Making Progress in the Management of Food Allergies: Diagnosis to Prognosis

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Food Allergy

- $24.8 billion annually in the US
- $4,184 annually per child
- No solid treatment options
- No cure
- Associated with poor quality of life
- $3500/child for a therapy
- Emerging data on prevention

Gupta RS, et al. JAMA Pediatrics 2013 167(11): 1026-1031.

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Objectives

- Review the guidelines
- Define food allergy vs food intolerance
- Discuss the prevalence and natural history
  - Risk Factors
- Review the pathophysiology and clinical manifestations
- Identify methods of evaluation (diagnosis) and management including prevention and referral recommendations

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NIAID Guidelines

- National Institute of Allergy and Infectious Disease (NIAID) released guidelines in 2010
  - American Academy of Allergy, Asthma, and Immunology (AAAAI)
  - American College of Allergy, Asthma, and Immunology (ACAAI)
  - 30+ other professional organizations
    - Including AAP, ACFP
  - Federal agencies
  - Consumer groups

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NIAID Guidelines

- Created by a variety of experts
  - Expert opinions from all the different areas
  - Evidence based with expert clinical opinion
    - 12,000+ papers thoroughly reviewed
  - Strength based (not radical new data)
- Provide recommendations for healthcare professionals across a variety of specialties
  - Allergy, Pulmonology, Gastroenterology
  - Primary care providers

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NIAID Guidelines

- Uniform standards for
  - Consensus definition
  - Best clinical management recommendations
  - Treatment
    - Management of anaphylaxis
- Identification of knowledge gaps
  - Develop research goals for future therapy
- Published in The Journal of Allergy and Clinical Immunology (AAAAI)
- Addendum (peanut) in 2017

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NIAID Guidelines

- NIAID created multiple free resources for healthcare professionals, patients, and families
  - Summary version
  - Patient- and family-friendly synopsis

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Definitions

- Sensitization
  - May not go on to proceed to a clinical disease
- Clinical food allergy
  - Sensitized and a particular allergen causes reproducible clinical symptoms
  - Characteristic IgE-mediated symptoms
- Multi-sensitized
  - May be difficult to diagnose which allergens actually cause symptoms

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Intolerances versus Allergy

- Clinically
  - Intolerance – your body cannot break down the food for some reason
    - GI symptoms (pain, cramping, vomiting, diarrhea)
    - Eat small amounts – do okay
  - Allergy – your body mistakes that food for something harmful, IgE mediated
    - Immune response – localized or systemic reaction
    - Can be triggered by eating a microscopic amount or even with touch or inhalation of the allergenic particles

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Definitions

- Peanuts - legumes
- Tree nuts – almonds, cashews, walnuts, Brazil nuts, hazelnuts, pistachios, chestnuts, macadamia nuts
- Shellfish – crab, lobster, crayfish, shrimp
- Mollusks – clams, oysters, and scallops
- Finned fish – salmon, tuna, cod, tilapia
- Egg – baked versus cooked
- Milk - baked versus cooked

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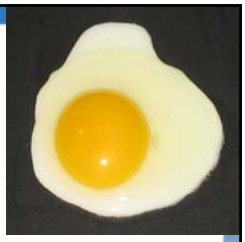
Prevalence of Food Allergy



- Perception by public: 20-25%
  - 10-12 million Americans (over diagnosed?)
- Confirmed allergy (oral challenge)
  - Adults: 1-3.5%
  - Infants/young children: 6-8%
- Specific allergens
  - Dependent upon societal eating and cooking patterns
- Prevalence is higher in those with:
  - Atopy, certain pollen allergies, latex allergy
- Prevalence seems to be increasing
  - Like other atopic conditions (i.e. asthma)

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Estimated Prevalence of Food Allergy

Food	Children (%)	Adults (%)
Cow's milk	2.5	0.3
Egg	1.3	0.2
Soy	0.3-0.4	0.04
Peanut	0.8	0.6
Tree nut	0.2	0.5
Crustaceans	0.1	2.0
Fish	0.1	0.4

Sampson H. J Allergy Clin Immunol; 113:805-

Natural History

- Dependent on food and mechanism
  - Allergies to peanuts, tree nuts, and seafoods typically persist
    - ~ 20% of peanut allergy resolve by age 5
    - ~ 80% of cow's milk, soy, egg and wheat allergy resolves by age 16
  - Good prognosis
    - PST <6mm/low specific IgE levels, ≥2 years avoidance, reaction was mild, mild atopy
  - Rarely re-develop allergy

Risk Factors for Development of Food Allergy

Local Factors (Rodent)

- Genetic susceptibility
- Pepsin digestion
- Gastrointestinal infections (gut flora)
- Malabsorption
- Rate of absorption
- Antigen processing
- Nature and dose of Ag

Host Factors

- Age (esp neonates)
- Genetic susceptibility
- FHx of atopy
- FHx of food allergy
- Atopic dermatitis
- Transdermal food exposure (peanut)

Adverse Food Reactions

Immunologic Mechanism

IgE-Mediated (most common)

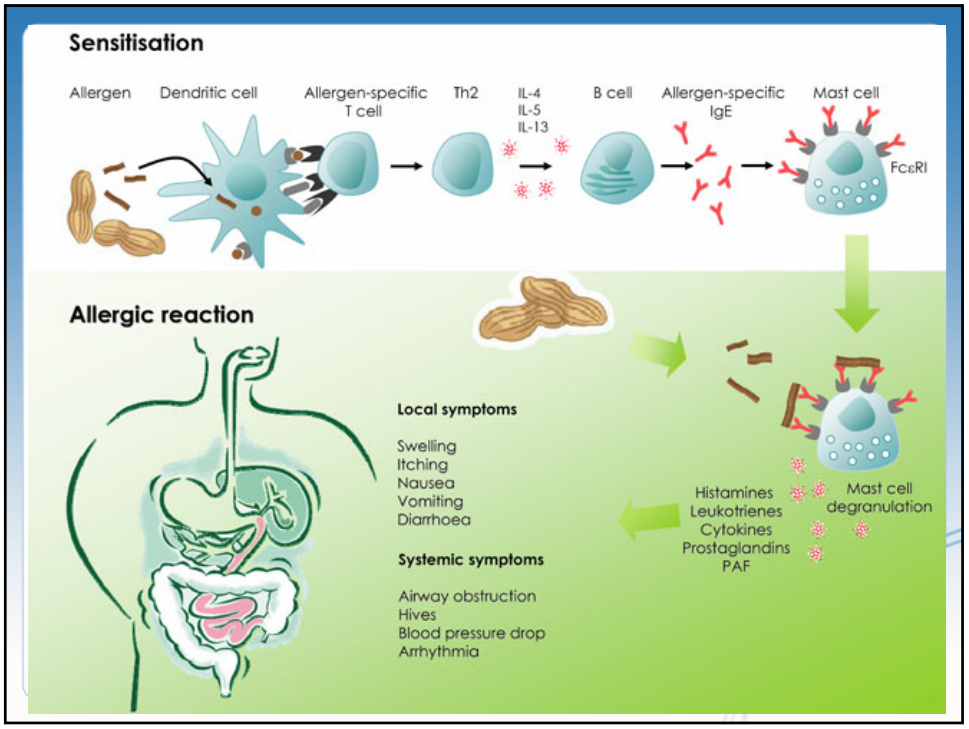
- Systemic (Anaphylaxis)
- Oral Allergy Syndrome
- Immediate gastrointestinal allergy
- Asthma/rhinitis
- Urticaria
- Contact urticaria

- Eosinophilic esophagitis
- Eosinophilic gastritis
- Eosinophilic gastroenteritis
- Atopic dermatitis

Non-IgE Mediated Cell-Mediated

- Protein-Induced Enterocolitis/Proctitis
- Protein-Induced Enteropathy
- Dermatitis herpetiformis
- Contact dermatitis

Sampson H. J Allergy Clin Immunol 2004;113:805-9, Chapman J et al. Ann Allergy Asthma & Immunol 2006;96:S51-68.



Cutaneous Reactions

- Acute urticaria (hives) and angioedema
- Contact urticaria
- Food allergy rarely causes chronic urticaria/angioedema
- 1/3 of children with moderate to severe atopic dermatitis may have food allergy (especially cow's milk, egg, soy, wheat)
- Contact dermatitis (food handlers)

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Respiratory Reactions

- Upper and lower respiratory tract symptoms may be seen
  - Rhinoconjunctivitis, laryngeal edema, asthma
- Usually accompany skin and GI symptoms
- Inhalational exposure may cause severe respiratory symptoms
  - Occupational
  - Restaurants
  - Kitchen/Home

Gastrointestinal Reactions

- Gastrointestinal Anaphylaxis or Immediate Gastrointestinal Allergy
  - IgE-mediated
  - Acute emesis/diarrhea/cramping abdominal pain
  - Can present without other signs or symptoms of an allergic reaction to food

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Anaphylaxis due to Food

- Food allergy = #1 cause of anaphylaxis in the Emergency Department
  - Frequency: ~ 150 deaths / year
  - Rapid-onset, up to 30% biphasic
  - May be localized (single organ) or generalized
  - Any food, highest risk:
    - Peanut, tree nut, seafood
    - Cow's milk and egg in young children
  - Food-dependent, exercise-induced: 2 forms
    - Specific foods (wheat and celery most common)
    - Any food (post-prandial)

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Fatal Food Anaphylaxis

- Clinical features:
  - Biphasic reaction–initially better, sx recur
  - Cutaneous symptoms may not be present
  - Respiratory symptoms prominent
- Risk factors:
  - **Underlying asthma, delayed epinephrine**
  - **Symptom denial, prior severe reaction**
  - **Adolescents, young adults**
- History: known food allergen
- Key foods: ***peanuts and tree nuts (~90% of fatalities)***, fish, crustaceans

Bock SA, et al. J Allergy Clin Immunol 2001;107:191-3.

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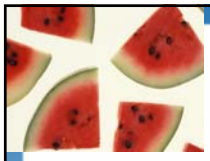

Pollen-Food Syndrome or Oral Allergy Syndrome

- Clinical features: rapid onset oral pruritus, rarely progressive
- Epidemiology: rhinitis due to prior sensitization to pollen
- Key foods: raw fruits and vegetables
- Allergens: Profilins
  - Heat labile (cooked food usually OK)
- Cause: cross reactive proteins pollen/food

Birch →	Apple, carrot, celery, cherry, pear, hazelnut
Ragweed →	Banana, cucumber, melons
Grass →	Melon, tomato, orange
Mugwort →	Melon, apple, peach, cherry

Latex-Fruit Syndrome

- 30-50% of those with latex allergy are sensitive to some fruits due to cross-reactive IgE
- Most common fruits: banana, avocado, kiwi, chestnut but other fruits and nuts have been reported
- **Can clinically present as anaphylaxis to fruit**
- Warn latex-sensitive patients of potential cross-reactivity
- Some fruit-allergic patients may be at risk for latex allergy

Evaluation of Food Allergy

- Accurate diagnosis and management of food allergy are important in prevention of a life-threatening food reaction
  - History
  - IgE or skin prick tests
  - Identify general mechanism
  - Allergy versus intolerance
  - IgE versus non-IgE mediated

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Evaluation of Food Allergy

- History: most important
  - Symptoms, timing, reproducibility, treatment and outcome
  - Concurrent exercise, concurrent meds, EtOH
- Diet details / symptom diary
  - Subject to recall
  - "Hidden" ingredient(s) may be overlooked
- Physical exam: assess for other allergic and alternative disorders

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Evaluation of Food Allergy

- Suspect IgE-mediated food allergy:
  - Panels/broad screening should NOT be done without supporting history
    - High rate of false positives (as high as 50%)
    - 90% sensitivity, 50% specificity
  - Prick skin tests
    - Best to use the real food
    - Commercially available products
  - In vitro tests for food-specific IgE

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Evaluation of Food Allergy

- Results
  - Positive test indicates presence of IgE
    - May not correlate with clinical symptoms
  - Larger skin tests/higher IgE correlates with likelihood of reaction but not severity
  - Negative prick test or specific IgE
    - Essentially excludes IgE antibody (>95% specific)

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Immunocap Results

TEST	RESULT	FLAG	UNITS	REF RANGE
Immunoglobulin E (IgE)	323	H	IU/mL	4-35
Codfish/Scrod IgE	<0.10		kU/L	<0.35
CLASS	0			
Egg White IgE	1.94	H	kU/L	<0.35
CLASS	2			
Milk Cow IgE	0.21		kU/L	<0.35
CLASS	0/1			
Peanut IgE	0.13		kU/L	<0.35
CLASS	0/1			
Soybean IgE	<0.10		kU/L	<0.35
CLASS	0			
Wheat IgE	0.15		kU/L	<0.35
CLASS	0/1			
Cat Dander IgE	<0.10		kU/L	<0.35
CLASS	0			
Dog Dander IgE	<0.10		kU/L	<0.35
CLASS	0			
Alternaria tenuis/alternata IgE	<0.10		kU/L	<0.35
CLASS	0			
Mite Dermatophagoides pteronyssinus IgE	<0.10		kU/L	<0.35
CLASS	0			
Cockroach German (Blatella germanica) IgE	<0.10		kU/L	<0.35
CLASS	0			

Elimination diets

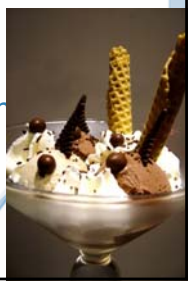
- Elimination diets (1 - 6 weeks) most useful for chronic disease (atopic dermatitis) and non-IgE mediated disease (GI syndromes)
  - Eliminate suspected food(s) or
  - Prescribe limited “eat only” diet or
  - Elemental diet
  - Reintroduce the food after elimination
  - May need to repeat in naturally waxing and waning conditions

Oral Food Challenges

- Oral challenge testing
  - Physician supervised
  - Emergency medications available
  - Open or Single-blind
    - Diagnostic if negative
    - Helpful if symptoms are reproduced
  - Double-blind, placebo-controlled (DBPCFC)
    - Gold Standard

Management of Food Allergy

- Appropriate diagnosis
- Ensure nutritional needs are being met
  - Periodic weight checks, calorie counts
  - Vitamin supplementation
- Education (all surrounding family/friends, etc)
  - ID bracelets
- Anaphylaxis Emergency Action Plan
  - Most accidental exposures occur away from home
  - Education on presentation of anaphylaxis



This frozen dessert could have peanut, tree nut, cow's milk, egg, wheat

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Management of Food Allergy

- Avoidance is the only effective therapy
  - Complete avoidance of specific food trigger
  - Hidden ingredients in restaurants/homes (peanut in sauces, egg rolls)
  - Labeling issues ("spices", changes, errors)
  - Cross contamination (shared equipment)
  - Seeking assistance
    - Food allergy specialist
    - Registered dietitian
    - Food Allergy Research Education
    - Local support groups

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Management of Food Allergy

- Reevaluation for development of tolerance
- Interval and decision to re-challenge:
  - Type of food allergy (IgE vs non-IgE)
  - Severity of previous symptoms
  - Allergen/Prognosis (cow's milk vs peanut)
  - Age of the child
  - Skin prick test/in vitro specific IgE should be negative prior to challenge
  - Decline in concentration of food specific-IgE is suggestive of development of tolerance

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Novel Therapies

- Oral and sublingual immunotherapy
  - Daily dose following oral or sublingual desensitization – altering immune response
    - Peanut, milk, egg in ICU setting
  - Prevent reaction from accidental exposures
  - Simple, low cost to maintain therapy, need patient compliance
  - Risks of anaphylaxis
  - Information is inadequate to support these measures as forms of therapy

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Emergency

- Early recognition is critical
- Administer epinephrine immediately
  - Do not delay to give steroids or antihistamines!
  - All contacts should know how to use it, especially you!
- Activate EMS – 911
- Give anti-histamines (H1 and H2) nebulizer/inhaler treatments, steroids, etc.
- Then, call emergency contacts

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Emergency

- Seek emergent supervised medical care
- Observe the patient for about 4-6 hours afterward
  - Biphasic reaction can occur even after the patient looks to be well along the way to recovery
- Discharge with epinephrine and make sure everyone knows how to use it

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AAAAI Anaphylaxis Wallet Card: Information and Medical Identification

ANAPHYLAXIS CAN BE FATAL !

Anaphylaxis is a sudden, severe allergic reaction.

www.aaaai.org

- Be able to recognize symptoms.
- Know and avoid your triggers.
- Have an Emergency Action Plan.
- Carry self-injectable epinephrine at all times.
- Inject epinephrine promptly if you have an allergic reaction.
- Call 911 or Rescue Squad.
- Train family and friends to help you in an emergency.

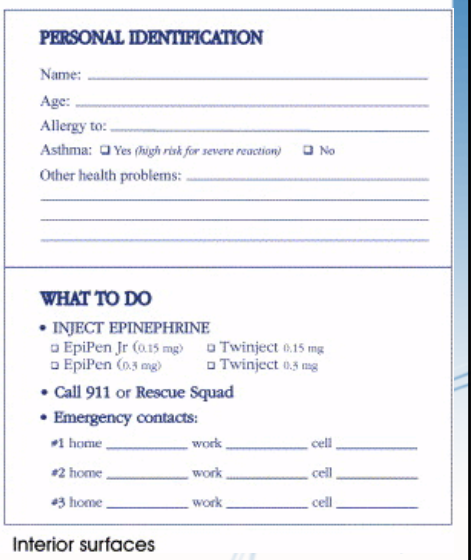
ANAPHYLAXIS SYMPTOMS

www.aaaai.org

MOUTH	itching; swelling of lips and/or tongue
THROAT*	itching, tightness, closure, hoarseness
SKIN	itching, hives, redness, swelling
GUT	vomiting, diarrhea, cramps
LUNG*	shortness of breath, cough, wheeze
HEART*	weak pulse, dizziness, passing out.

Only a few of these symptoms may be present.
** Some symptoms can be life-threatening! ACT FAST!*

Exterior surfaces



PERSONAL IDENTIFICATION

Name: _____

Age: _____

Allergy to: _____

Asthma: ❑ Yes *(high risk for severe reaction)* ❑ No

Other health problems: _____

WHAT TO DO

- INJECT EPINEPHRINE
  - ❑ EpiPen Jr (0.15 mg) ❑ Twinject 0.15 mg
  - ❑ EpiPen (0.3 mg) ❑ Twinject 0.3 mg
- Call 911 or Rescue Squad
- Emergency contacts:

#1 home _____ work _____ cell _____

#2 home _____ work _____ cell _____

#3 home _____ work _____ cell _____

Interior surfaces

Management: Infant Formulas

- Soy (confirm soy IgE negative) – try first
  - <15% soy allergy among IgE-CMA
  - ~50% soy allergy among non-IgE CMA
    - Not recommended in this group
- Cow's milk protein extensive hydrolysates
  - Alimentum and Nutramagen
  - >90% tolerance in IgE-CMA, introduce under supervision
- Partial hydrolysates
  - Not hypoallergenic, avoid in CMA
- Elemental amino acid-based formulas
  - Lack allergenicity or immunogenicity
  - Treatment of multiple food allergy syndrome

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What do we eat now?

- Options for cow's milk substitution – soy, coconut, almond, or rice milk.
- Options for peanut substitution – sunflower butter, soy butter

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Food Allergy Prevention

Pre-2000s
- No advice set in stone
- Do what your grandmother did

2000
- Delay introduction of highly allergenic foods
- Avoid them during pregnancy/breastfeeding

2008
- No convincing evidence to delay highly allergenic foods
- No guidance on introduction

2010 2014
- Data suggests delaying introduction past 4-6 months may increase risk of food allergy, asthma, eczema
- Early introduction may be beneficial

Food Allergy Prevention

- Prior recommendations for children at risk of food allergy include a delay in introduction of certain foods:
  - Solid foods — after age 6 mos
  - Cow's milk — after age 1 yr
  - Egg — after age 2 yrs
  - Peanut, tree nut, seafood — after age 3-4 yrs

- **New guidelines from AAAAI/ACAAI /AAP**
  - **Do not withhold at any age: no convincing evidence during pregnancy, breast feeding, or after birth**
    - **Requires further study**
    - **Exclusive breast feeding for 4-6 months**

American Academy of Pediatrics Committee on Nutrition. Pediatrics 2000;106:346-9.

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LEAP

- 2008 Du Toit found 10 fold increase risk in peanut allergy in UK babies avoiding peanut until age 3 vs Israeli babies fed before 9 months
- RCT of early vs delayed peanut introduction in infants at "high risk" for peanut allergy
  - Eczema or an egg allergy
  - Bamba or peanut butter

Du Toit G et al. NEJM 2015; 372: 803-813
Du Toit G et al. JACI 2008: 122: 984-991

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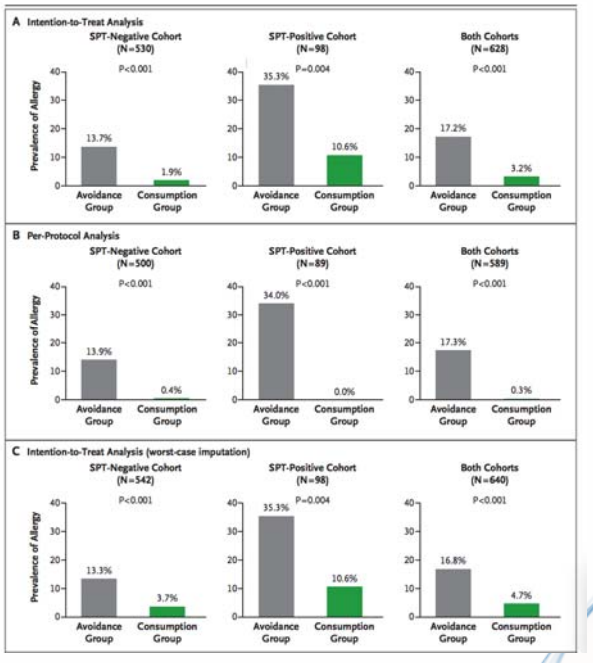
LEAP

Patients
- Infants 4-11 months with either or both:
  - Moderate to severe eczema OR egg allergy

Screening
- Skin testing, if ≥ 5 mm, excluded

Randomized
- Stratified based on skin testing: 0 mm vs 1-4 mm
  - Consume peanut vs avoid after oral challenge

Challenge
- Assessed food frequency and house dust peanut levels
- In-office peanut challenge at age 5



Du Toit G et al. NEJM 2015; 372: 803-813

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LEAP

- Final recommendation:
- "The early introduction of peanuts significantly decreased the frequency of the development of peanut allergy among children at high risk for this allergy and modulated immune responses to peanuts."

Du Toit G et al. NEJM 2015; 372: 803-813

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LEAP

- Benefit was greater in the sensitized group
- Single study, referred population
- No placebo group or low risk group
- >96% retention rate at 5 years, bias?
- ”High risk” criteria are arbitrary
- Standard risk infants were not assessed
- Did not assess long-term status

LEAP ON

- Primary outcome
  - Percentage of patients with peanut allergy after 12 months of peanut discontinuation
  - Both consumption and avoidance groups
- Results
  - “12-month period of peanut avoidance was not associated with an increase in the prevalence of peanut allergy.”
  - “Long term effects are unknown.”

Du Toit G et al. NEJM 2016; 374:1435-1443.

LEAP Effects

- Recommended “immediate” implementation
- Screening “high risk” infants 4-8 months of age
  - Skin test negative, start peanut three times per week
  - Skin test 1-4 mm, challenge in the office
  - Skin test ≥5 mm, do not introduce
- Is there a duty to replicate this
- Can we generalize this to the US
- Skin testing cut-off point adjustment?
- Parent and provider compliance
- NIAID Guideline revision

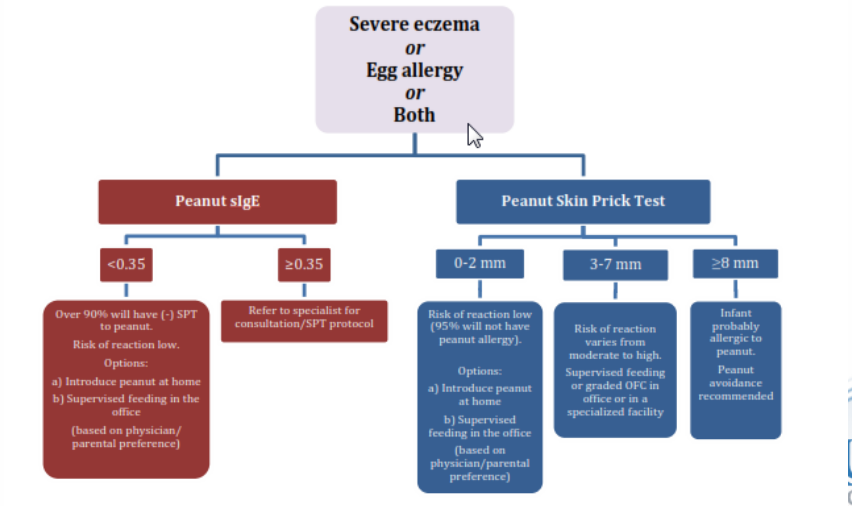
Gruchalla RS and Sampson HA. N Engl J Med 2015: 372: 875-877

NIAID Guideline Revision

Addendum Guideline	Infant Criteria	Recommendations	Earliest Age of Peanut Introduction
1	Severe eczema, egg allergy, or both	Strongly consider evaluation with peanut-specific IgE and/or skin prick test and, if necessary, an oral food challenge. Based on test results, introduce peanut-containing foods.	4 to 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

https://www.niaid.nih.gov/sites/default/files/peanut-allergy-prevention-guidelines-clinician-summary.pdf

NIAID Guideline Revision



https://www.niaid.nih.gov/sites/default/files/peanut-allergy-prevention-guidelines-clinician-summary.pdf

What about other foods?

- Can we generalize this data to other foods
- EAT
- HEAP
- STEP
- PETIT

EAT Trial

- Early introduction in breastfed infants 3 vs 6 months of age
  - Milk, then egg, fish, sesame, wheat, and peanut randomly
  - Assessed allergy at 1-3 years of age, n=1303
  - 68% were unable to follow the protocol
- No significant difference

Perkin et al NEJM 2016; OI: 10.1056/NEJMoa1514210

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HEAP

- Similar to LEAP only with egg
  - Screening IgE: 23/406 were positive
    - 16/17 were challenged and 11 had placebo
    - Used raw egg
  - High rate of severe initial reactions
  - Findings were not statistically significant

Bellach J et al J Allergy Clin Immunol 2016; in press

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STEP

- Non-eczema population, no exclusion based on testing, n=407
- Egg vs placebo at 4-6 months vs 10 months
- Challenge at 12 months, >90% tolerated baked/cooked egg
- Effect was not significant, no anaphylaxis, underpowered
- No harm for introduction

Palmer et al J Allergy Clin Immunol August 2017

PETIT

- RDBPC trial, infants 4-5 months with eczema (Japan), tolerance at 12 months
  - Excluded infants with prior ingestion or history of reaction
  - 50 mg of heated egg powder
  - Eczema was treated
- Results: heated egg was safe and efficacious in high risk infants, terminated due to efficacy
  - 4/47 (9%) in consumption group vs 18/47 (38%) in the avoidance group
    - RR 0.222[95%CI 0.081-0.607];p-0.0012

Natsume, Osamu et al. The Lancet , Volume 389 , Issue 10066 , 276 - 286

Reasons for Allergy Referral

- Persons with a diagnosed or concern for food allergy
- Atopic families with, or expecting, a newborn who are interested in identifying risks and prevention
- Infants with recalcitrant gastroesophageal reflux or older individuals with recalcitrant reflux symptoms, particularly if they experience dysphagia
- Persons with known eosinophilic inflammation of the gut
- Infants with gastrointestinal symptoms including vomiting, diarrhea (particularly with blood), poor growth, and/or malabsorption whose symptoms are otherwise unexplained, not responsive to medical management, and/or possibly food-responsive
  - Even if screening allergy tests are negative

Leung D, et al. J Allergy Clin Immunol 2006;117:S495-523.

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Role of the Allergist

- Identification of causative food
- Institution of elimination diet
- Education on food avoidance
- Development of an Anaphylaxis Emergency Action Plan
- Prevention of other allergies
- Follow-up to ascertain tolerance

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Summary and Conclusions

- The history and physical are paramount
- Elimination diets, skin testing, in vitro assays, and food challenges also have roles in diagnosis
- Avoidance, education, and preparation for emergencies are the pillars of current management
  - Don't forget to give epinephrine
  - Instruct on epinephrine use and anaphylaxis recognition
- No need to avoid foods during pregnancy, breastfeeding or after birth in patients who are not considered "high risk"

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Summary and Conclusions

- Introduce peanut as early as 4-6 months of age
  - Consider testing prior if high risk if they have not already had ingestion
  - High risk infants may benefit the most
- No conclusion on egg
- Still waiting on other foods: milk, wheat, tree nuts

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There is help!

- Seeking assistance
  - Food allergy specialist
  - Registered dietitian: (www.eatright.org)
  - Food Allergy Research & Education (FARE)
  - Local support groups
  - NIAID website

Resources

- AAAAI www.aaaai.org
- ACAAI www.acaai.org
- Food Allergy and Anaphylaxis Network (FAAN) www.foodallergy.org
- Food Allergy Initiative (FAI) www.faiusa.org
- National Institute of Allergy and Infectious Disease (NIAID) www.niaid.nih.gov/