumps around the mouth after eating different foods but especially fruits and tomato.
- 6-week-old with flecks of blood in the stool
- 8-month-old male with 4 episodes of emesis several hours after ingesting rice for the first time
- 10-year-old female presents to your clinic with lip tingling/itching, hives around mouth; she has seasonal allergies and notices this with certain fresh fruits



Skin Prick Testing

Advantages:

- Quick results, can be done same day in allergy clinic
- Result is evident to the patient, which can be used for education
- High sensitivity, high negative predictive value
- Allows testing with fresh foods

Limitations:

- Low specificity, low positive predictive value (frequent false positives)
- Need to stop oral antihistamines
- Skin should be free of eczema

Serum Specific IgE Testing

Tree Nut Panel

Visible to patient: Yes (MyChart) Dx: Multiple food allergies

	Ref Range & Units	2mo ago
Almonds IgE	<0.35 kUA/L	<0.35
Brazil Nut IgE	<0.35 kUA/L	<0.35
Cashew	<0.35 kUA/L	0.44 ^
Pecan Nut IgE	<0.35 kUA/L	<0.35
Hazelnut IgE	<0.35 kUA/L	2.75 ^
Walnut (food) IgE	<0.35 kUA/L	<0.35

Resulting Agency [redacted]

Narrative Perforr

Concentration /Class Level Chart

kU/L	Level of Allergy	Class
<0.35	Absent	0
0.35-0.70	Low	1
0.70-3.50	Moderate	2
3.50-17.5	High	3
17.5-50.0	Very High	4
50-100	Very High	5
>100	Very High	6

Advantages

- Able to measure exact quantity of allergen-specific IgE
- High sensitivity, high negative predictive value
- Do not need to stop oral antihistamines

Limitations

- Low specificity, low positive predictive value (frequent false positives)
- More expensive than skin prick testing
- Limited range of allergens available

Should we consider food allergy panel testing in our clinic?

Food Allergy Panel Testing is NOT recommended.

The AAP, ACAAI, and AAAAI all recommend against food allergy panel testing or food specific IgE testing without a convincing IgE-mediated food allergy given frequent false positives and misdiagnosis of food allergy which can place a psychological and economic burden on the family

Food panel testing should not be performed in a child with eczema as food allergies do not cause dermatitis. If there is a question of a true IgE-mediated food allergy, they should be seen by a local allergist for additional testing.

Component Resolved Diagnostics

Measuring IgE to Specific Food Proteins of a Food Allergen

Advantages:

- Higher specificity (for Ara h 2 peanut, Cor a 9/14 hazelnut)
- Can help differentiate between primary food allergy and irrelevant IgE cross-reactivity

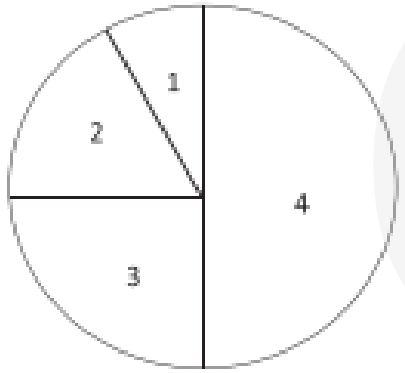
Limitations:

- Not as informative for foods beyond peanut, hazelnut
- Limited range of components available

Oral Food Challenge

Gold standard of diagnosis for food allergy

Used to confirm a food allergy if history and diagnostics are inconclusive or used to determine if a patient has outgrown a food allergy

Four Dose Protocol	Six Dose Protocol
Divide the serving as outlined below. Dose 1 = 1/12th of the total serving Dose 2 = 1/6th of the total serving Dose 3 = 1/4 of the total serving Dose 4 = 1/2 of the total serving 	Dose 1 = 1% of total dose Dose 2 = 4% of total dose Dose 3 = 10% of total dose Dose 4 = 20% of total dose Dose 5 = 30% of total dose Dose 6 = 35% of total dose

Bird JA, et al. Conducting an Oral Food Challenge: An Update to the 2009 Adverse Reactions to Foods Committee Work Group Report. J Allergy Clin Immunol Pract. 2020 Jan;8(1):75-90.e17.

Food Allergy Treatment

WHAT'S ALL THIS TALK ABOUT FOOD IMMUNOTHERAPY?

There is no ‘cure’ for food allergy currently

American Academy of Pediatrics
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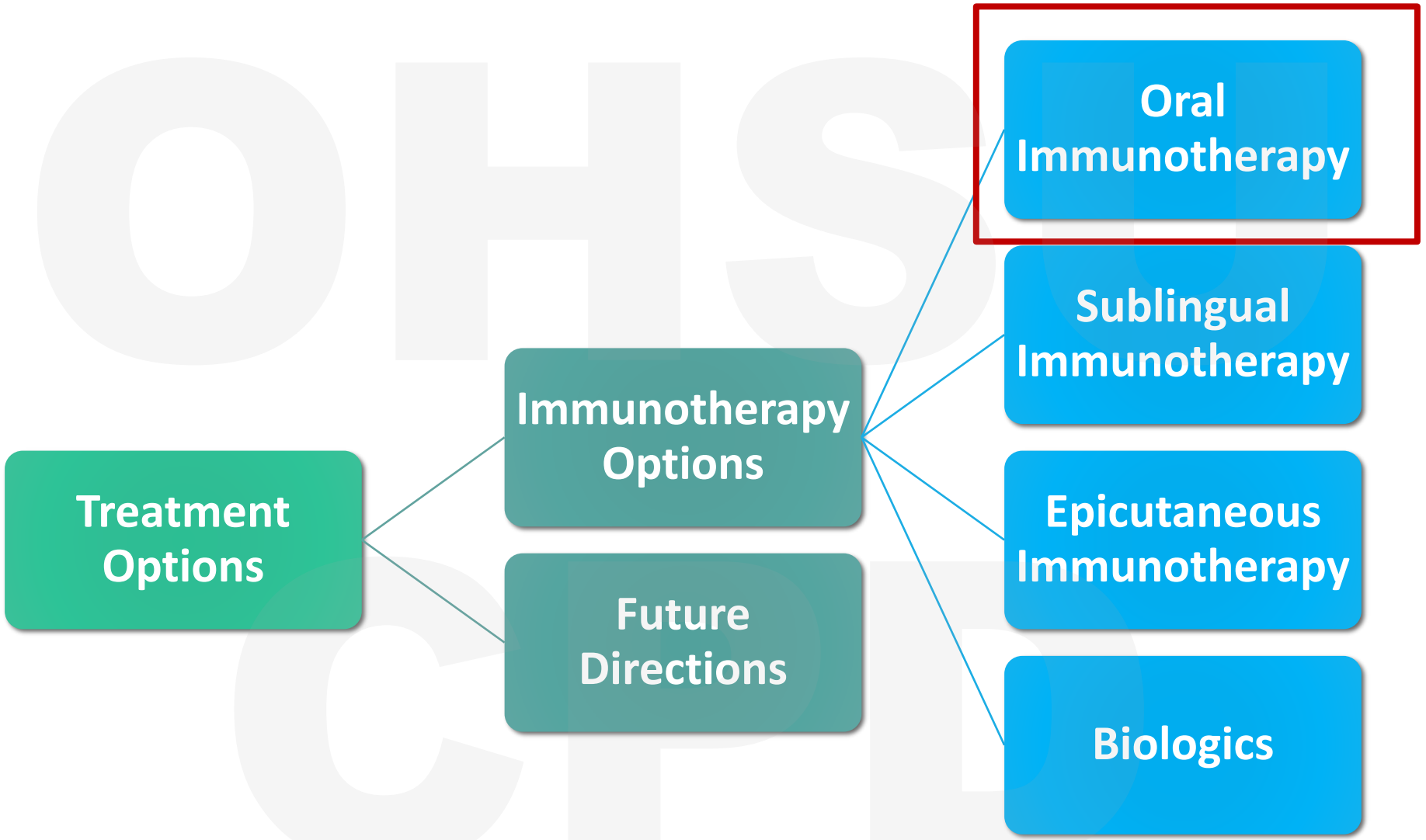
Acute Management of Anaphylaxis

- How do you treat?
  - EPI, EPI, EPI
  - There is not a role for corticosteroids in anaphylaxis
  - Oral antihistamine (only after epinephrine has been administered)
  - IV fluids
- Epinephrine Options
  - Epinephrine auto-injector
  - Intranasal epinephrine (now FDA approved)
    - 15-30 kg: one spray of 1 mg
    - >30 kg: one spray of 2 mg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Epicutaneous Immunotherapy
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Oral Immunotherapy (OIT)

Initial Day Escalation or Entry Challenge

Up dosing

(receive increasing amounts of protein every 2 weeks in office until maintenance reached)

Maintenance

(continue this dose daily)

OIT Efficacy & Safety

Defining desensitization vs tolerance (or sustained unresponsiveness)

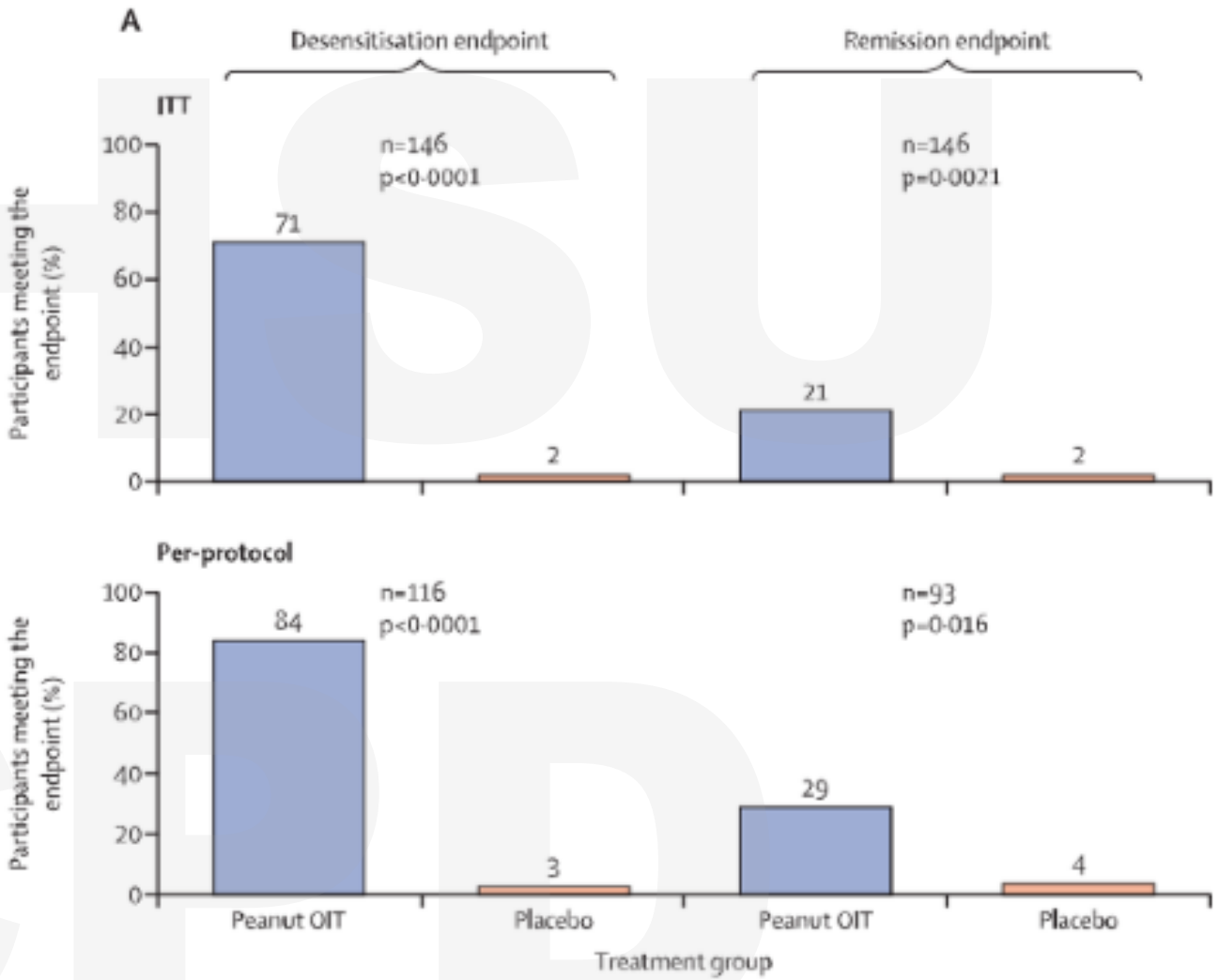
Studies have demonstrated ability of OIT to induce desensitization but not necessarily sustained unresponsiveness (or tolerance)

Maintenance dose for OIT has varied between studies

There is risk with increased adverse events, risk of anaphylaxis, and epinephrine use in those on OIT

OIT IMPACT Study

While the overall rate of remission for those on peanut OIT was 21%, remission was more common in those who were younger and had lower serum IgE levels.



Single Food vs Multi-Food OIT

PROS:

- Potentially lower treatment burden
- Single food challenge
- Easier to delineate side effect trigger
- May capitalize on food cross-reactivity (eg, cashew/pistachio, walnut/pecan)

CONS:

- Longer time if multiple foods needed
- Increased costs to family related to number of office visits

PROS:

- Less time in office/less office visits
- Reduced cost to family

CONS:

- Possible increased adverse symptoms
- Difficult to delineate the culprit food
- More complex for clinical staff/practice

ADP101 multifood oral immunotherapy for food-allergic patients: Harmony phase 1/2 randomized clinical trial

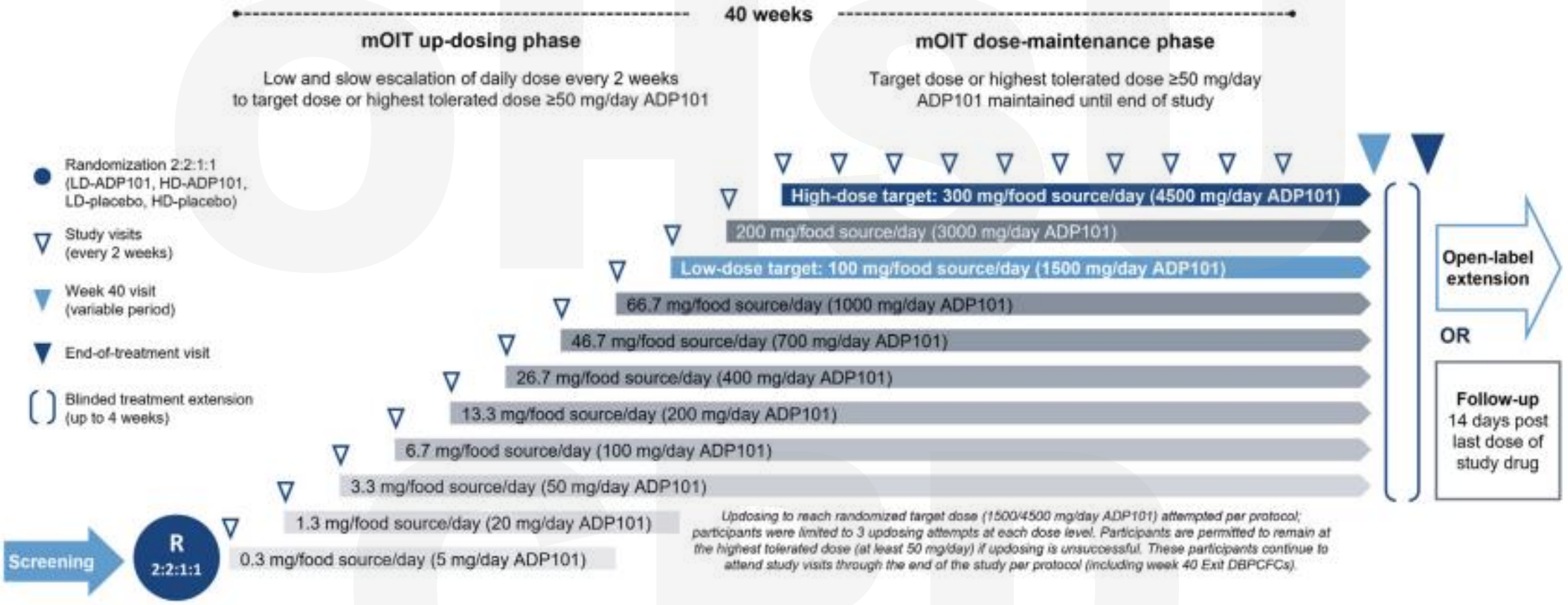


FIG 1. Harmony trial design and updosing schedule. Updosing was attempted every 2 weeks and permitted through Week 38. Dose (in mg) refers to protein content. *mOIT,* Multifood OIT; *R,* randomization.

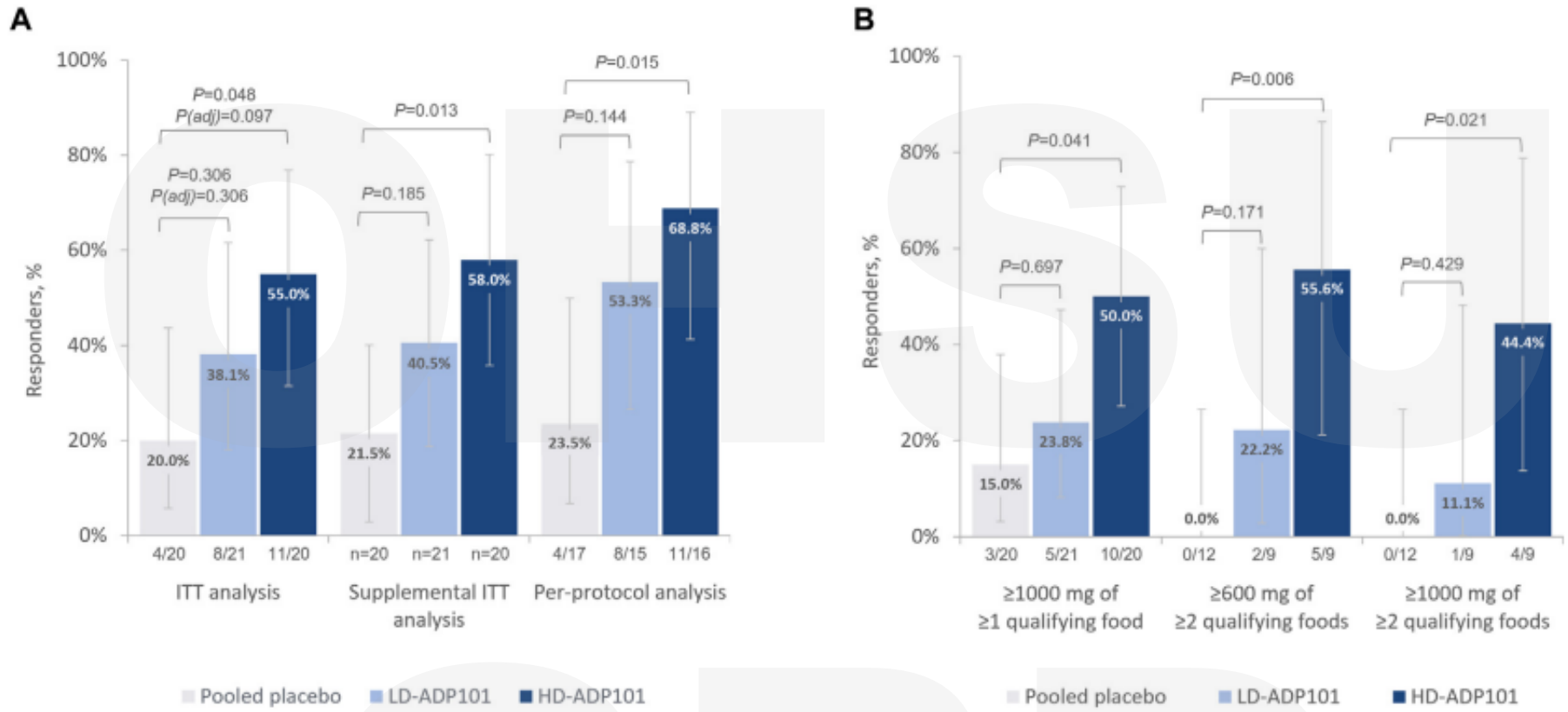


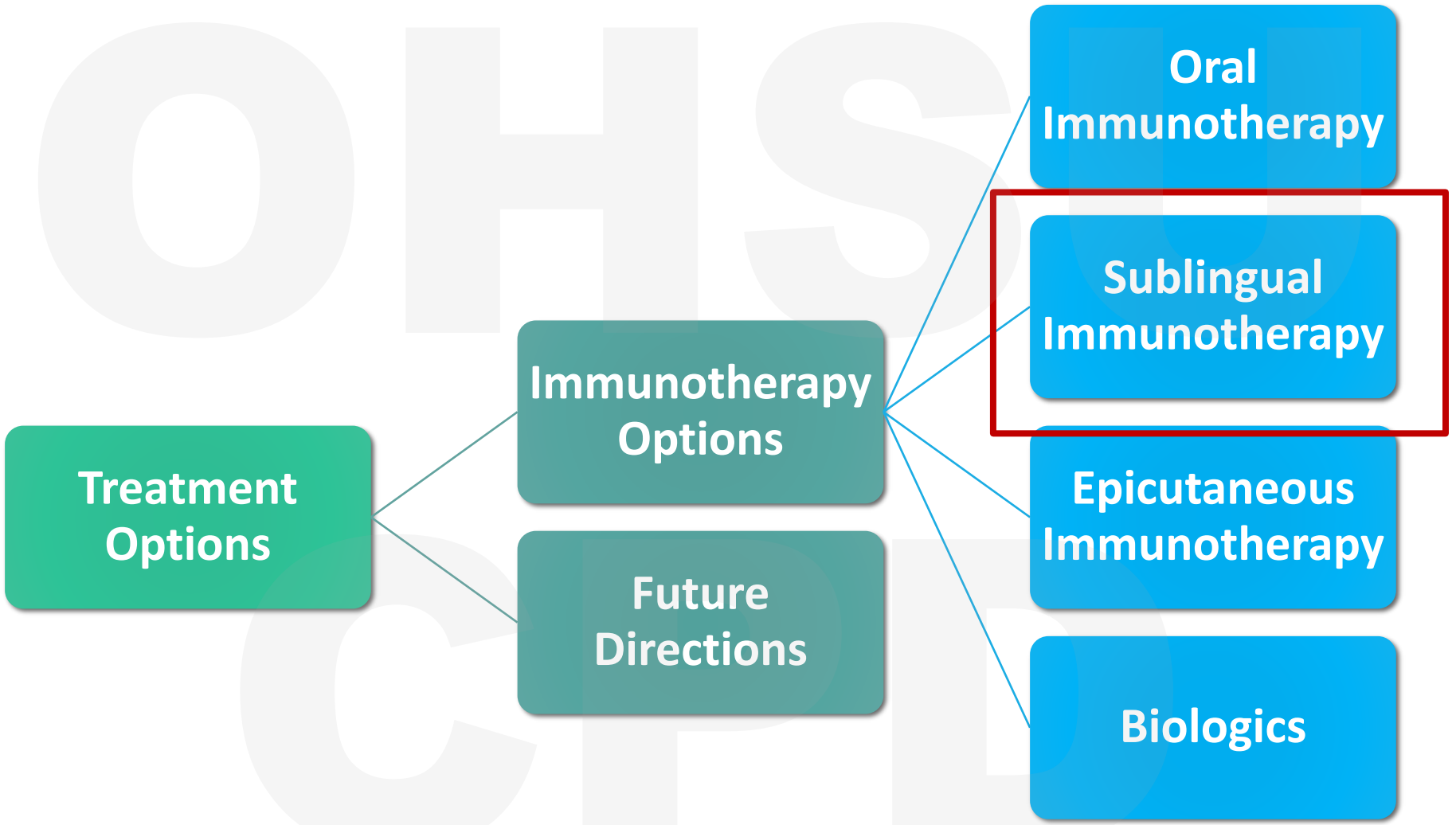
FIG 3. Response rates for primary and secondary efficacy endpoints (pediatric participants). **(A)** Primary efficacy endpoint; participants tolerating ≥600 mg of ≥1 qualifying food at Exit DBPCFC. ITT population was defined as all randomized participants. The primary endpoint was not met after adjustment for multiple comparisons. In supplemental ITT analysis, response status was imputed using multiple imputation for participants discontinuing for administrative reasons; all other discontinuations were considered nonresponse. Per-protocol population is defined as all participants from ITT population without major protocol deviations that affect statistical analysis, conducted as a sensitivity analysis of primary efficacy endpoint. **(B)** Secondary efficacy endpoints. *P* values are unadjusted unless otherwise stated, determined by Fisher exact test. Adjusted *P* values were determined by Simes global test with Holm procedure. Error bars depict 95% CI of proportion, estimated by Clopper-Pearson exact method. Dose (in mg) refers to protein content. *Adj,* Adjusted; *CI,* confidence interval.

OIT: Clinical Use & Limitations

FDA-approved peanut OIT product, Palforzia

Off-label OIT

Limitations of OIT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Sublingual Immunotherapy (SLIT)

SLIT is a daily treatment that is placed and held under the tongue for 2 minutes prior to swallowing

Like OIT, you build up every few weeks until you reach your maintenance dose and if you discontinue you will lose your protection over time

SLIT Efficacy

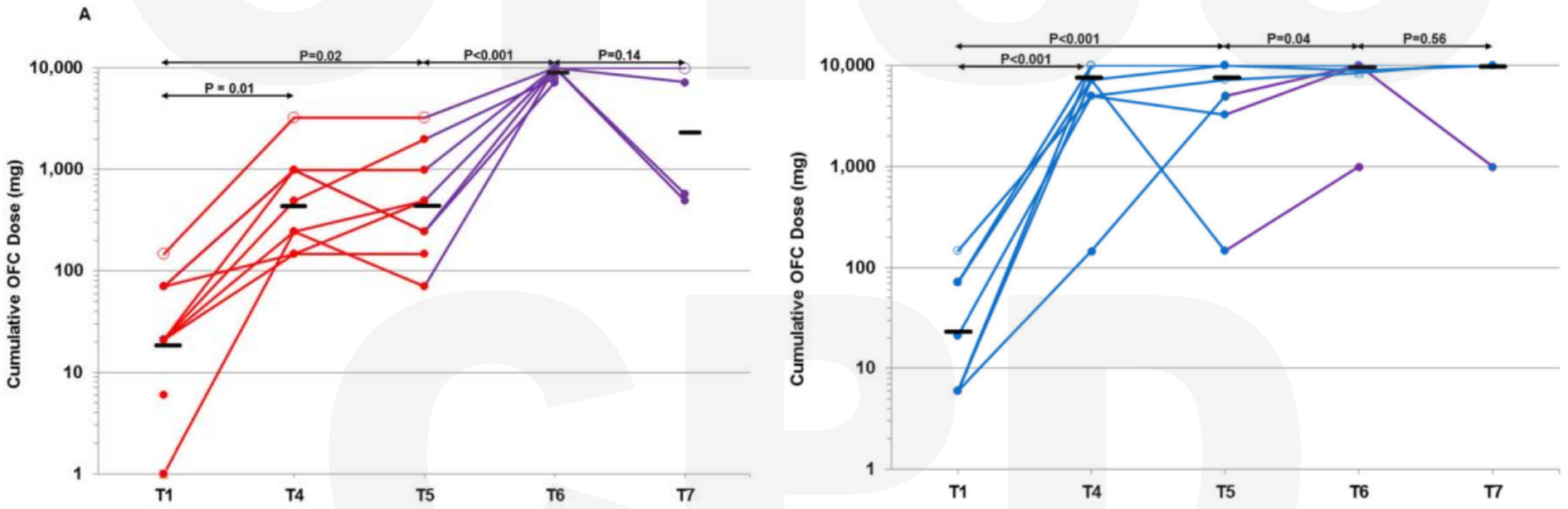
Studies have demonstrated that SLIT significantly increases reaction threshold to an allergen (desensitization) but unclear if results in sustained unresponsiveness over longer periods of time

Maintenance doses used are much less than those seen with OIT (eg, 2 mg/day compared to 300 mg/day or more)

High rate of compliance in studies (up to 95%)

SLIT Efficacy

Direct comparison of SLIT to OIT



Narisety SD, Frischmeyer-Guerrerio PA, Keet CA, et al. A randomized, double-blind, placebo-controlled pilot study of sublingual versus oral immunotherapy for the treatment of peanut allergy. *J Allergy Clin Immunol.* 2015;135(5):1275-82.e1-6. doi: 10.1016/j.jaci.2014.11.005.

SLIT Efficacy

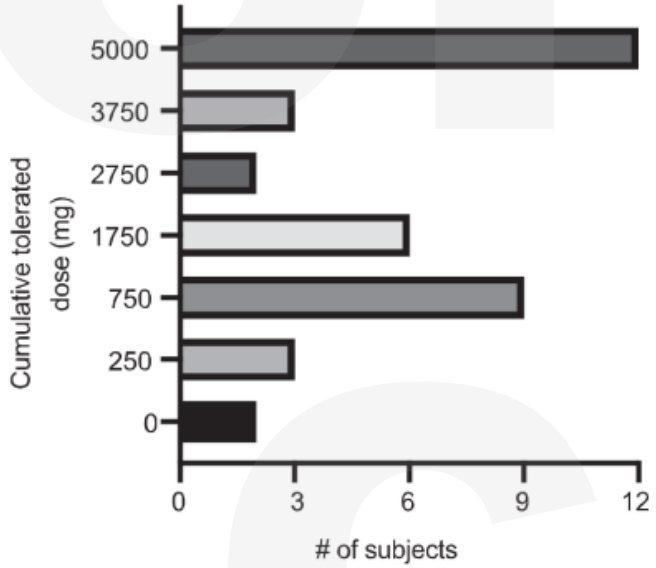


FIG 2. Desensitization thresholds during DBPCFC post-SLIT therapy: Maximum cumulative tolerated dose achieved for each subject during post-SLIT therapy 5000 mg DBPCFC.

During the DBPCFC, 32 participants (ITT 67%; PP 86.5%) successfully consumed 750 mg or more, 23 participants (ITT 48%, PP 62.2%) successfully consumed 1750 mg ore more.

12 participants (ITT 25%, PP 32.4%) tolerated 5000 mg without clinical symptoms.

Kim EH, Yang L, Ye P, et al. Long-term sublingual immunotherapy for peanut allergy in children: Clinical and immunologic evidence of desensitization. *J Allergy Clin Immunol.* 2019;144(5):1320-1326.e1. doi: 10.1016/j.jaci.2019.07.030.

Open-label study of the efficacy, safety, and durability of peanut sublingual immunotherapy in peanut-allergic children

Check for updates

Edwin H. Kim, MD, MS,[a] Corinne A. Keet, MD, PhD,[a] Yamini V. Virkud, MD, MPH,[a] Stacy Chin, MD,[b] Ping Ye, PhD,[a] Anusha Penumarti, PhD,[a] Johanna Smeekens, PhD,[a] Rishu Guo, MD, PhD,[a] Xiaohong Yue, MS, DDS,[a] Quefeng Li, PhD,[c] Michael R. Kosorok, PhD,[c] Michael D. Kulis, PhD,[a] and A. Wesley Burks, MD[a] *Chapel Hill, NC; and Silver Spring, Md*

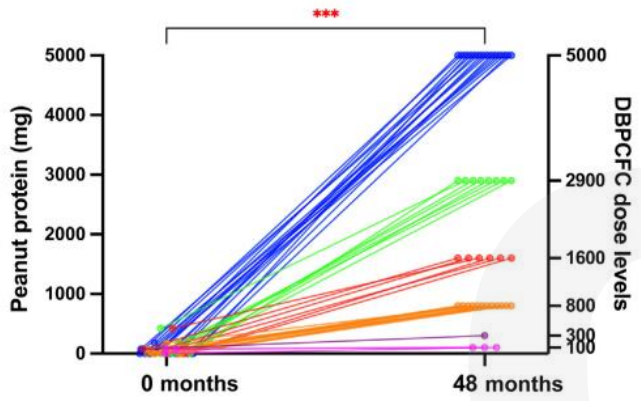


FIG 2. Mean SCD during DBPCFC for the PP group at baseline and after 48 months of peanut SLIT. Colors represent the different levels of SCD achieved during the 48-month DBPCFC. ***$P < .0001$.

SLIT Efficacy

- 47 peanut allergic children aged 1-11 years old treated with open-label peanut SLIT 4 mg for 48 months, then underwent 4000 mg DBPCFC
- The mean successfully consumed dose (SCD) during the DBPCFC increased from 48 to 2723 mg of peanut protein after SLIT ($P < .0001$), with 70% achieving clinically significant desensitization (SCD > 800 mg) and 36% achieving full desensitization (SCD 5000 mg). Modeled median time to loss of clinically significant desensitization was 22 weeks.

SLIT Safety

Shown to be well-tolerated with fewer side effects than OIT

Side effects are typically self-limited

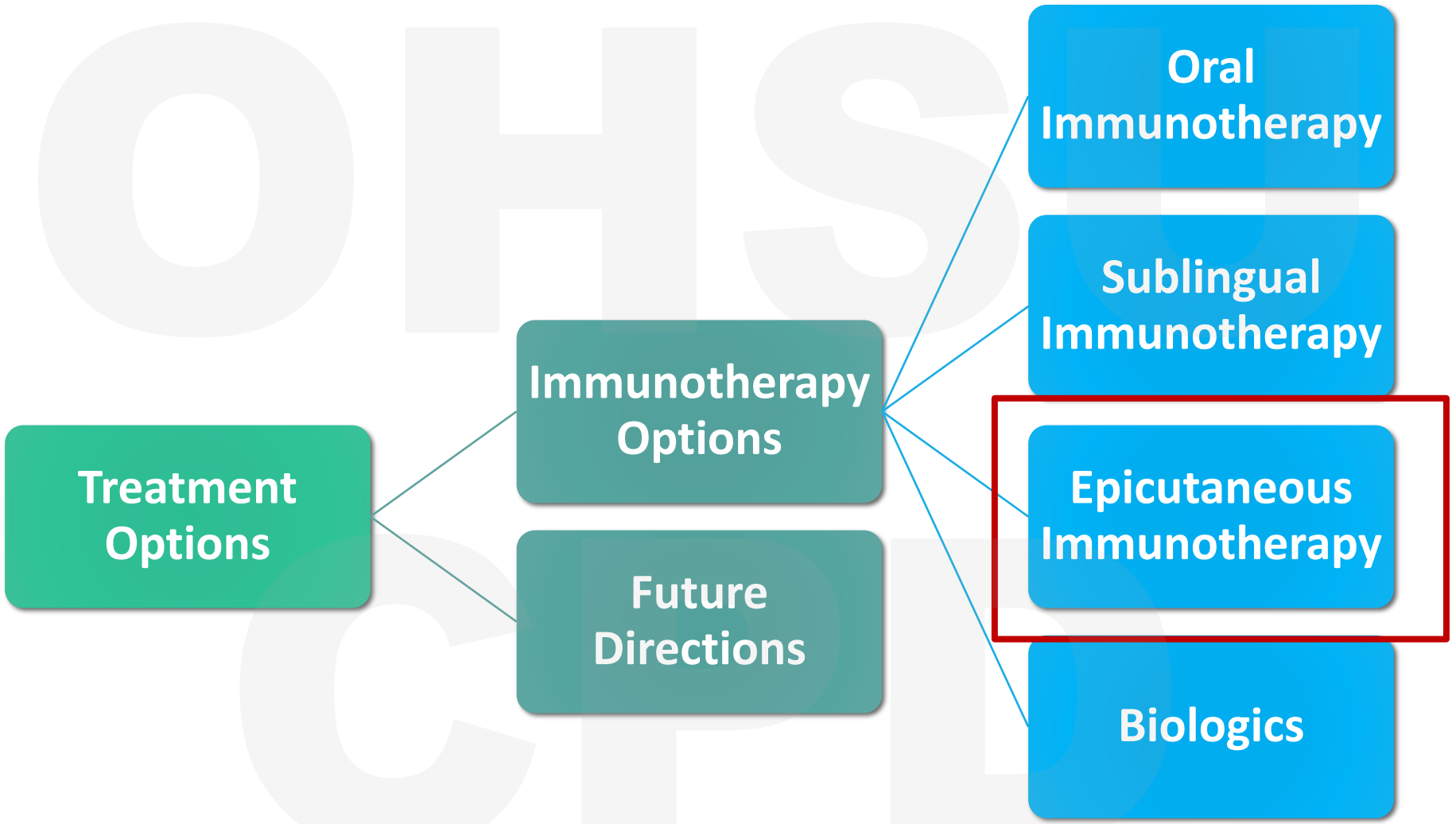
Most common symptom is **oropharyngeal itching**. Other less common symptoms include lip swelling, rhinorrhea, sneeze, wheezing, cough, and mild gastrointestinal distress

SLIT Clinical Use

Use of SLIT outside of clinical trials

Limitations/Obstacles to use of SLIT

https://dbclinic.com.sg/sublingual-immunotherapy-slit/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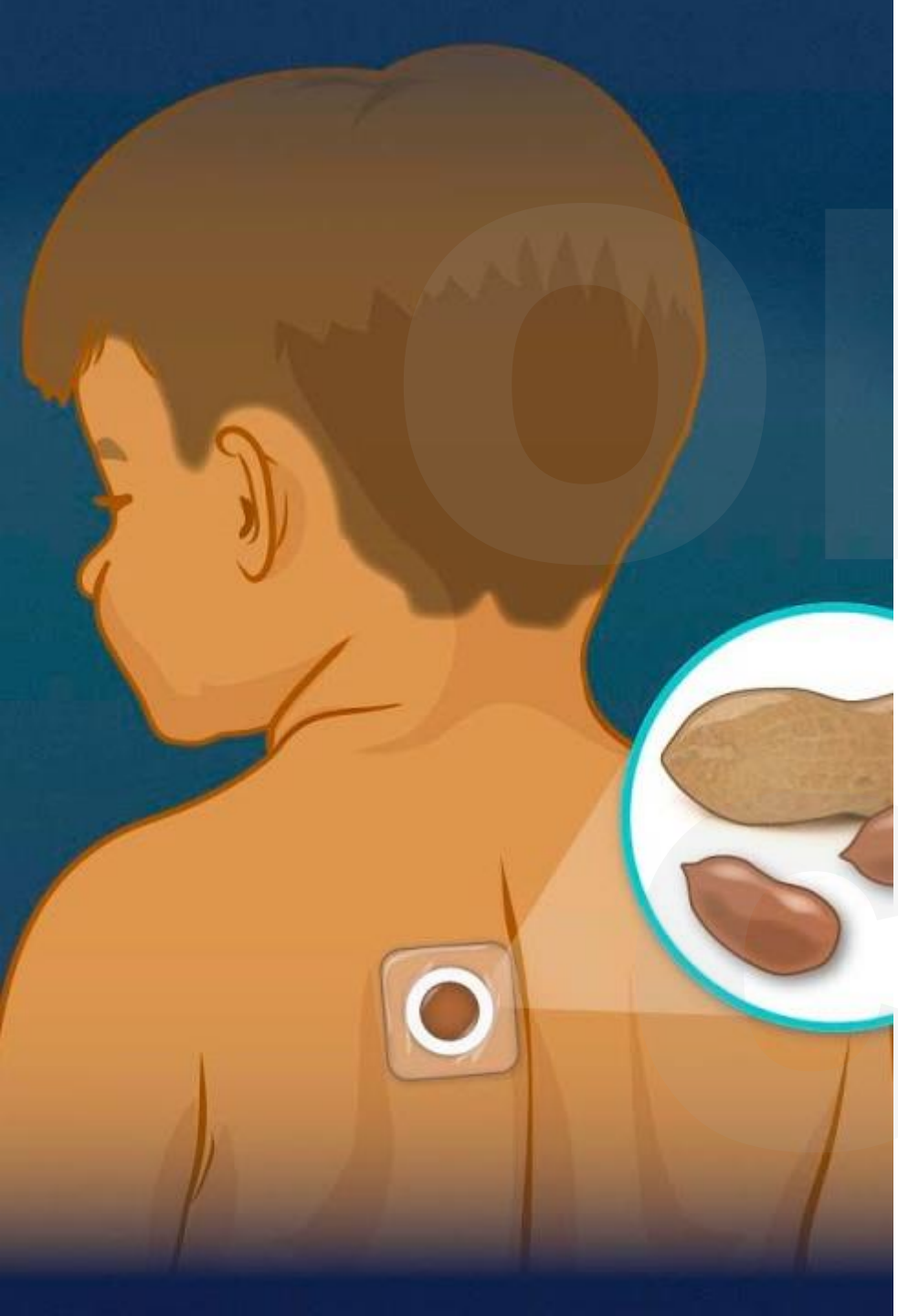
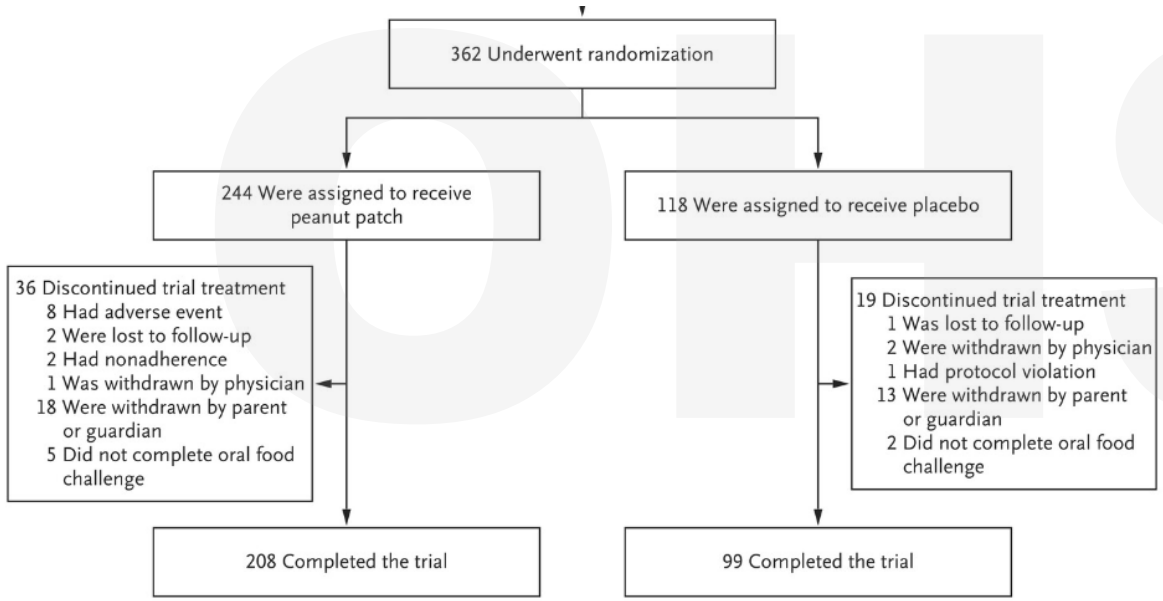


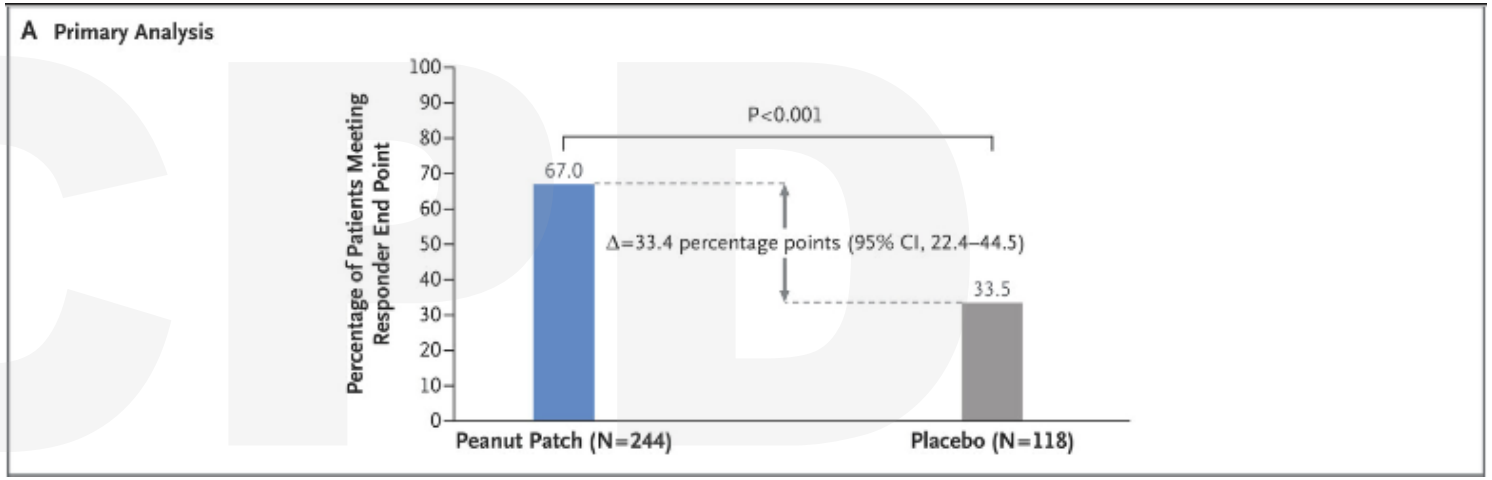
Epicutaneous Immunotherapy (EPIT)

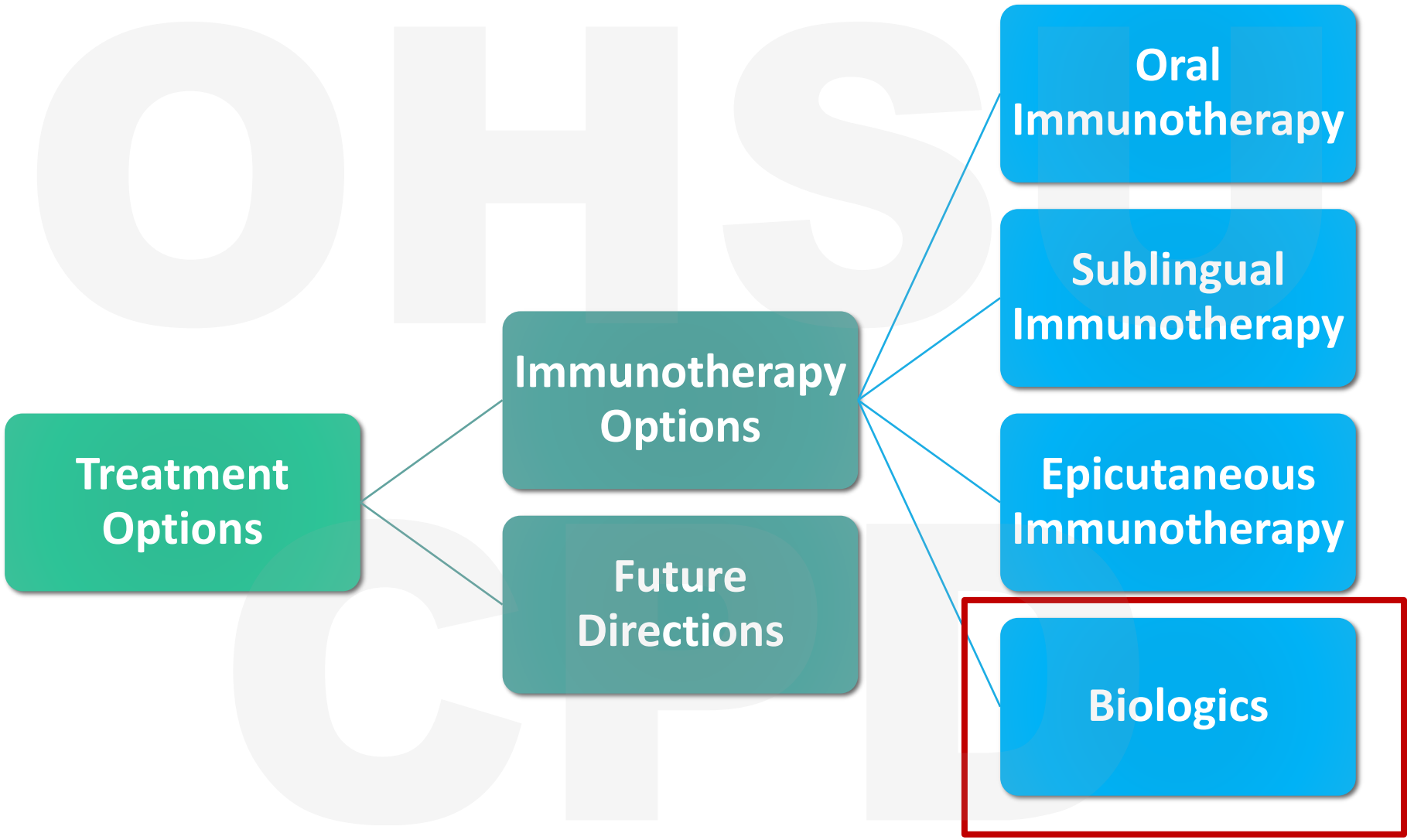
The peanut patch is intended to be worn all day on the back and replaced daily. Unlike OIT and SLIT which require up dosing, during the first few weeks using the patch, you slowly increase the time it is worn.

It has been shown to be safe and effective in Phase 3 clinical trials

Currently still being studied and not FDA approved


362 Underwent randomization
244 Were assigned to receive peanut patch
118 Were assigned to receive placebo
36 Discontinued trial treatment
8 Had adverse event
2 Were lost to follow-up
2 Had nonadherence
1 Was withdrawn by physician
18 Were withdrawn by parent or guardian
5 Did not complete oral food challenge
19 Discontinued trial treatment
1 Was lost to follow-up
2 Were withdrawn by physician
1 Had protocol violation
13 Were withdrawn by parent or guardian
2 Did not complete oral food challenge
208 Completed the trial
99 Completed the trial


A Primary Analysis
Percentage of Patients Meeting Responder End Point
100
90
80
70
60
50
40
30
20
10
0
P<0.001
67.0
Δ=33.4 percentage points (95% CI, 22.4–44.5)
33.5
Peanut Patch (N=244)
Placebo (N=118)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A CLOSER LOOK AT THE ROLE OF OMALIZUMAB

Omalizumab

Monoclonal antibody that binds free IgE, lowers free IgE levels, and causes FcεRI receptors on basophils and mast cells to be downregulated

Requires first 3 injections to be performed in clinic with observation given small risk of anaphylaxis

Dosing depends on indication

It is used for asthma, chronic hives, nasal polyps, and now, food allergy

Omalizumab facilitates rapid oral desensitization for peanut allergy

Andrew J MacGinnitie [1], Rima Rachid [1], Hana Gragg [2], Sara V Little [1], Paul Lakin [2],
Antonella Cianferoni [3], Jennifer Heimall [3], Melanie Makhija [4], Rachel Robison [4]

Omalizumab in IgE-Medi[illegible] Systematic Review and M[illegible]

Torsten Zuberbier [1], Robert A Wood [2], Carsten
R Sharon Chinthrajah [5], Margitta Worm [6], Anto
Alexandra F Santos [9], Xavier Jaumont [10], Paolo

Affiliations + expand

PMID: 36529441 DOI: 10.1016/j.jaip.2022.11.0

[illegible]tnev Roonev [3].

Omalizumab for the Treatment of Multiple Food Allergies

R.A. Wood, A. Togias, S.H. Sicherer, W.G. Shreffler, E.H. Kim, S.M. Jones, D.Y.M. Leung, B.P. Vickery, J.A. Bird, J.M. Spergel, A. Iqbal, J. Olsson, M. Ligueros-Saylan, A. Uddin, A. Calatroni, C.M. Huckabee, N.H. Rogers, N. Yovetich, J. Dantzer, K. Mudd, J. Wang, M. Groetch, D. Pyle, C.A. Keet, M. Kulis, S.B. Sindher, A. Long, A.M. Scurlock, B.J. Lanser, T. Lee, C. Parrish, T. Brown-Whitehorn, A.K.R. Spergel, M. Veri, S.D. Hamrah, E. Brittain, J. Poyser, L.M. Wheatley, and R.S. Chinthrajah

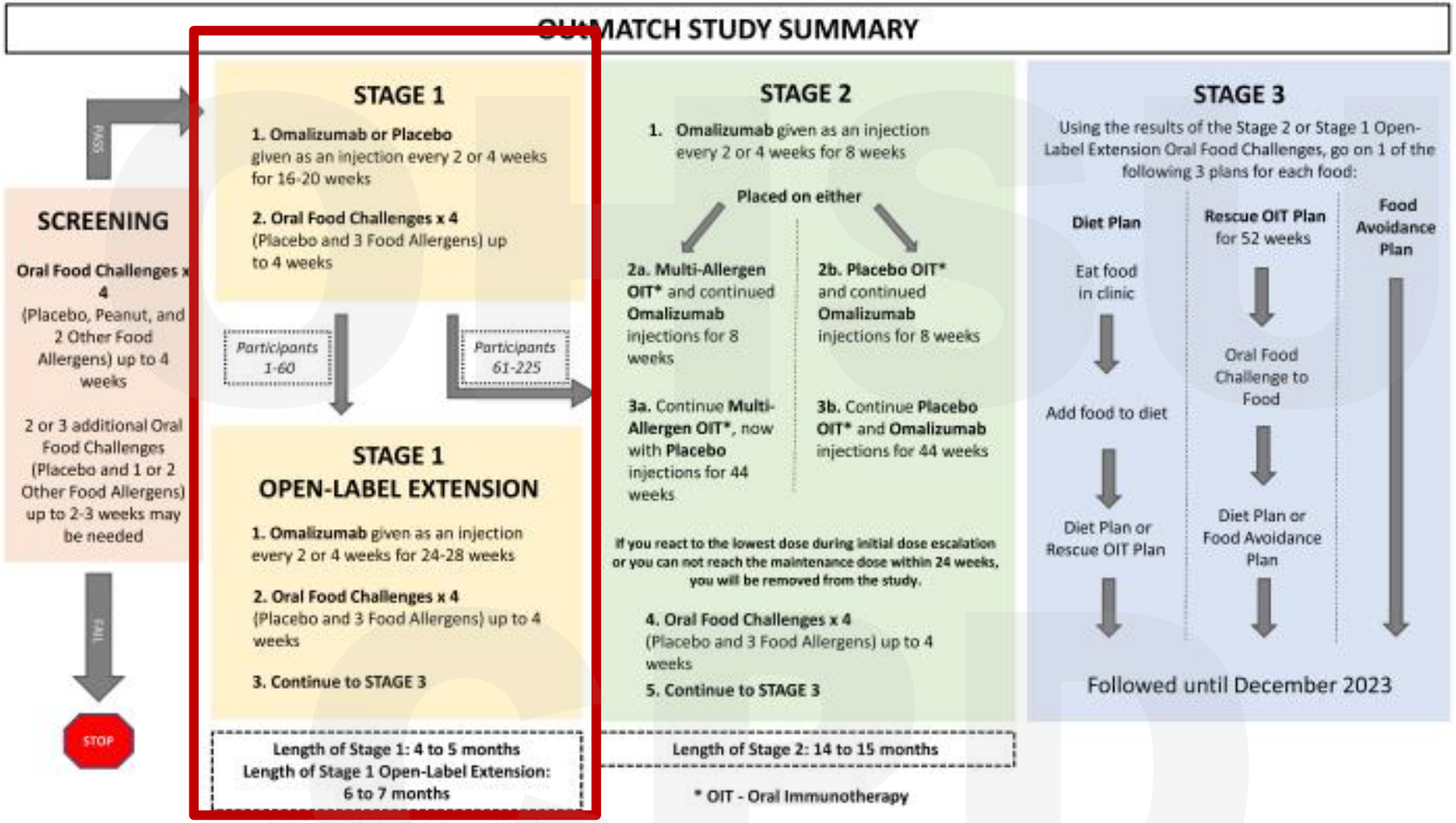


FIG 1. Study summary schematic.

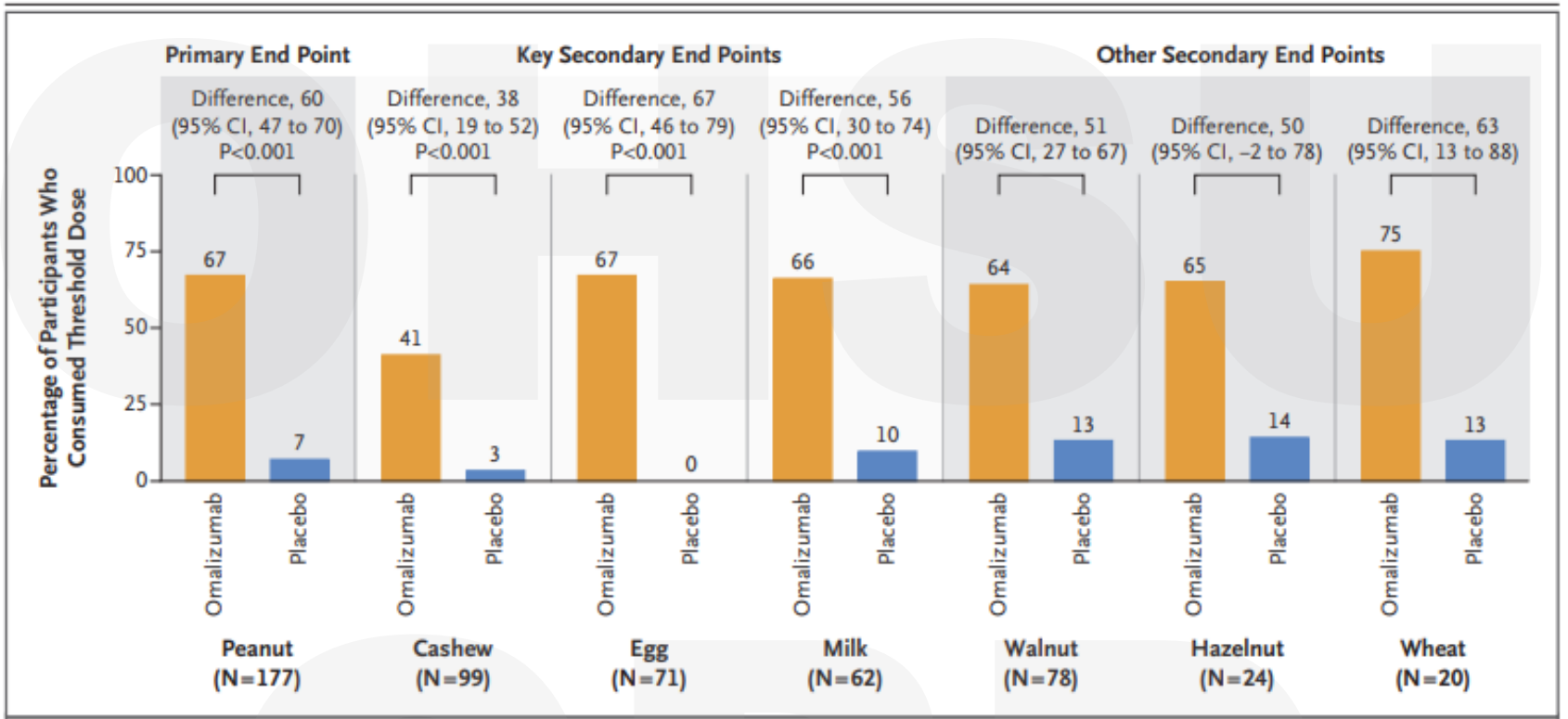


Figure 1. Successful Consumption of Prespecified Threshold Dose at Week 16.

Shown are the percentages of participants in the two groups who consumed the prespecified threshold doses without dose-limiting symptoms during food challenges at the end of the first stage of the trial; these food challenges were started at week 16 and were conducted during separate visits spanning up to a 4-week period. The prespecified threshold dose of peanut protein was a single dose of at least 600 mg; for cashew, egg, milk, walnut, hazelnut, and wheat protein, the prespecified threshold was a single dose of at least 1000 mg. The 95% confidence intervals for the differences were calculated with the use of exact unconditional confidence limits. The P values for the primary and key secondary end points are unadjusted, two-sided values derived from Fisher's exact test.

FDA NEWS RELEASE

FDA Approves First Medication to Help Reduce Allergic Reactions to Multiple Foods After Accidental Exposure

Monday, March 3, 2025

Omalizumab treats multi-food allergy better than oral immunotherapy

High rate of oral immunotherapy side effects in NIH trial explains superiority of omalizumab.

Today, the U.S. Food and Drug Administration approved Xolair (omalizumab) injection for immunoglobulin E-mediated food allergy in certain adults and children 1 year or older for the reduction of allergic reactions (Type I), including reducing the risk of anaphylaxis, that may occur with accidental exposure to one or more foods. Patients who take Xolair must continue to avoid foods they are allergic to. Xolair is intended for repeated use to reduce the risk of allergic reactions and is not approved for the immediate emergency

Leading Us to the Question…

HOW AND WHEN DO WE USE OMALIZUMAB IN OUR CLINIC?

Xolair

PROS

- Not food specific
- Intermittent dosing
- Efficacy, Safety
- Control of comorbidities

CONS

- Requirement of long-term use
- Cost
- Dosing restrictions (eg IgE levels, if too high, exclude certain patients from treatment

Patient Considerations

- Age
- Reaction History
- Anxiety, Quality of Life
- Specific Food Allergies
- Additional factors that make avoidance difficult
- Comorbidities

How do we know it’s working?

Other Biologics?

- Dupilumab (anti IL4 receptor alpha monoclonal antibody) was studied as a monotherapy in pediatric patients with peanut allergy; results were not promising for desensitization; it is now being studied in combination with omalizumab
- Ligelizumab (anti IgE monoclonal antibody): NCT05678959 an extension study to evaluate the long-term safety and efficacy of ligelizumab in particiants who have completed a ligelizumab Phase III study in food allergy. Participants will receive up to 3 years treatment with ligelizumab after which they will enter a follow-up period for 16 weeks.

Let's Summarize

FDA approved therapies:

Palforzia: Peanut OIT product ages 1-17 years (approved in 2020)

Omalizumab: Multiple food allergies ages 1 year and up; injection medication (approved in 2024)

'Off-Label' Therapies

OIT: Safe and effective; available in many clinics across the US and globally; available for many different allergens; age depends on clinic

SLIT: Safe and effective for peanut in research studies; available in some private practices for many different allergens; less adverse symptoms than OIT

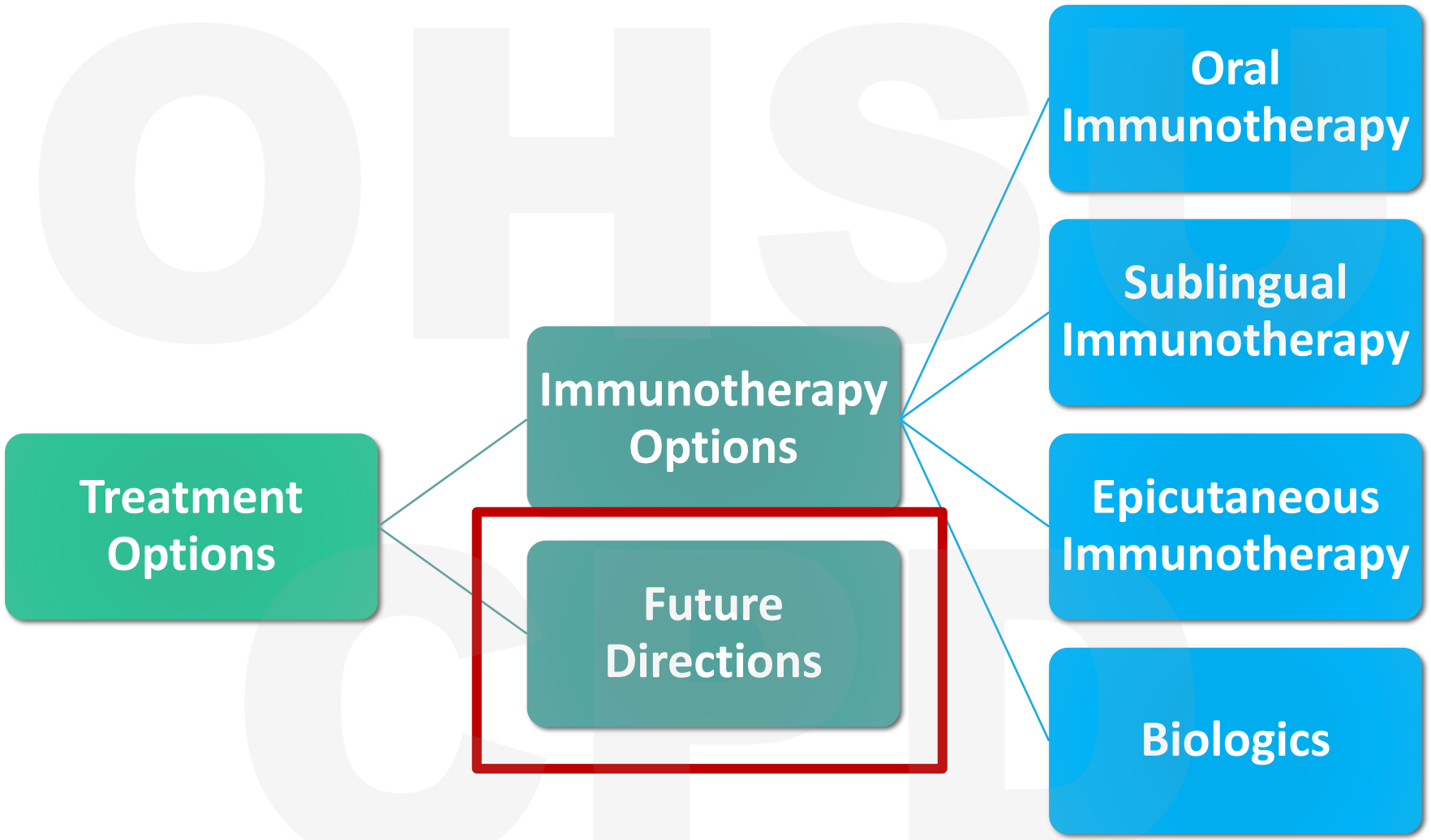
Still under study:

EPIT: Peanut patch has shown some level of effectiveness but currently undergoing safety trials as they reformulated the patch

Food allergy treatment is not one size fits all

Patient Cases

- 14-year-old female with peanut and tree nut allergies that is on peanut OIT (current maintenance dose 1000 mg). She is a volleyball player and has practices several times per week. She has been experiencing frequent symptoms with her OIT doses including hives, rash, and difficulty breathing that she treats with antihistamines. She hates doing her OIT doses and it is difficult for her to be consistent.
- 8-year-old male with peanut allergy and asthma that is currently well-controlled. Parents are interested in immunotherapy as he has had several accidental exposures resulting in trips to the ER. He has a full schedule with soccer and basketball and doesn't get home until later at night on some days. He hates shots and is adamant about that.
- 18-month-old female with milk, egg, and peanut allergies. She is tolerating baked egg and baked milk. Parents are concerned about her peanut allergy and want to know if there are any treatments to give her protection against peanut exposure. She is in daycare during the day but home with both parents at night.
- 20-year-old college student with multiple food allergies that has had 4 ED visits over the last year due to accidental exposures at the dining hall and when out with friends. They are looking for something to help lower their risk of reactions.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Other Therapies Being Studied…

- Other pharmacologic therapies:
  - Oral JAK inhibitor abroctinib (NCT05069831)
  - BTK inhibitor remibrutinib (NCT05432388)
  - Infusions of nano-particle coated peanut protein (NCT05250856)
- Oral encapsulated fecal microbiota transplant in peanut allergic patients (NCT02960074)

Take Home Points

- While there is no cure for food allergies, we do have immunotherapy options that can help to 'desensitize' a patient or provide protection from accidental exposures; these include OIT, SLIT, and Xolair
- OIT, SLIT, and EPIT are for single allergens in general, although you can do multi-food OIT/SLIT. Xolair is an injection for multiple food allergens with dosing based on weight and total IgE
- Dupilumab has been studied but was not shown to effective as a monotherapy or adjunct therapy to OIT
- Food allergy treatment is not one size fits all. You need to consider your patient and what stage of life they are in. Their treatment may change as they get older and have different needs. It's all about shared decision making.
- Other potential treatments are being studied including JAK and BTK inhibitors, as well as oral encapsulated fecal microbiota transplant

Thank you!
Questions?

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