Food Allergy with an episode of "What is happening in the world of peanut allergy? (I hear you can cure it!!)"

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Disclosure

- ✓ Aimmune is a pharmaceutical company founded by allergists. I was a paid consultant with them from 2018 – 2019. I am no longer involved with Aimmune in any way.

Financial Disclosure

Current Relationships:
Speaker/Consultant – Boehringer Ingelheim
Speaker – Grifols Pharmaceuticals
Speaker/Consultant – Meda Pharmaceuticals
Consultant – Aimmune Pharmaceuticals
Advisory Board - AstraZeneca

LEARNING OBJECTIVES

- 1. Discuss the epidemiology, natural history and prevalence of food allergy.
- 2. Describe important aspects of history required to evaluate patients with adverse reactions to foods
- 3. Educate on interpretation of skin testing and in vitro testing in the evaluation of food allergy
- 5. Briefly discuss other allergic conditions, such as atopic dermatitis and oral allergy syndrome
- 6. Review the acute and long term management of food allergic patients
- 7. Discuss the appropriate indications for referral to an allergist

Definitions

- ***Food allergy:*** any adverse health effect caused by a specific immune response (immune-mediated) that occurs reproducibly on exposure to offending food

- ***Food allergens:*** specific components (proteins) of food that cause specific immune reactions

Sampson HA, et al. J Allergy Clin Immunol 2014;134:1016-25

Types of immunologic food reactions

IgE-mediated	Mixed IgE/Non IgE	Non-IgE Mediated Cell-Mediated
Systemic (anaphylaxis)	Eosinophilic Esophagitis (EoE)	Food Protein-Induced Enterocolitis (FPIES)
Oral Allergy Syndrome	Eosinophilic Gastritis	Food Protein-Induced Enteropathy or Prococolitis
Asthma/Rhinitis	Eosinophilic Gastroenteritis	Dermatitis herpetiformis
Urticaria	Atopic dermatitis	Contact dermatitis

Ige-mediated food allergy

- IgE-mediated food allergy involves release of mediators from mast cells and can induce reactions and anaphylaxis

- Diagnosis of immune-mediated food allergy requires both ***clinical symptoms*** upon exposure to the offending food, as well as ***positive testing***

Boyce JA, et al. J Allergy Clin Immunol 2010; 126: S18-19

Symptoms

- Cutaneous
  - *flushing, urticaria, angioedema, pruritis, atopic dermatitis*
- Gastrointestinal
  - *abdominal pain, nausea, vomiting, diarrhea*
- Respiratory
  - *cough, wheezing, shortness of breath, laryngeal edema*
- Cardiovascular
  - *hypotension, arrythmias, tachycardia*
- Neurological
  - *syncope, lightheadedness*

ORAL ALLERGY SYNDROME

- ***Oral Allergy Syndrome:*** patients develop symptoms (itchy mouth and throat, tingling) following ingestion of certain foods

- Plant proteins cross-react with airborne allergens

- Birch: apple, potato, pear, carrot, celery
  Ragweed: melon, banana,
  avocado

Sampson HA, et al. J Allergy Clin Immunol 2014; 134:1016-1025

Birch

Apple Peach Plum Pear Cherry Apricot Almond
Rosaceae

Carrot Celery Parsley Caraway Fennel Coriander Aniseed
Apiaceae

Soybean Peanut
Fabaceae (old Leguminosae)

Hazelnut
Betulaceae

Ragweed

Cantaloupe Honeydew Watermelon Zucchini Cucumber
Cucurbitaceae

Banana
Musaceae

Mugwort

Celery Carrot Parsley Caraway Fennel Coriander Aniseed
Apiaceae

Bell pepper
Solanaceae

Black pepper
Piperaceae

Mustard Cauliflower Cabbage Broccoli
Brassicaceae

Garlic Onion
Liliaceae

Orchard

Cantaloupe Honeydew Watermelon
Cucurbitaceae

Peanut
Fabaceae (old Leguminosae)

White potato Tomato
Solanaceae

Timothy

Swiss chard
Amaranthaceae

Orange
Rutaceae

ATOPIC DERMATITIS

- ***Atopic Dermatitis:*** Chronic inflammatory skin disorder that causes pruritis and can lead to lichenification and/or secondary infections
    - Infants: face, extensor surfaces
    - Older children/adults: flexor surfaces, neck, upper trunk
    - Food allergy can play a role in 10-30% of patients

prevalence of food allergy

- True prevalence can be difficult to measure
- Approximately 6% of children, 4% of adults
- Largely over-reported by the public - up to 25%

- According to 2013 study by CDC, food allergies among children increased by 50% between 1997 and 2012

- So why are food allergies on the rise?
  - ▪ “Hygiene hypothesis”
  - ▪ Epigenetics

Branum AM, et al. Pediatrics 2009; 124: 1549-55
Boyce JA, et al. J Allergy Clin Immunol 2010; 126: S11-S13
Sampson HA, et al. J Allergy Clin Immunol 1997; 103: 981-95

Risk factors

- Family history
- Atopic dermatitis
- Other allergic conditions

- Up to 75% of patients with food allergy have evidence of another allergic condition

Liem JJ, et al. Allergy, Asthma & Clinical Immunology 2008; 4: 144-149
Sicherer SH, et al. J Allergy Clin Immunol 2000; 106: 53-56
Hourihane JO, et al. British Medical Journal 1996; 313: 518-521
Boyce JA, et al. J Allergy Clin Immunol 2010; 126: S12-13

Common food allergens

natural history of Food allergy

- Most common foods are peanut, treenuts, milk, egg, soy, wheat, fish, shellfish
- - Sesame on the rise
- - Anything containing proteins can be an allergen source
- Most children with milk, soy, egg and wheat allergy will eventually tolerate the food
- Outgrowing peanut and tree nut significantly less common
- Shellfish/fish allergy can be later onset

Boyce JA, et al. J Allergy Clin Immunol 2010; 126: S13
Sastre J. Clinical and Experimental Allergy, 2010;40:896-904

When to suspect food allergy?

- Any local or systemic reaction following ingestion of food
- Infants with moderate to severe atopic dermatitis
- Infants with persistent atopic dermatitis despite appropriate therapy
- Patients with eosinophilic GI disease

Sampson HA, et al. J Allergy Clin Immunol 2014; 134: 1016-1025

- **Which of the following is most useful in diagnosing food allergy?**

a) Skin prick testing
b) Serum-specific IgE testing
c) Clinical history
d) None of the above

- **Which of the following is most useful in diagnosing food allergy?**

a) Skin prick testing
b) Serum-specific IgE testing
c) Clinical history
d) None of the above

Pathophysiology- Why doesn't everyone have a food allergy?

- "The intestine has an unenviable task: to identify and respond to a constant barrage of environmental stimuli that can be both dangerous and beneficial. The proper execution of this task is central to the homeostasis of the host,… this system generates a robust T cell–mediated responsiveness called **oral tolerance**."

Mechanisms of immune tolerance relevant to food allergy

Brian P. Vickery, MD,[a] Amy M. Scurlock, MD,[b] Stacie M. Jones, MD,[b] and A. Wesley Burks, MD[a] *Durham, NC, and Little Rock, Ark*

Antigen Handling by the GI Tract

Physiologic barriers

- Breakdown of ingested antigens:

  Gastric acid, pepsins, pancreatic/intestinal enzymes
  Block penetration of ingested antigens:
  - Intestinal mucus coat (Glycocalyx)
  - Microvillus membrane

Immunologic barriers

- Block penetration of ingested antigens:
  - Antigen specific secretory IgA (sIgA) in gut lumen
- Clear antigens penetrating GI barrier:
  - Serum antigen specific IgA and IgG →complexes cleared by phagocytes

Rationale for Food Allergies

- **Infants and young children:**
  - Immaturity of gut barrier
  - ↑ Intestinal permeability
  - ↑ Gastric pH
  - ↓ Activity of the proteolytic enzymes (till 2 years)
  - ↓ Secretion of IgA
  - ↑ T cell reactivity towards food antigens

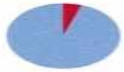
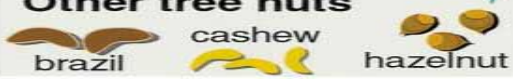
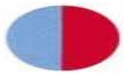
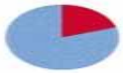
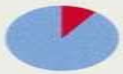
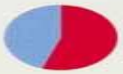
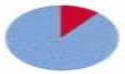
- **Adults:**
  - ↓ Basal acid has been shown to lead to de novo production of sIgE to food in 15% of adult

Middleton's Allergy. 7th Edition

Why might people react sometimes and not others?

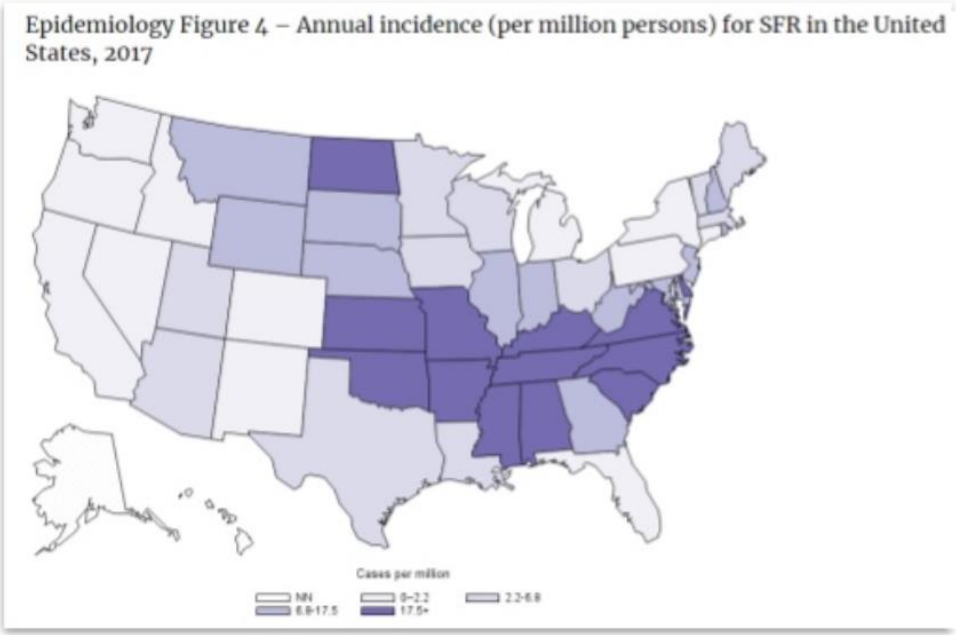
- Factors that **decrease antigen absorption**:
  - Increased stomach acidity
  - Presence of other food

- Factors that **increase antigen absorption:**
  - Decreased stomach acidity
  - Alcohol ingestion
  - ASA / NSAIDS
  - Exercise
  - Infection (virus)

If Allergic to:	Risk of Reaction to at Least One:	Risk:
A legume* 	Other legumes 	5% 
A tree nut 	Other tree nuts 	37% 
A fish* 	Other fish 	50% 
A shellfish 	Other shellfish 	75% 
A grain* 	Other grains 	20% 
Cow's milk* 	Beef 	10% 
Cow's milk* 	Goat's milk 	92% 
Cow's milk* 	Mare's milk 	4% 
Pollen 	Fruits/vegetables 	55% 
Peach* 	Other Rosaceae 	55% 
Melon* 	Other fruits 	92% 
Latex* 	Fruits 	35% 
Fruits 	Latex 	11% 

Alpha Gal – the story of the tick that keeps on biting!

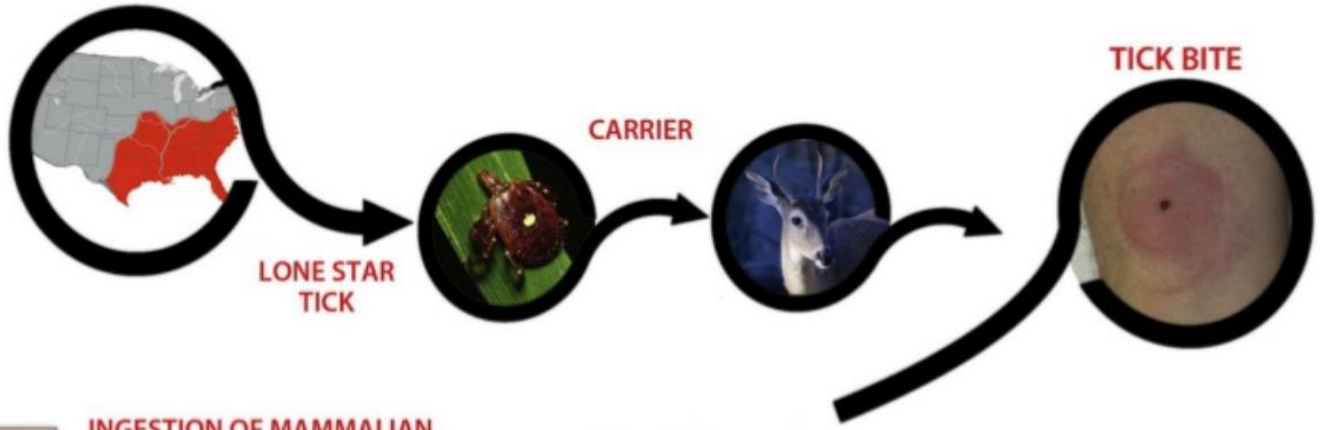
Incidence of Rocky Mountain spotted fever



Distribution of Lone Star Tick

Tripathi A. et al. J Allergy Clin Immunol Pract 2014;2:259-65
https://www.cdc.gov/rmsf/stats/index.html

Summary of alpha-gal sensitization leading to clinical symptoms of red meat allergy



INFUSION OF CETUXIMAB

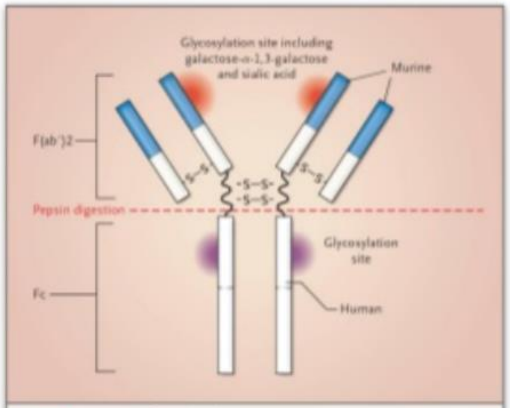
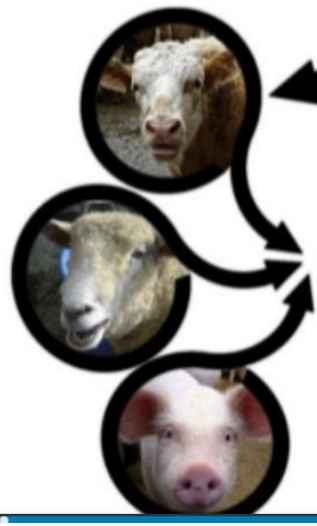


Figure 2. **Structure of Cetuximab.**
The amino acid sequence of cetuximab has potential glycosylation sites at Asn43 of the light chain and at Asn88 and Asn299 of the heavy chain. The sugars on the Fab portion include galactose-α-1,3-galactose and the sialic acid *N*-glycolylneuraminic acid. In contrast, the glycosylation site at Asn43 is not glycosylated, and glycosylation of the Fc portion of the heavy chain includes only oligosaccharides that are commonly present on human proteins.[17,18] S–S denotes a disulfide bond.

INGESTION OF MAMMALIAN PRODUCTS

IgE to alpha-gal (1-3 months)



2-6 hours

Urticaria
Angioedema
Anaphylaxis

J Allergy Clin Immunol 2015;135:589-96.

CLINICAL HISTORY

- **Obtain detailed history of reaction:**
  - Symptoms
  - Timing
  - Amount of food
  - Route of exposure (ingestion, contact, inhalation)
  - Raw vs. cooked; Baked vs. whole

Boyce J, et al. JACI 2010;126:S1-58
Simonte S, et al JACI 2003; 112: 180-2
Sampson HA, et all. J Allergy Clin Immunol 2001; 891-896

Clinical history

- Previous tolerance
- Presence of risk factors
- Introduction of other high risk foods
- Concurrent exercise, meds, alcohol

Physical exam

- Assess for other disorders, especially comorbid allergic conditions

- Physical Exam findings may include:
  - Conjunctivitis, allergic shiners
  - Nasal turbinate hypertrophy, nasal polyps, post nasal drainage
  - Atopic dermatitis/eczema
  - Urticaria, angioedema
  - Wheezing, cough

Boyce J, et al. JACI 2010;126:S1-58
Sampson HA, et al. JACI 2014; 134:1016-25

Diagnostics

- Skin Prick Testing (SPT)
- Allergen Specific Serum Ige (sIgE) Testing
- Food elimination
  - Can be useful in non IgE-mediated FA and EoE
- Oral food challenges
  - Gold standard

Not recommended:

- Patch testing
- Allergen IgG panels
- Applied kinesiology/muscle response testing
- Hair analysis
- Electrodermal testing

Boyce J, et al. J Allergy Clin Immunol 2010; 126: S1-S58
Sampson HA, et al. J Allergy Clin Immunol 2014; 134: 1016-1025

Skin prick testing

- **Skin prick testing (SPT):**
- ▪ Diluted allergen is applied on the surface of the skin and area of test is observed for 15 minutes
- ▪ Measures IgE bound to cutaneous mast cells by causing mast cell degranulation on surface of the skin which causes local reaction
- ▪ Measure wheal and flare
- ▪ Wheal ≥ 3 is considered positive test
- ▪ Larger skin tests do not necessarily correlate with severity

Skin prick testing

- Indicates presence of IgE antibody but does not always correlate with reactivity
- Interpret results using skin testing and history

- Sensitivity: ~90%
- Specificity: ~50%

- A *negative* skin prick test can essentially exclude IgE mediated food allergy 95%

Boyce J, et al. J Allergy Clin Immunol 2010; 126: S1-S58
Sampson HA, et al. J Allergy Clin Immunol 2014; 134: 1016-1025

Serum IgE testing

- Detects food-specific IgE antibodies in the serum
- Presence reflects sensitization which does not always correlate with clinical allergy
- Sensitivity: ~90%
- Specificity: ~50%
- Using specified 95% predictive values, they can often be more useful than SPT
- Results are in Classes 1-6, your report will go into this
- Broad serum IgE panels are not recommended, they don't tell you what you want!

ORAL FOOD CHALLENGE

- Double blind placebo controlled food challenge is the gold standard for diagnosis of food allergy
- Single-blind or open-food challenges may also be done

- If no reaction (negative challenge) then FA can be ruled out

- If SPT or sIgE testing negative but history highly suggestive = perform oral food challenge

Serum component testing

- Each allergen source contains multiple allergenic proteins (components)
- Component testing helps to identify whether sensitization is due to primary allergen, or cross-reactivity
- Helps to evaluate risk of reaction on exposure, and sometimes severity
- Available and widely used for peanut, milk, egg; Other foods the clinical utility remains unclear

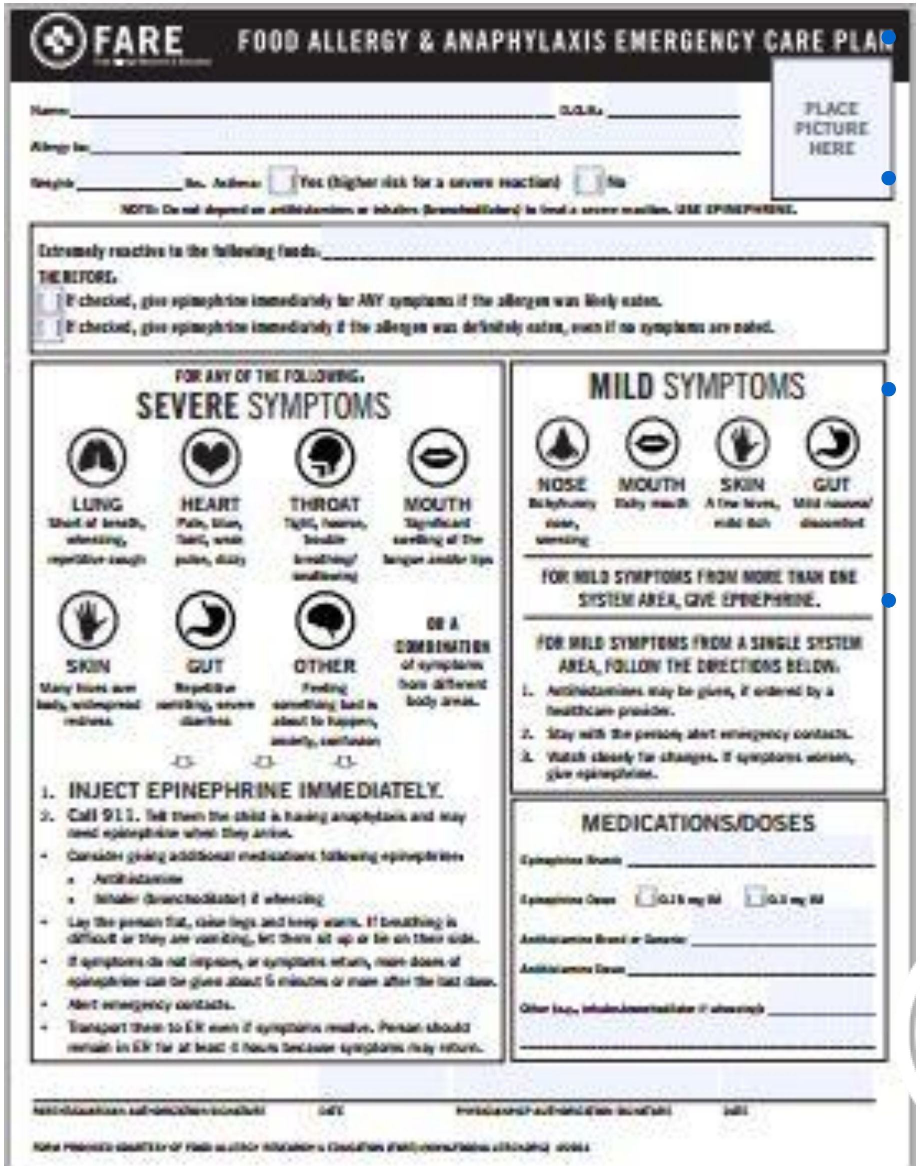
Sastre J. Clin and Exper Allergy, 2010; 40:896-904
Burks AW, et al. Ann Allergy Asthma Immunol 2014; 112: 200-206

Management of food allergy

- Dietary avoidance if allergy is confirmed
  - Complete vs. Partial avoidance
  - Elemental/Amino Acid formulas
- Epinephrine auto-injector
- Nutritional counseling
- Education on reading food labels
- Cross-contamination risk
- Periodic re-evaluation and follow up testing
- Food Allergy Action Plan

Sampson HA. J Allergy Clin Immunol 2004;113:805-19

Food allergy action plan


FARE
FOOD ALLERGY & ANAPHYLAXIS EMERGENCY CARE PLAN

PLACE PICTURE HERE

FOR ANY OF THE FOLLOWING:
SEVERE SYMPTOMS

LUNG
HEART
THROAT
MOUTH
SKIN
GUT
OTHER
OR A COMBINATION of symptoms from different body areas.

1. INJECT EPINEPHRINE IMMEDIATELY.
2. Call 911.

MILD SYMPTOMS

NOSE
MOUTH
SKIN
GUT

FOR MILD SYMPTOMS FROM MORE THAN ONE SYSTEM AREA, GIVE EPINEPHRINE.

FOR MILD SYMPTOMS FROM A SINGLE SYSTEM AREA, FOLLOW THE DIRECTIONS BELOW:

MEDICATIONS/DOSES

- Should be renewed annually by physician
- Discuss and educate when to administer epinephrine based on patient's history of severity
- Helps physician, family, school nurse, daycare staff be more informed
- FARE (Food Allergy Research & Education) Website:
  www.foodallergy.org

Rapid recognition and treatmenT

Food Allergies

FIRST major change – give ‘em nuts!

- ✓First question – can we REDUCE the number of kids with peanut allergies?

Peanut Allergy

✓Peanut allergy is an increasingly troubling global health problem, which affects between 1-3% of children in many westernized countries.

✓Prevalence has more than quadrupled in the past 13 years, growing from

0.4% in 1997 to 1.4% in 2008 to more than 2% in 2010.

✓Peanut allergy has become the leading cause of anaphylaxis and death related to food allergy in the United States.


THE GAMEWELL CO. NEWTON MASS
BEWARE
OF
PEANUT

"Avoid high allergen foods in pregnant moms, during breastfeeding and avoid some these foods in infants and children till 3 years of age – specifically milk introduction at age 1, egg introduction at age 2 and nuts at age 3.

-AAP Statement 2004

"Although solid foods should not be introduced before 4 to 6 months of age, there is no current convincing evidence that delaying their introduction beyond this period has a significant protective effect on the development of atopic disease."

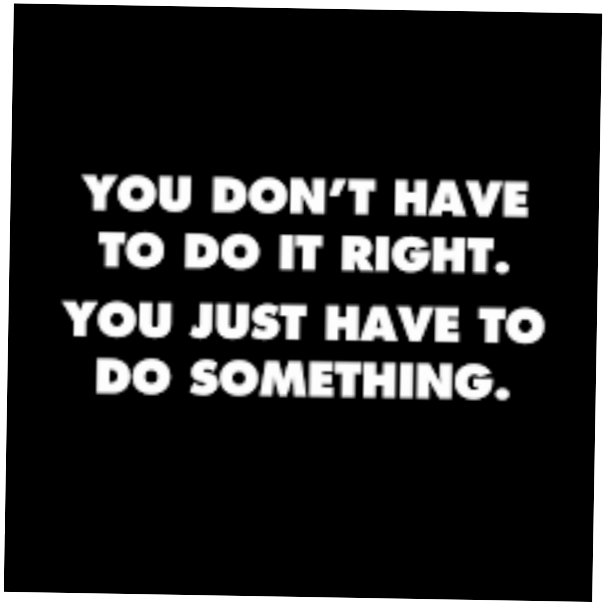
-AAP Statement 2010

"Recommendation is to add peanuts to the diet of high risk infants

-AAP Statement 2017

Primary Prevention


DO
SOME
THING


YOU DON'T HAVE
TO DO IT RIGHT.
YOU JUST HAVE TO
DO SOMETHING.


DO SOMETHING
DO ANYTHING

Observational Data

Koplin et al, JACI 2010

- ✓ 2589 children followed and skin tested / challenged with egg at 1 year; comparing introduction at 4-6 months vs later
- ✓ Much higher (OR of 3.4) risk of egg allergy with delayed egg introduction

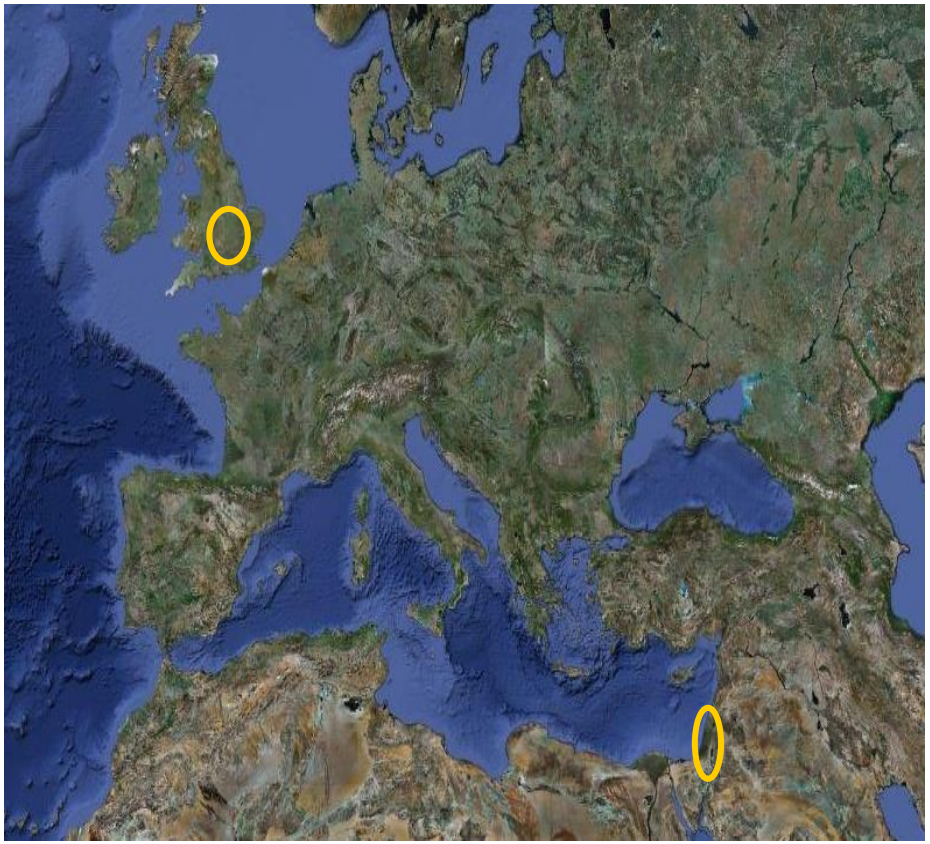
Can early introduction of egg prevent egg allergy in infants?
A population-based study.Koplin JJ, Osborne NJ, Wake M, et al JACI 2010

Observational Data

- ✓ Jewish children in UK had 10X the risk of their Jewish counterparts in Israel
- ✓ Similar ancestory
- ✓ UK children typically do not consume peanut-based foods in first year of life
- ✓ Israel children have peanut-based products introduced by 7 months of age
- ✓ Hypothesis – early peanut is protective

Peanut Consumption in Infants at Risk for Peanut Allergy:NEJM Feb 2015

Early consumption of peanuts in infancy is associated with a low prevalence of peanut allergy

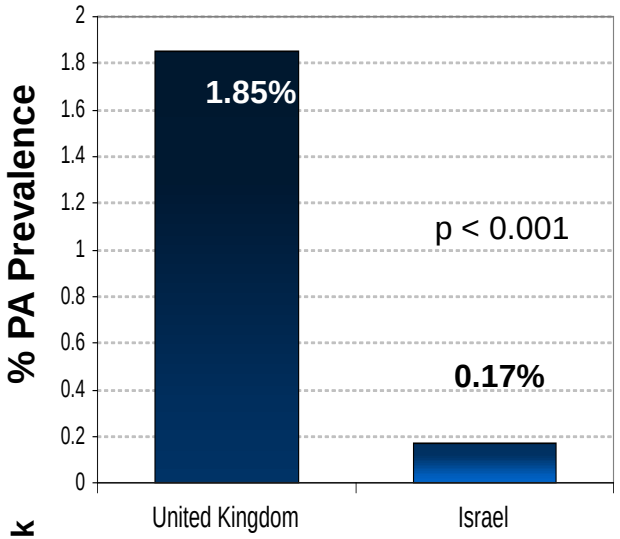


Methods

- ✓ 5171 Jewish school children in UK and 5615 Jewish school children in Israel were compared for peanut allergies and atopy.
- ✓ Questionnaire based assessment of peanut allergy validated by challenges.

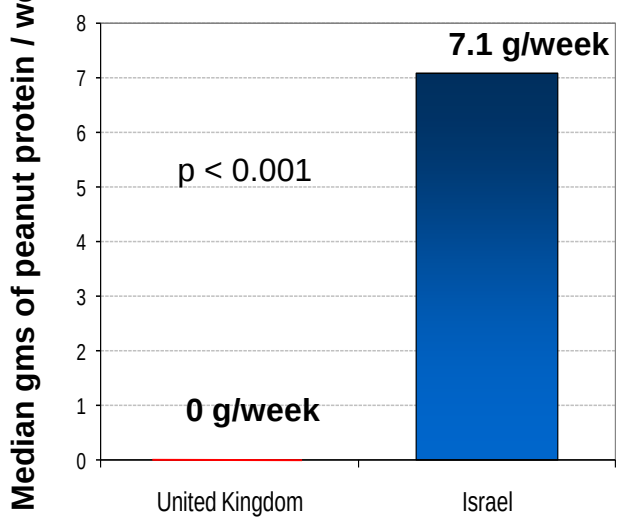
Early consumption of peanuts in infancy is associated with a low prevalence of peanut allergy. Du Toit G[1], Katz Y et al. J Allergy Clin Immunol 2008; 122: 984-91.

Early consumption of peanuts in infancy is associated with a low prevalence of peanut allergy



Prevalence of Peanut Allergy in Children 4-18yrs

United Kingdom	**5171**
Israel	**5615**



Peanut Protein Consumption 8-14 month

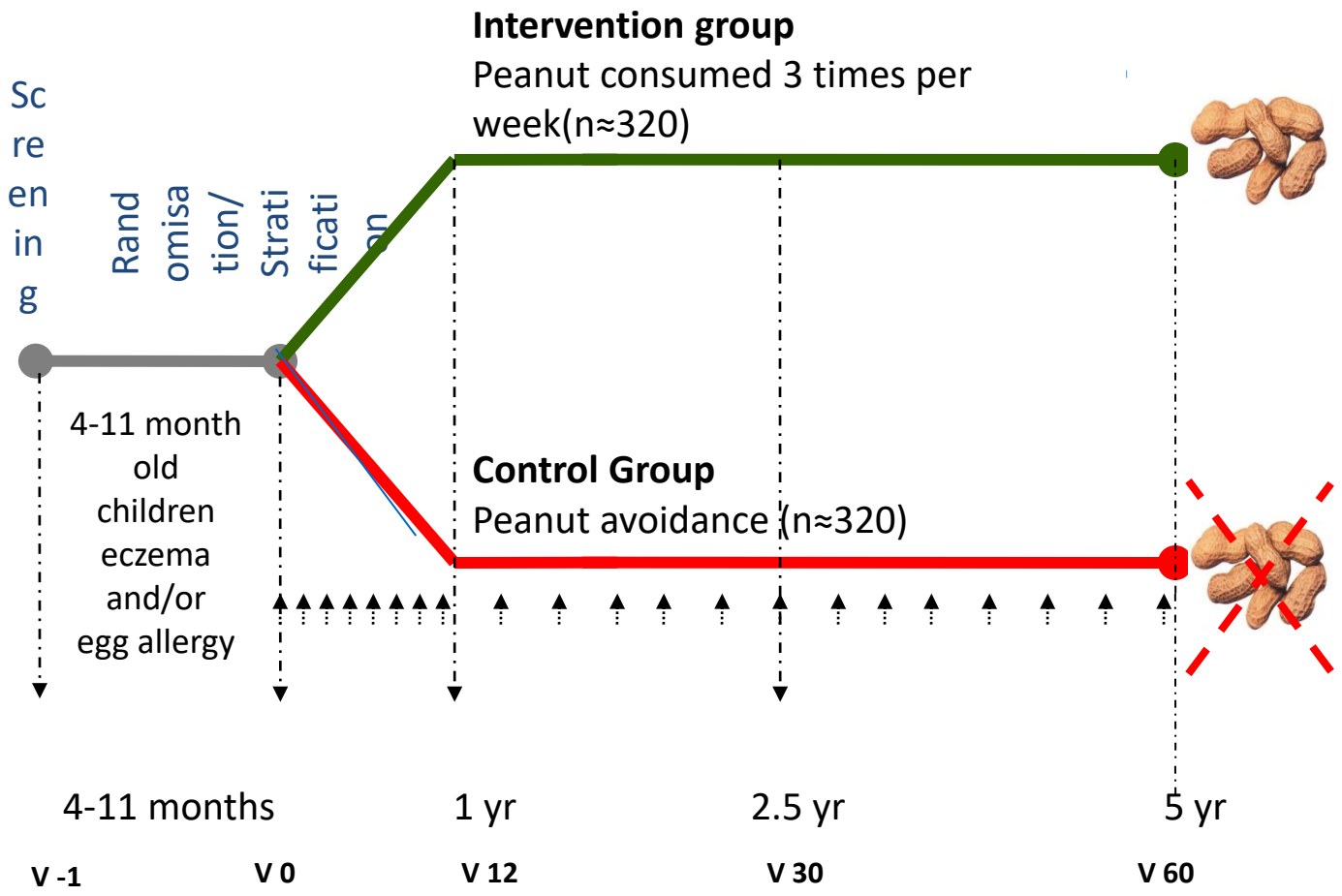
Du Toit G et al. J Allergy Clin Immunol 2008; 122: 984-91.


NORMAL
PEANUT
BUTTER

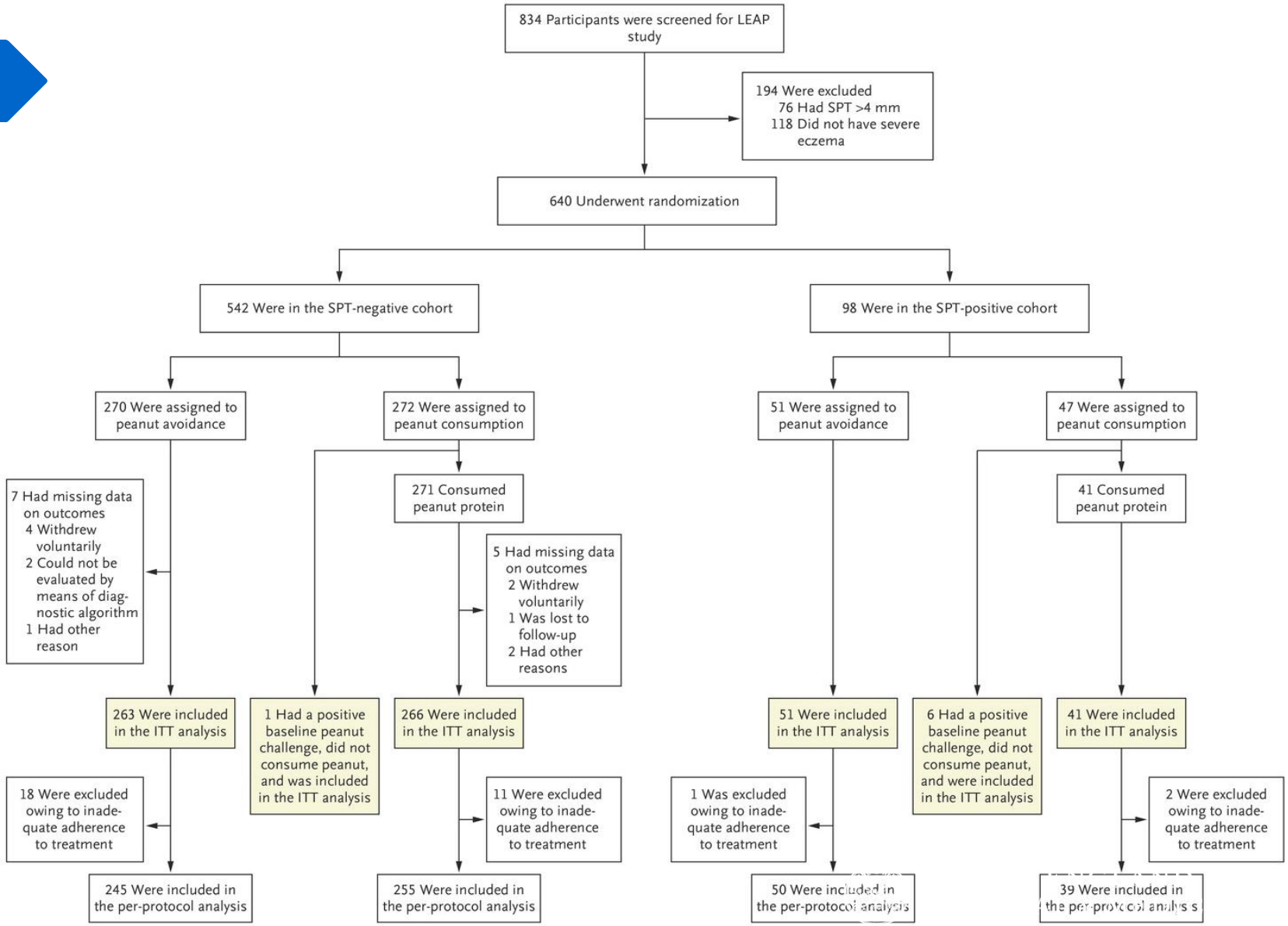
LEAP Study

Learning **E**arly **A**bout **P**eanut Allergies

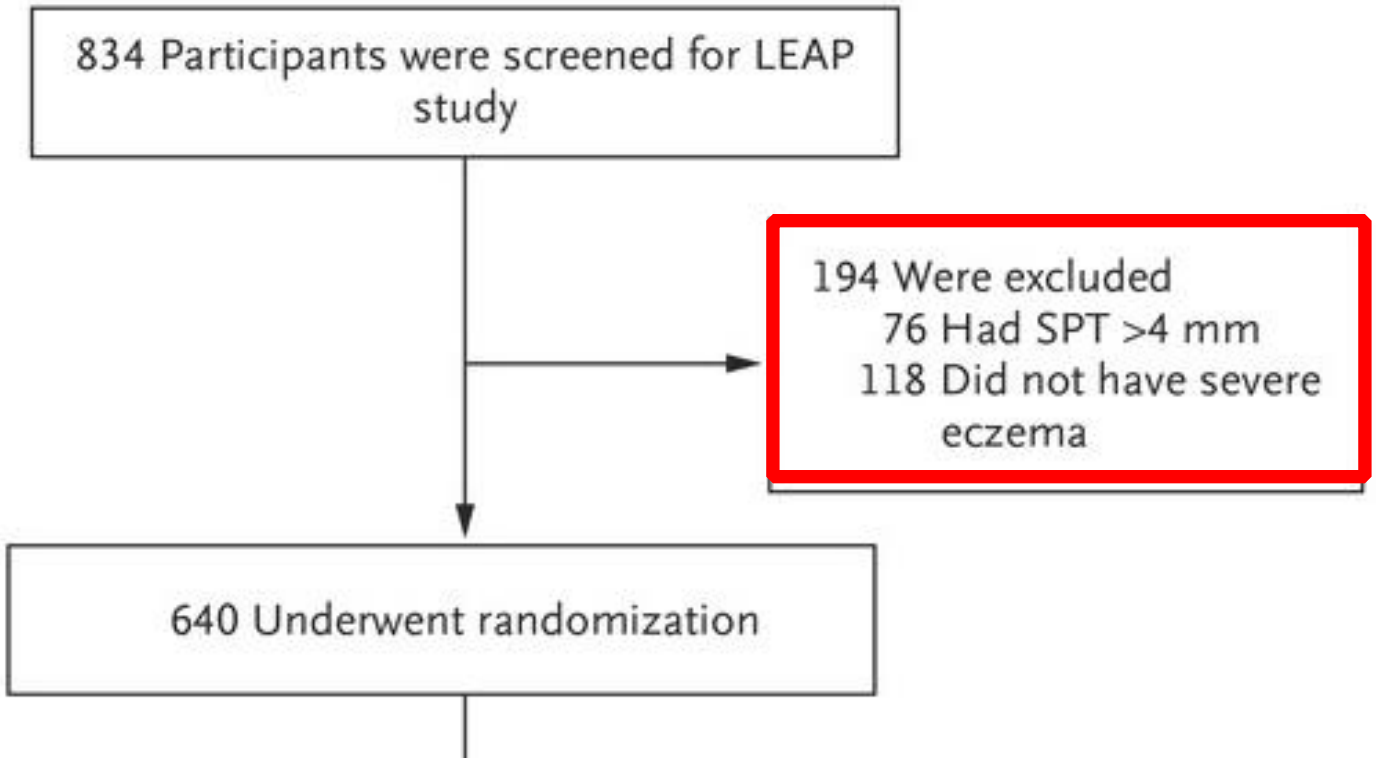
Learning Early About Peanut Allergy (LEAP Study)



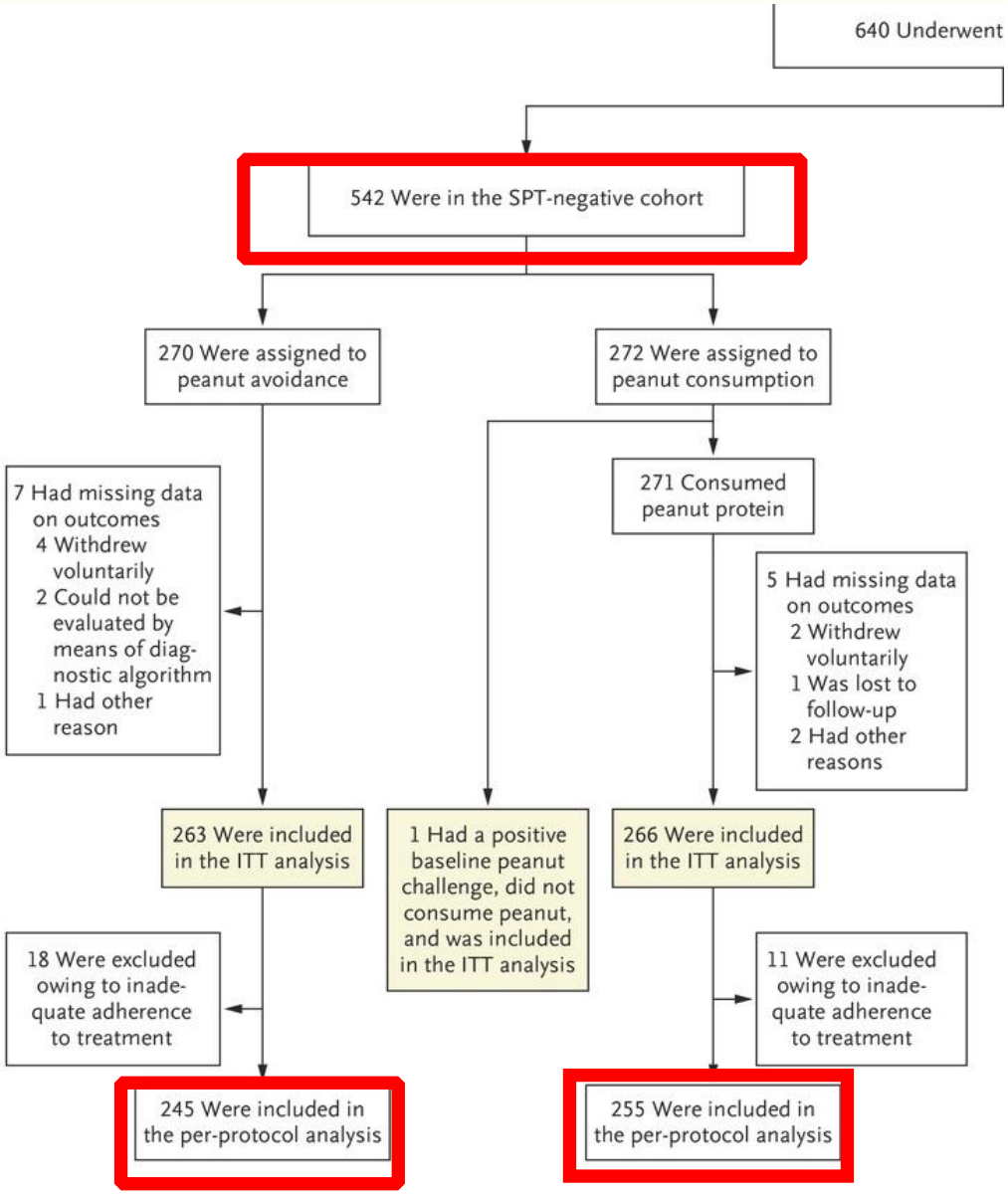
Enrollment and Randomization.

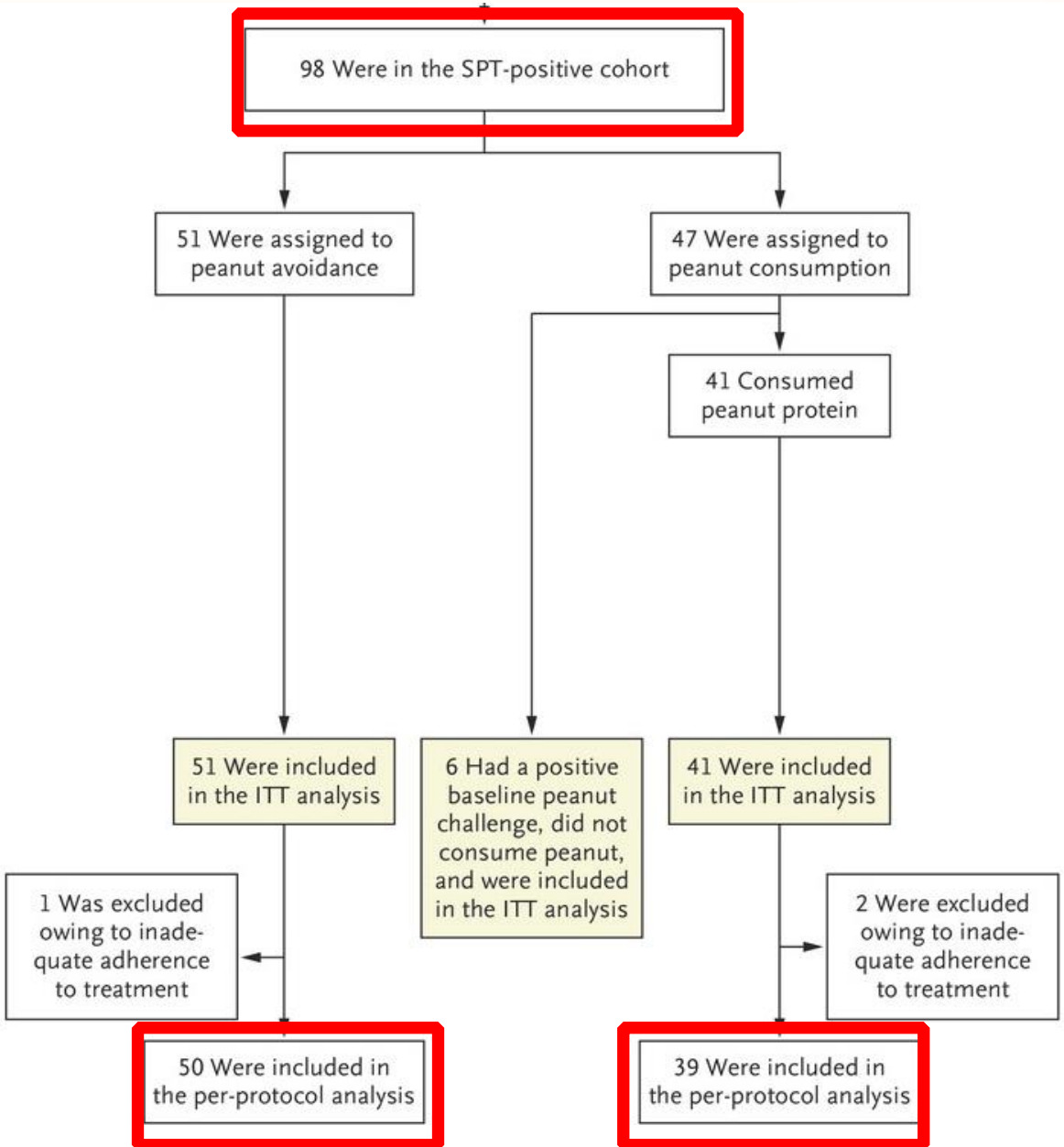


4 months to 11 months of age
Had to have severe eczema, egg allergy, or both
(markers for risk of food allergy)

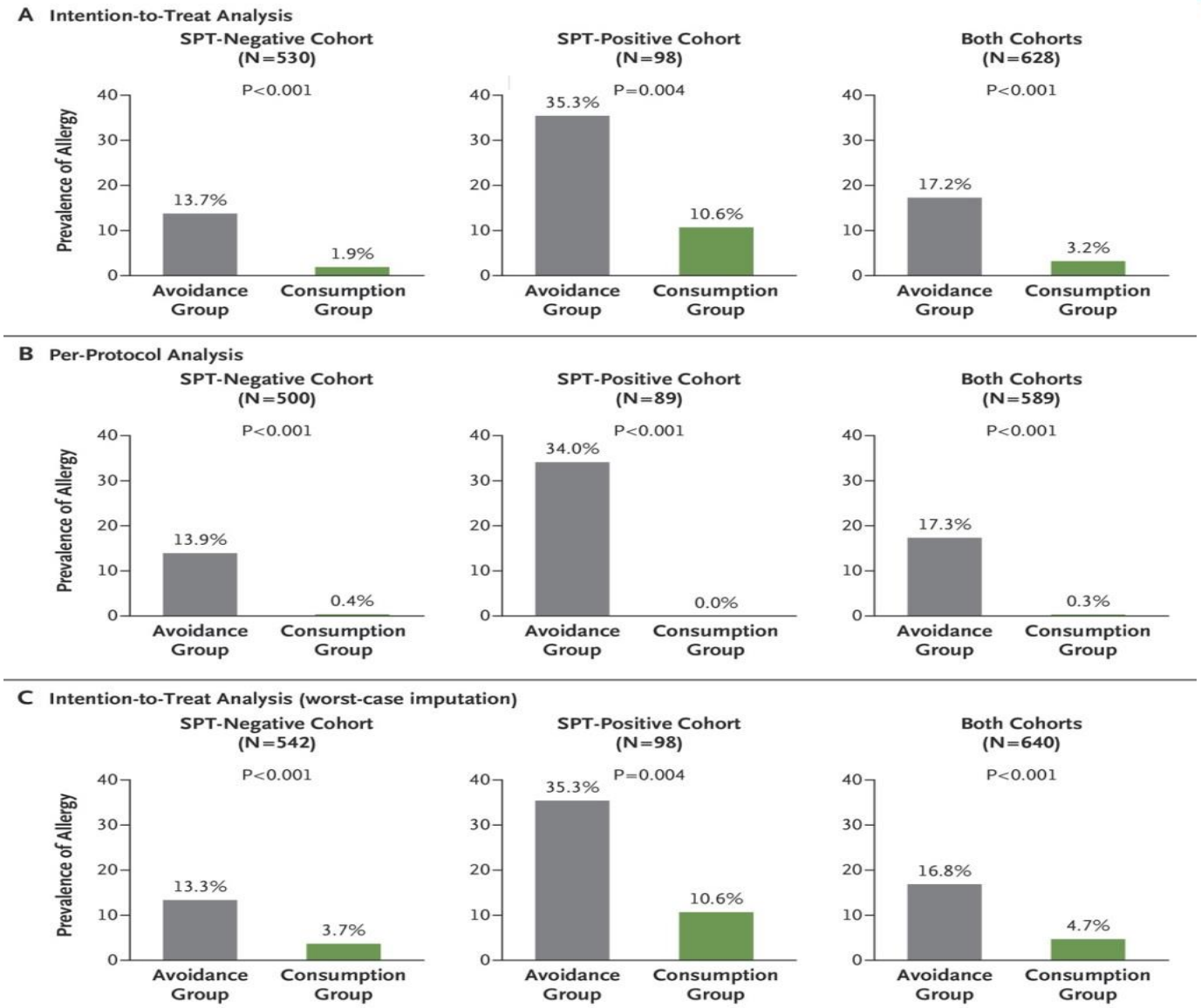


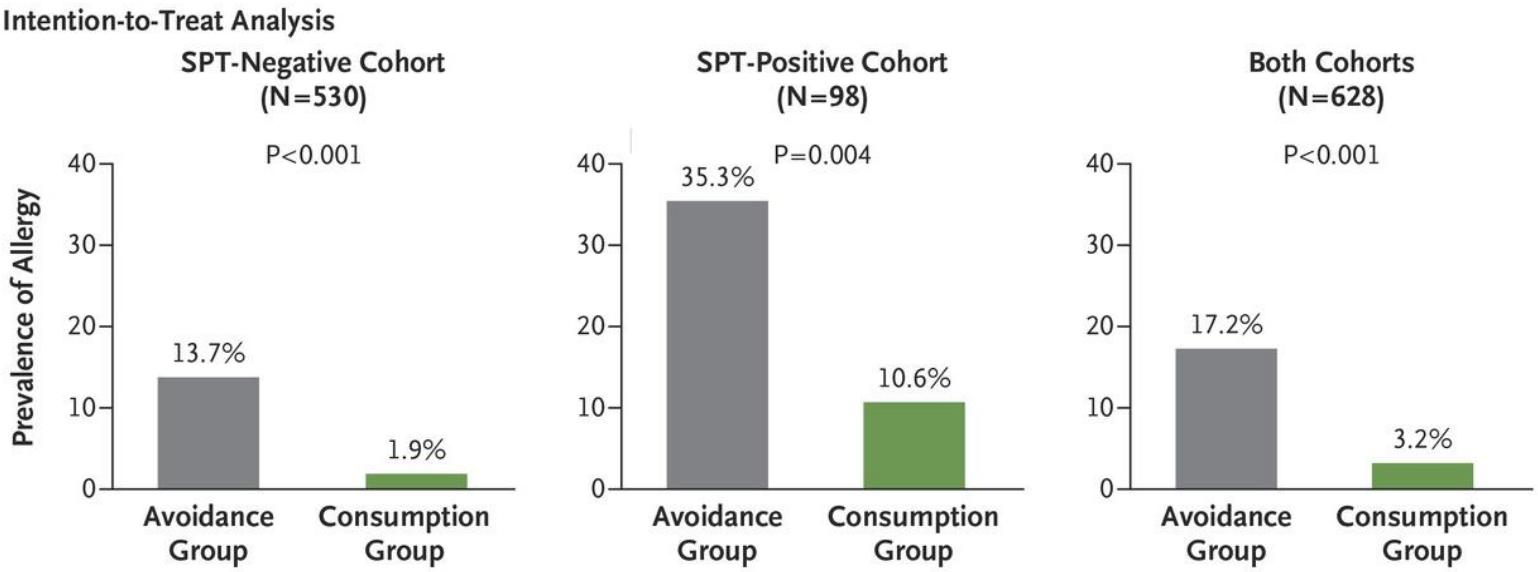
Peanut Consumption in Infants at Risk for Peanut Allergy: NEJM Feb 2015


640 Underwent
542 Were in the SPT-negative cohort
270 Were assigned to peanut avoidance
272 Were assigned to peanut consumption
7 Had missing data on outcomes
4 Withdrew voluntarily
2 Could not be evaluated by means of diagnostic algorithm
1 Had other reason
271 Consumed peanut protein
5 Had missing data on outcomes
2 Withdrew voluntarily
1 Was lost to follow-up
2 Had other reasons
263 Were included in the ITT analysis
1 Had a positive baseline peanut challenge, did not consume peanut, and was included in the ITT analysis
266 Were included in the ITT analysis
18 Were excluded owing to inadequate adherence to treatment
11 Were excluded owing to inadequate adherence to treatment
245 Were included in the per-protocol analysis
255 Were included in the per-protocol analysis


98 Were in the SPT-positive cohort
51 Were assigned to peanut avoidance
47 Were assigned to peanut consumption
41 Consumed peanut protein
51 Were included in the ITT analysis
6 Had a positive baseline peanut challenge, did not consume peanut, and were included in the ITT analysis
41 Were included in the ITT analysis
1 Was excluded owing to inadequate adherence to treatment
2 Were excluded owing to inadequate adherence to treatment
50 Were included in the per-protocol analysis
39 Were included in the per-protocol analysis

Primary Outcome





86.1% relative reduction in the prevalence of peanut allergy

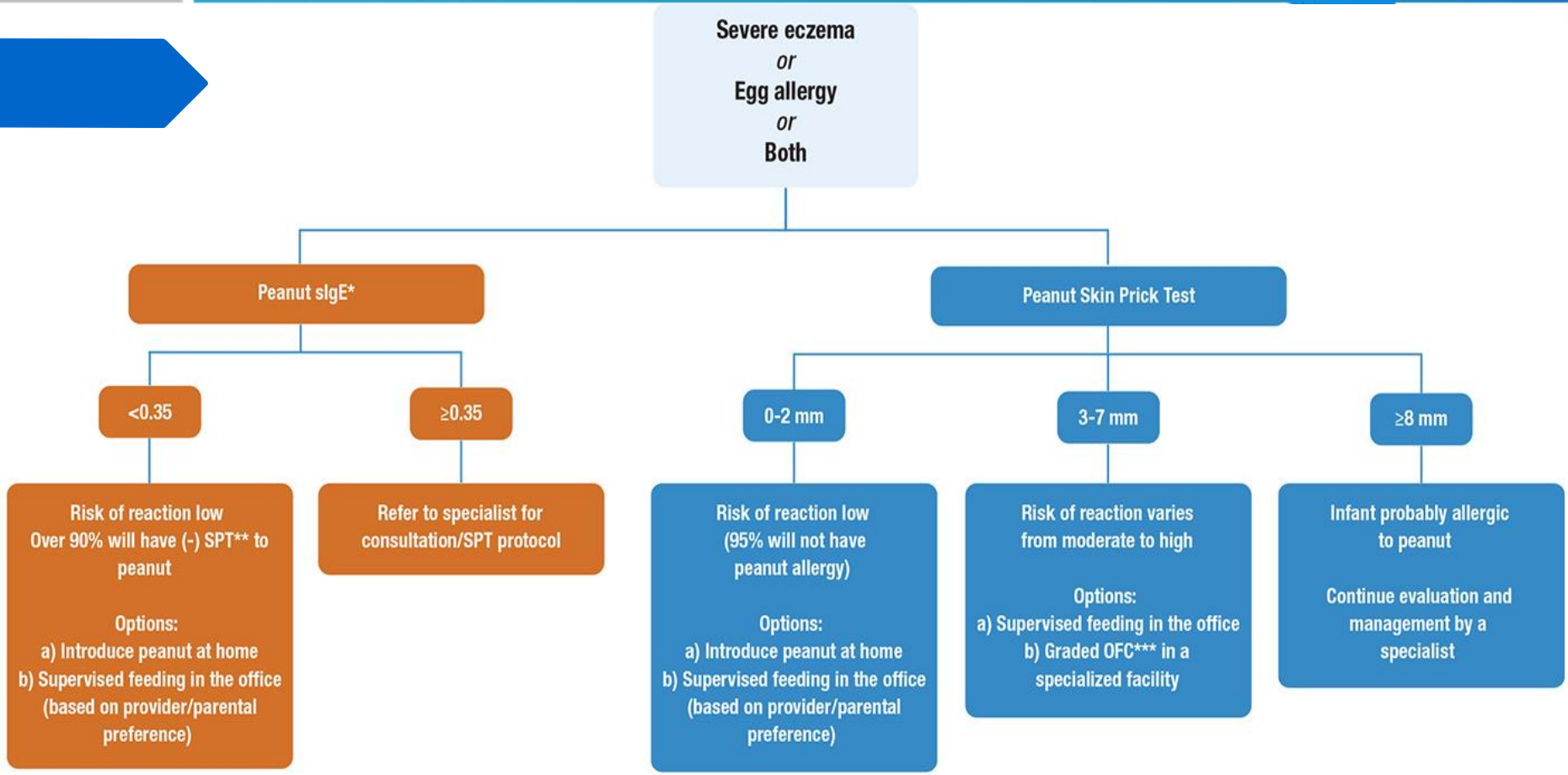
Peanut Consumption in Infants at Risk for Peanut Allergy: NEJM Feb 2015

Eat Peanuts Baby!!!

LEAP-ON Study

- ✓ 556 of LEAP participants enrolled (88.5%)
- ✓ Avoid peanut for one year
- ✓ Challenge with peanut
- ✓ Avoidance group --- 18.6% peanut allergy
- ✓ Consumption group --- 4.8% peanut allergy
- ✓ P< 0.001
- ✓ Conclusion: benefit of early introduction is enduring

2016 Guideline Addendum



* To minimize a delay in peanut introduction for children who may test negative, testing for peanut-specific IgE may be the preferred initial approach in certain health care settings. Food allergen panel testing or the addition of sIgE testing for foods other than peanut is not recommended due to poor positive predictive value.

** skin prick test

*** oral food challenge

Addendum guideline	Infant criteria	Recommendations	Earliest age of peanut introduction
1	Severe eczema, egg allergy, or both	Strongly consider evaluation by sIgE measurement and/or SPT and, if necessary, an OFC. Based on test results, introduce peanut-containing foods.	4-6 months
2	Mild-to-moderate eczema	Introduce peanut-containing foods	Around 6 months
3	No eczema or any food allergy	Introduce peanut-containing foods	Age appropriate and in accordance with family preferences and cultural practices

What does this mean to YOU?

- ✓ Need for ALL PA's to recognize that early introduction of some foods, especially peanut, can be helpful – Especially high risk infants
- ✓ Manage severe eczema better
- ✓ Need for allergists to find a way to see these infants in a timely manner, so not to delay introduction
- ✓ Need to change mindset of population towards early introduction

Second Major Change: Let them eat^2

- ✓We talked over reducing the risk, but what if they are already allergic?

Oral Immunotherapy: The Future of Food Allergy

Rethinking Food Allergy

- **History – most important**
- **Diagnostic testing – careful opening the can of worms**
- **Responding to test results**
  - **historically: avoid, repeat q 1-2 years**
  - **now: contrast in vitro with in vivo test, total IgE, component testing, challenge**
- **Treat – oral immunotherapy (OIT) with food or FDA approved product ($$$)**

Stukus DR, Mikhail I. Curr Allergy Asthma Rep 2016;16(5)34.

Oral Food Challenge (OFC)

- Introduced into clinical practice 1976
- Serial increasing ‘doses’ of food
- Useful when
  - suspicion of sensitivity is low
  - desire to eat food is high
  - family anxiety is high
- Allergy tests are not an absolute indication or contraindication
- 2-3% anaphylaxis rate

Value of a Food

- QOL of patient and family improves, even if a positive challenge
- Delaying challenge leads to increased costs
- Late phase (biphasic) reactions rare, 1.5-4%
- 1 known fatality in USA

Clin Exp Allergy 2010;40:476-85

Allergy 2014;69:1255-7

Allergy Asthma Proc 2013;34:220-6

What percentage of patients will outgrow peanut allergy?

a. 5%

b. 10%

c. 20%

d. 40%

e. 60%

f. 80%

What percentage of patient will outgrow peanut allergy?

a. 5%

b. 10%

c. 20%

d. 40%

e. 60%

f. 80%

Skolnik et al. J Allergy Clin Immunol Feb. 2001

Wanted: Food Allergy Treatment!!!

Avoidance Management Strategy

- 12% to 35% of patients experience accidental exposures
- >200,000 ER visits/year
- Only 25% of severe reactions treated with epinephrine
- 31 deaths reported in the US 2001-2006 – est. 1/million/year
- Most anaphylactic deaths occurred in patients who knew they were allergic to food that killed them

Jarvinen K CurrOpin in Allergy and ClinImmunol 2011 11 255-261

Commonly Treated Foods

The Explanation

- Allergic reactions are caused by cross-linking enough antigen specific IgE on the surface of mast cells to trigger them
- The protocol fills the specific antigen receptors so slowly that triggering doesn’t occur
- If all the receptors are filled without cross- linking, there is no reaction

Explanation Continued

- Saturating antigen specific receptors on T cells down regulates IgE production
- The protocol may result in tolerance that can be sustained when the concentration of food allergen is reduced
- It may never be possible to maintain tolerance without continuing high dose antigen exposure

The OIT Process

- Parents of appropriate patients are offered the opportunity to have their child treated
- Parents are provided a custom consent form
- Approximately two weeks prior to the initiation of treatment, patients are evaluated for stability of asthma and allergy

The Protocol – Day One

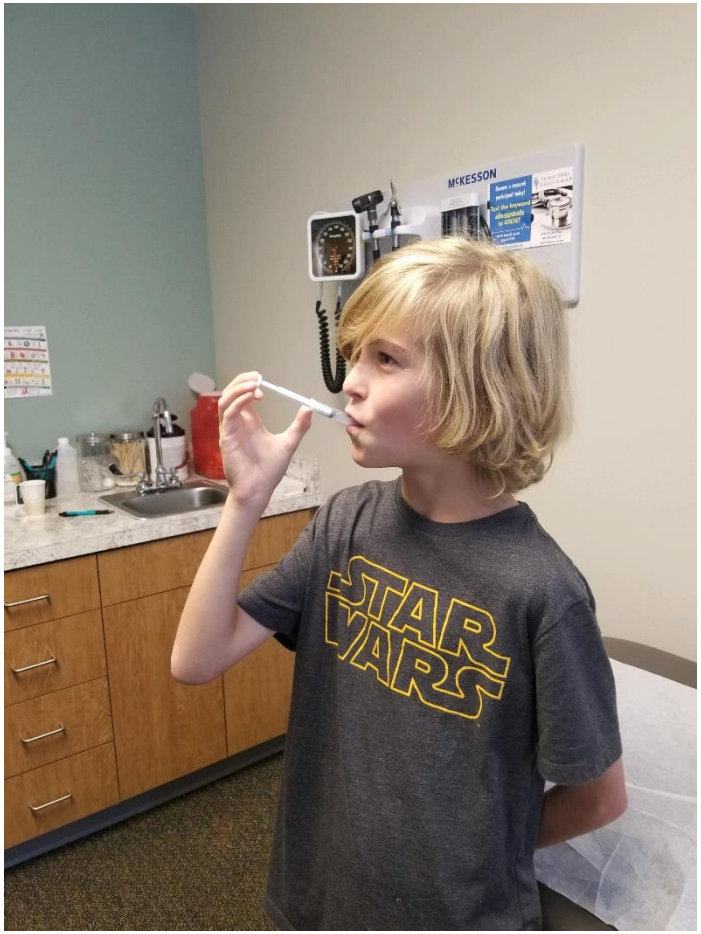
- Patients arrive and are examined
  - Dosing is initiated (0.02 mg to 0.2 mg protein)
  - Up to 4 to 6 doses are administered at 20 minute intervals
  - One hour observation after the last dose (1-5 mg protein)

OIT Day One

Protocol – Escalation Phase

- Usually doubling the previous dose
- Patients take the last tolerated dose once daily for at least seven days
- Return to the office for a updosing to the next dose
- Patients are observed for 45 minutes

OIT Administration



Supplies For Oral Immunotherapy

Peanut Build Up

Visits			mg Protein
2	" "	1 ml	5
3	Peanut fraction	0.03 gm	7.5
4	" "	0.05 gm	12.5
5	" "	0.08 gm	20
6	" "	0.13 gm	33
7	" "	0.22 gm	55
8	" "	0.36 gm	90
9	" "	0.6 gm	150
10	1 Peanut	1 gm	* 250
11		1.7 gm	425
12	3 Peanuts	3 gm	750
13	5 Peanuts	~5 gm	1.25 gm
14	8 Peanuts	~8 gm	2 gm
15	24 peanut tolerance	24 gm	* 6 gm

* 300 mg ↓ risk by > 95%

* Can freely eat

OIT Typical Dosing- Maintenance

- 1-2 gm protein:
  - 1/3 to 1/2 egg, 2- 3 oz milk, 3-8 peanuts, 1-6 tree nuts, 1/3 bagel, 5-6 gm sesame seeds etc…
- Frequency of dosing:
  - QD → 3 times a week, FOREVER

OIT Success Rates- FAST 2019

		Started	D/C	**Success rate**
Single food	TX	549	90	**83.6%**
	UT	349	24	**93.1%**
	FL	216	29	**86.6**
Multi-food	TX	68	11	**83.8%**
	UT	187	11	**94.1%**
	FL	49	8	**83.7**

Outcome

"Eating PBJ with my daughter is a dream come true - THANK YOU"

"We took our son to Texas Roadhouse tonight with all the peanuts around him and he was fine!!!...in July we went to Five Guys and that was surreal too.."

"The freedom from fear of food that you have given my daughter is immeasurable. Just today her friend ate a peanut butter granola bar in front of her and she didn't have to ask her not to."


Jacob
3-28-19
7-23-19
Peanut


PAWFECT
TOGETHER
TAGs 17TH
OIT Grad


CARHARTT


I love Peanuts!


Our 2nd OIT
Graduate
6-28-18


The
Allergy
Group


TAGs 16TH
OIT Grad
The Allergy Group
Treasure Valley
Medical Research
TAGs 24TH
OIT Grad
TAGs 12
OIT Grad
OIT
Graduates
TAGs 13
OIT Grad
TAGs 19
OIT Grad
Congrats
Certificate of Completion
cant belive
graduated !
You Allergy Group
helped Me so Much !

FDA NEWS RELEASE

FDA approves first drug for treatment of peanut allergy for children

More Press Announcements

Press Announcements

For Immediate Release: January 31, 2020

Español

Today the U.S. Food and Drug Administration approved Palforzia [Peanut (Arachis hypogaea) Allergen Powder-dnfp] to mitigate allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanuts. Treatment with Palforzia may be initiated in individuals ages 4 through 17 years with a confirmed diagnosis of peanut allergy and may be continued in individuals 4 years of age and older. Those who take Palforzia must continue to avoid peanuts in their diets.

"Peanut allergy affects approximately 1 million children in the U.S. and only 1 out of 5 of these children will outgrow their allergy. Because there is no cure,

AR101 for Peanut Allergy

Designed for Peanut Allergy Therapy

A first-of-its-kind, investigational, orally administered, biologic immunotherapy to reduce the frequency and severity of peanut allergy reactions in children and adolescents.

AR101 is an investigational biologic oral immunotherapy designed to reduce the frequency and severity of allergic reactions in case they are accidentally exposed to peanut.

Patients ingest controlled, increasing amounts of AR101 over a period of about six months or longer. The result is that the patient's immune system tolerates larger amount of peanut. After the dose escalation period, the patient continues to take a daily therapeutic dose to maintain desensitization.

Upon approval, our standardized treatment protocol will give allergists access to a medication that aims to provide predictable and reliable peanut allergy tolerance for their patients.

PALISADES Phase 3 Trial

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 NOVEMBER 22, 2018 VOL. 379 NO. 21

AR101 Oral Immunotherapy for Peanut Allergy

The PALISADE Group of Clinical Investigators*

ABSTRACT

BACKGROUND

Peanut allergy, for which there are no approved treatment options, affects patients who are at risk for unpredictable and occasionally life-threatening allergic reactions.

METHODS

In a phase 3 trial, we screened participants 4 to 55 years of age with peanut allergy for allergic dose-limiting symptoms at a challenge dose of 100 mg or less of peanut

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Food OIT vs Palforzia

- Carry epinephrine autoinjector- Both!
- Maintenance dose for desensitization- Both!
- ? peanut powder in capsules vs real food
- ? Freely eat
- ? Standardized product – Need?
- Cost - ? Grocery store VS Drug Store($$$$)!
- Health coverage – FOREVER with Paliforzia!


#OITworks
PEOPLE WITH NO INTEREST, EDUCATION, OR AWARENESS CAN'T HURT MY CHILD ANYMORE.
Nor can accidental oversight, poor labeling or kitchen errors.
No more exclusion, hurt feelings, family tension or food fear.

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