Disclosures (past 24 months)

- Grants: ITN-NIAID, DBV Technologies, Astellas Pharma, Thermofisher, Nutricia, Nestle
- Advisory Board: Merck, Alk-Abello, Regeneron
- Honoraria (speaking): Nestle, Nutricia, Thermofischer
- Royalties: Up To Date
- Deputy Editor for the Annals of Allergy, Asthma and Immunology
- Chair, medical advisory board, International FPIES Association
- Chair, FAED Interest Section, AAAAI

2 *The opinions reflected in this presentation are those of the speaker and independent of Nutricia North America*

Learning objectives

- Describe acute manifestations of food allergy (IgE- and non-IgE mediated)
- Identify interventions that can be utilized at home
- List indications for activation of emergency services

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Food Allergy: Immune-Mediated Adverse Food Reactions

IgE-mediated	Mixed	Non-IgE-mediated
Immediate; min-2 hrs	Delayed, chronic	Delayed, chronic
• **Anaphylaxis;** FDEIA	• Atopic dermatitis	• Eosinophilic esophagitis/ gastroenteritis
• Urticaria/angioedema	• Asthma	• Dermatitis herpetiformis
• Immediate GI symptoms		• Celiac disease
• Pollen food allergy syndrome		• **Food protein-induced enterocolitis syndrome (FPIES)**
• Bronchospasm		• Food protein-induced allergic proctocolitis (FPIAP)
		• Food protein-induced enteropathy (FPE)
		• Heiner's syndrome

FDEIA=food-dependent, exercise-induced anaphylaxis; FPIES=food protein-induced enterocolitis syndrome; FPIAP=food protein-induced allergic proctocolitis; FPE=food protein-induced enteropathy; GI=gastrointestinal.

Anaphylaxis

Ava: 15-year-old female with asthma and severe cow milk allergy

- Most recent reaction was 6 months ago, milk in a cookie-itchy mouth, followed by vomiting, coughing and generalized hives, treated with epi x 2 in the pediatric emergency department (PED)
- Drinks about 4 fl oz of a smoothie that instead of almond milk contained cow milk
- C/o funny feeling in his mouth
- What do you recommend?

Journal of Allergy and Clinical Immunology
Volume 145, Issue 4, April 2020, Pages 1082-1123

Reviews and feature article

Anaphylaxis—a 2020 practice parameter update, systematic review, and Grading of Recommendations, Assessment, Development and Evaluation (GRADE) analysis

Marcus S. Shaker MD, MSc [a], Dana V. Wallace MD [b], David B.K. Golden MD [c], John Oppenheimer MD [d], Jonathan A. Bernstein MD [e], Ronna L. Campbell MD, PhD [f], Chitra Dinakar MD [g], Anne Ellis MD [h], Matthew Greenhawt MD, MBA, MSc [i], David A. Khan MD [j], David M. Lang MD [k], Eddy S. Lang MD [l], Jay A. Lieberman MD [m], Jay Portnoy MD [n], Matthew A. Rank MD [o], David R. Stukus MD [p], Julie Wang MD [q], Collaborators ... Julie Wang

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Anaphylaxis: definition

Anaphylaxis is an acute, life-threatening systemic allergic reaction that may have a wide range of clinical manifestations. May be fatal!

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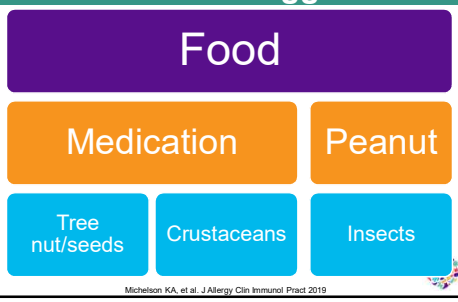
Anaphylaxis: rising incidence

- Cross-sectional study of ED visits for anaphylaxis from 2008-2016 using the Healthcare Utilization Project (HCUP) Nationwide Emergency Department Sample (NEDS)
- includes a 20% sample of all ED visits, allowing for nationally representative estimates

Incidence of emergency visit per million person years increased in persons younger than 55 years; with the steepest increase observed among those younger than 5 years and also 15-17 years

Michelson KA, et al. J Allergy Clin Immunol Pract 2019

Anaphylaxis: food is the most common identified trigger



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Michelson KA, et al. J Allergy Clin Immunol Pract 2019

Anaphylaxis: fatalities

Population prevalence of fatal anaphylaxis:

- **0.47 and 0.69 per million persons (0.25%-0.33% of anaphylaxis hospitalizations or ED visits)**

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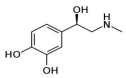
Anaphylaxis: management

0.01 mg/kg using a 1:1000 dilution IM (max 0.3mg children, 0.5mg adults)

Repeated doses every 5 to 15 min if no significant improvement in symptoms

IV dosing 1:10,000 dilution

Epinephrine is first line treatment



- α1-adrenergic agonist
  - ↑ vasoconstriction, peripheral vascular resistance
  - ↓ mucosal edema
- β1-adrenergic agonist
  - ↑ inotropy and chronotropy
- β2-adrenergic agonist
  - Bronchodilation
  - ↓ mediator release from mast cells and basophils

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Boyce, et al. J Allergy Clin Immunol 2010

Anaphylaxis: early use of epinephrine can improve outcomes

- Hasbro Children's Hospital/Rhode Island Hospital
  Early epinephrine associated with significantly **decreased risk of hospitalization**
- Canada (C-CARE study)
  Pre-ED epinephrine associated with **decreased likelihood of multiple epinephrine doses** in the ED

	ED epinephrine ≥2 doses	
Variable	OR[1]	95% CI
Prehospital epinephrine[2]	0.22*	0.13-0.37
Prehospital corticosteroids	0.79	0.19-3.39
Prehospital antihistamines[3]	0.58*	0.41-0.82

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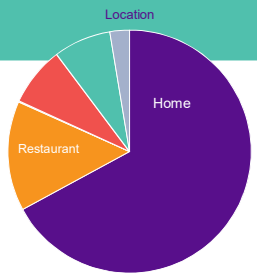
Fleming JT, et al. J Allergy Clin Immunol Prac 2015
Gabrielli S, et al. J Allergy Clin Immunol Pract 2019

Food anaphylaxis: where?

- Children 0-17 years, n=647
- Reactions tx with epi: 26%
- 2 or more doses of epi: 11%



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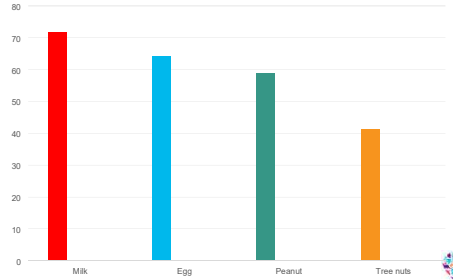
Tsuang A, et al. Ann All Immunol 2018

Food anaphylaxis: what foods cause reactions at home?



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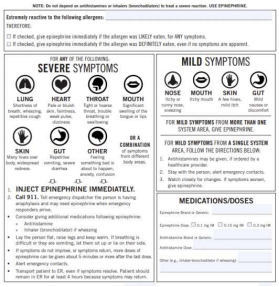
Tsuang A, et al. Ann All Immunol 2018

Food anaphylaxis: standard advice


NOTE: Do not depend on antihistamines or inhalers (bronchodilators) to treat a severe reaction. USE EPINEPHRINE.

Extremely reactive to the following allergens: _____

THEREFORE:

☐ If checked, give epinephrine immediately if the allergen was LIKELY eaten, for ANY symptoms.

☐ If checked, give epinephrine immediately if the allergen was DEFINITELY eaten, even if no symptoms are apparent.

FOR ANY OF THE FOLLOWING:

SEVERE SYMPTOMS

LUNG — Shortness of breath, wheezing, repetitive cough

HEART — Pale or bluish skin, faintness, weak pulse, dizziness

THROAT — Tight or hoarse throat, trouble breathing or swallowing

MOUTH — Significant swelling of the tongue or lips

SKIN — Many hives over body, widespread redness

GUT — Repetitive vomiting, severe diarrhea

OTHER — Feeling something bad is about to happen, anxiety, confusion

OR A COMBINATION of symptoms from different body areas.

1. INJECT EPINEPHRINE IMMEDIATELY.
2. Call 911. Tell emergency dispatcher the person is having anaphylaxis and may need epinephrine when emergency responders arrive.
- Consider giving additional medications following epinephrine:
  - Antihistamine
  - Inhaler (bronchodilator) if wheezing
- Lay the person flat, raise legs and keep warm. If breathing is difficult or they are vomiting, let them sit up or lie on their side.
- If symptoms do not improve, or symptoms return, more doses of epinephrine can be given every 5 minutes or more after the last dose.
- Alert others.
- Transport patient to ER, even if symptoms resolve. Patient should remain in ER for at least 4 hours because symptoms may return.

MILD SYMPTOMS

NOSE — Itchy or runny nose, sneezing

MOUTH — Itchy mouth

SKIN — A few hives, mild itch

GUT — Mild nausea or discomfort

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

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

1. Antihistamines may be given, if ordered by a healthcare provider.
2. Stay with the person; alert emergency contacts.
3. Watch closely for changes. If symptoms worsen, give epinephrine.

MEDICATIONS/DOSES

Epinephrine Brand or Generic: _____

Epinephrine Dose: ☐ 0.1 mg/kg ☐ 0.15 mg IM ☐ 0.3 mg IM

Antihistamine Brand or Generic: _____

Antihistamine Dose: _____

Other (e.g., inhaler-bronchodilator if wheezing): _____

FARE (Food Allergy Research & Education), ©2020

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HASSENFELD CHILDREN'S HOSPITAL AT NYU LANGONE

Revised anaphylaxis management algorithm during COVID pandemic

⚠

Patients with history of severe anaphylaxis such as intubated /ventilated, or reactions treated with more than 2 doses of epinephrine should continue their routine anaphylaxis plan and activate emergency services immediately when anaphylaxis is recognized.

IMPORTANT REMINDER: Anaphylaxis is a potentially life-threating, severe allergic reaction.
If in doubt, give epinephrine.

HASSENFELD CHILDREN'S HOSPITAL AT NYU LANGONE

SEVERE SYMPTOMS: any of the following


⚠ Patients with history of severe anaphylaxis such as those who have been intubated and ventilated, or had reactions treated with more than two doses of epinephrine should follow their routine anaphylaxis plan and activate emergency services immediately when anaphylaxis is recognized.

IMPORTANT: Anaphylaxis is a potentially life-threatening, severe allergic reaction. If in doubt, give epinephrine.

SEVERE SYMPTOMS: ANY OF THE FOLLOWING

LUNG — Shortness of breath Wheezing, repetitive cough

HEART — Pale or bluish skin, faintness, weak pulse, dizziness

GUT — Repetitive vomiting, severe diarrhea

THROAT — Tight or hoarse throat, trouble breathing or swallowing

SKIN — Many hives over body, widespread redness

MOUTH — Significant swelling of the tongue or lips

OTHER — Feeling something bad is about to happen, anxiety, confusion

Mild symptoms from more than one system area:

Itchy runny nose, sneezing and/or itchy mouth and/or few hives, mild itch and /or mild nausea or discomfort

1. INJECT EPINEPHRINE IMMEDIATELY while seated, have telephone within reach
2. Notify a housemate or neighbor to help you
3. Lay down with legs elevated near the doorway, which should be unlocked or open to allow others to enter and help. Keep children in a position of comfort, to minimize respiratory distress and agitation and risk of aspiration in case of vomiting.
4. Administer oral antihistamine, preferably non-sedating (e.g. cetirizine)
5. Administer albuterol for respiratory symptoms if prescribed and available
6. Monitor symptoms and blood pressure/pulse if possible

Casale, Wang, Nowak-Wegrzyn, JACI in Practice 2020

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HASSENFELD CHILDREN'S HOSPITAL AT NYU LANGONE

SEVERE SYMPTOMS: after the 1st dose of epi

SYMPTOMS DON'T IMPROVE OR WORSEN

Repeat epinephrine injection in 5 minutes or sooner if symptoms escalate rapidly

SEVERE SYMPTOMS DON'T IMPROVE OR WORSEN:

Activate Emergency Services (Call 911)

SEVERE SYMPTOMS RESOLVE

- Continue to monitor for 4-6 hours for the recurrence of symptoms
- Be ready to administer treatment if symptoms reappear (biphasic anaphylaxis)
- Notify your physician on a non-urgent basis
- Replenish emergency medications

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HASSENFELD CHILDREN'S HOSPITAL AT NYU LANGONE

Ava: 15-year-old female with asthma and severe cow milk allergy

- Most recent reaction was 6 months ago, milk in a cookie-itchy mouth, followed by vomiting, coughing and generalized hives, treated with epi x 2 in the PED
- Drinks about 4 fl oz of a smoothie that instead of almond milk contained cow milk (CM)
- C/o funny feeling in his mouth after drinking 4 fl oz of smoothie made with CM
- What do you recommend?
- Consider impending anaphylaxis: recent severe reaction, large dose of CM, administer epi, observe at home or call 911

HASSENFELD CHILDREN'S HOSPITAL AT NYU LANGONE

FPIES (Food protein-induced enterocolitis syndrome)

HASSENFELD CHILDREN'S HOSPITAL AT NYU LANGONE

Jack: 8-month-old male with FPIES to oatmeal

- Age 6 months: 2 hrs after ingesting 1 oz of oat baby cereal, Jack developed profuse emesis, lethargy, in the PED rehydrated with IVF
- Age 8 months: grabs a "bunch" of Cheerios™ from his older sister and eats them
- What do you do at this time?

Cheerios is a trademark of General Mills, Inc..

FPIES PHENOTYPES

Acute
- Ingestion following a period of avoidance (at least several days)
- Onset of emesis: **1- 4 hours**
- Lethargy, limpness ("septic appearance")
- 20% go into **shock**
- 15% with methemoglobulinemia
- 6-8 hours later: diarrhea
- Onset: usually under 12 months; F/SF children, adults

Sxs resolve within 24 h

Chronic
- Young infants fed continuously with milk or soy formulas
- Watery diarrhea
- Mucous, blood in stools
- Intermittent emesis
- Low albumin and t. protein
- Failure to thrive
- Onset: first 1-3 months of life

Sxs resolve within days-weeks, may require TPN

Management of acute FPIES

SUMMARY STATEMENT 17: Treat acute-FPIES as a medical emergency, and be prepared to provide aggressive fluid resuscitation as approximately 15% of patients may develop hypovolemic shock. [Strength of Recommendation: Strong; Evidence Strength: IIa; Grade: B]

24 Nowak-Wegrzyn et al. International FPIES Guidelines, JACI in Practice, 2017

Treatment of acute FPIES

- **Fluid bolus: Normal saline 10-20 mL/kg**
- **Methylprednisolone 1 mg/kg/dose i.v.** (single dose)
- Potential role of **ondansetron**
0.15 mg /kg/dose i.v. [serotonin receptor inhibitor]
- Epinephrine generally not helpful in acute reactions without fluid replacement-do not RX epi autoinjector routinely
- Extreme cases: vasopressors, life support

Acute Management

- **Acute reaction—Have emergency treatment plan**
  - Go to the Emergency Room
  - Call 911
  - Child needs fluids to recover
- Mild reaction—Can manage at home

Severe past FPIES reaction: prolonged hospitalization and support

Food that caused past severe reaction was definitely ingested OR shows signs of FPIES reaction:

1. **Activate emergency services (EMS) or go to the emergency department (ED) by private car if prolonged waiting time for ambulance**
2. **If available, immediately administer ondansetron orally for patients older than 6 months, 0.15 mg /kg, max dose 8 mg; may repeat once if patient vomited within 10 minutes after the first dose**

Moderate past FPIES reaction: intravenous hydration in the ED or hospital

Food that caused past moderate reaction was definitely ingested OR shows signs of FPIES reaction:

- **If available, immediately administer ondansetron orally for patients older than 6 months, 0.15 mg /kg, max dose 8 mg; may repeat once if patient vomited within 10 minutes after the first dose**
- **<u>If symptoms appear</u>:**
  - **Go the ED by private car and wait outside, enter ED only if symptoms worsen, e.g., continued forceful emesis, lethargy, signs of dehydration**
  - **Attempt oral rehydration with clear liquids or breast milk, small amount, e.g., ice chips or 1 teaspoon 20 min after vomiting episode, advance as tolerated; monitor for dehydration (tears, saliva, wet diapers) while in the car**
  - **If initial symptoms are severe (lethargy, unresponsiveness, floppy, dusky appearance) activate EMS or go to the ED by private car if prolonged waiting time for ambulance**

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Mild past FPIES reaction: recovered at home

Food that caused past mild reaction was definitely ingested OR shows signs of FPIES reaction:

- **Monitor for symptoms.**
- **<u>If symptoms appear</u>:**
  - **If available, administer ondansetron orally for patients older than 6 months, 0.15 mg /kg, max dose 8 mg; may repeat once if patient vomited within 10 minutes after the first dose**
  - **Attempt oral rehydration with clear liquids or breast milk, small amount, e.g., ice chips or 1 teaspoon 20 min after vomiting episode, advance as tolerated; monitor for dehydration (tears, saliva, wet diapers)**
- **If symptoms continue, go the ED by private car and wait outside, enter ED only if symptoms worsen, e. g., continued forceful emesis, lethargy, signs of dehydration**
- **If initial symptoms are severe (lethargy, unresponsiveness, floppy, dusky appearance) activate EMS or go to the ED by private car if prolonged waiting time for ambulance**

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Jack: 8-month-old with FPIES to oatmeal

- Age 6 months: 2 hrs after ingesting 1 oz of oat baby cereal, Jack developed profuse emesis, lethargy, in the PED rehydrated with IVF
- Age 8 months: grabs a "bunch" of Cheerios™ from his older sister and eats them
- What do you do at this time?

- Observe for symptoms
- If vomiting develops: administer ondansetron po and monitor with attempts of oral rehydration (clears, BM)
- If lethargic, floppy, unable to take po: take to the ED, IVF

Cheerios is a trademark of General Mills, Inc.

Summary: Anaphylaxis

- Epinephrine is the drug of choice for treatment of anaphylaxis
- Severe anaphylaxis and/or the need for >1 dose of epinephrine to treat anaphylaxis are risk factors for biphasic anaphylaxis.
- Antihistamines and/or glucocorticoids are the second line therapies
- Current advice, considering COVID-19 pandemic: after the 1st dose observe at home, activating EMS not mandatory unless past h/o severe anaphylaxis (prolonged observation in the ED, hospitalization, intubation and ventilation)

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Summary: FPIES

- Manage reactions according to the past history and severity of the current symptoms
- Utilize oral ondansetron judiciously
- Monitor for dehydration, lethargy, shock

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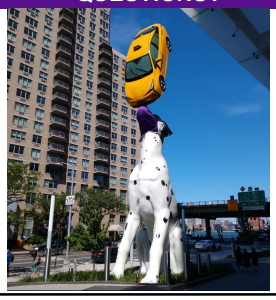
THANK YOU FOR YOUR ATTENTION!

QUESTIONS?



Food Allergen Labeling: What You Need to Know Today

Carina Venter, PhD, RD
Associate Professor
Pediatric Allergy and Immunology
October 23, 2020

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Disclosures

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- Consultant and educational lectures provided to Danone/Nutricia, Nestle Nutrition Institute, Abbott Nutrition, Mead Johnson Nutrition
- Advisory board affiliations: Before Brands and Else Nutrition
- Royalties: None
- Research grants: Reckitt Benckiser; National Peanut Board

The opinions reflected in this presentation are those of the speaker and independent of Nutricia North America

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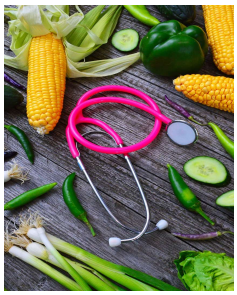
Overview

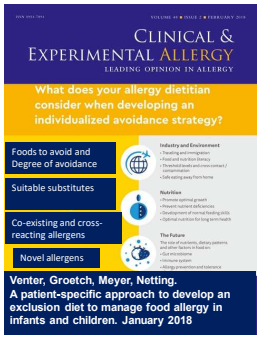
1) Explain food allergen labelling laws in the U.S.

2) Illustrate proposed changes to FDA (U.S. Food & Drug Administration) food allergen labeling during an international pandemic

3) Show practical suggestion about how to communicate pros and cons of precautionary advisory labeling to your patients



A patient-specific approach when developing an exclusion diet to manage food allergy in infants and children



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Label Reading
Food Allergen Labeling Consumer Protection Act (FALCPA)

- Milk
- Egg
- Wheat
- Soy
- Peanut
- Tree nut* *the list is very long and contains coconut*
- Fish*
- Crustacean shellfish*
- *Specific species must be listed

https://www.fda.gov/food/food-allergensgluten-free-guidance-documents-regulatory-information/food-allergen-labeling-and-consumer-protection-act-2004-questions-and-answers

Which of the following requires a "Contains" statement?

A) Ingredients: Enriched wheat flour, water, farina (wheat), yeast, salt, sugar, soybean oil, wheat gluten, grain vinegar, soy lecithin, whey (milk), peanut

B) Ingredients: Enriched wheat flour, water, farina (wheat), yeast, salt, sugar, soybean oil, wheat gluten, grain vinegar, soy lecithin, whey, peanut

Contains: wheat, soy, milk, peanut

FALCPA-regulated allergens can be identified in one of three ways:
1. In the ingredient list, using the allergen's common name.
2. Parenthetically in the ingredient list, if the ingredient is not the common name.
3. In a "Contains" statement (if "Contains" statement is used, all allergens must be included.)

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Incidental Ingredients

A "major food allergen" may not be omitted from the product label even if it is only a minor ingredient

Allergens not considered "major" may remain unidentified on product labels

https://www.fda.gov/food/food-allergensgluten-free-guidance-documents-regulatory-information/food-allergen-labeling-and-consumer-protection-act-2004-questions-and-answers

Read every label: Ingredients may be different even in the same product of a different size!

Small snack size

INGREDIENTS: CORN SYRUP, SUGAR, PALM OIL, AND LESS THAN 2% OF MONO- AND DIGLYCERIDES, HYDROGENATED COTTONSEED OIL, MALIC ACID, SALT, SOY LECITHIN, NATURAL FLAVORS, BLUE 1, RED 40, YELLOW 5.
CONTAINS: SOY INGREDIENT.

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The larger size of the same products contains egg ingredients.

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Cross contact

- Precautionary Allergen Labeling (PAL)
  - May contain…
  - Manufactured in a facility…
  - Manufactured on shared equipment…
- VOLUNTARY AND UNREGULATED - companies must be truthful and not misleading - arbitrarily adding PAL is not allowed!

Remington BC, Baumert JL, Blom WM, Houben GF, Taylor SL, Kruizinga AG. Unintended allergens in precautionary labelled and unlabelled products pose significant risks to UK allergic consumers. Allergy. 2015;70(7):813-9.

What you need to know about "may contain"

- You cannot "risk stratify based on the term used"
- One of the most difficult discussions: The lack of PAL does not guarantee that is it not contaminated…
- The foods contaminated and the allergens that they are contaminated with differ between countries

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1. Ford LS, Taylor SL, Pacenza R, Niemann LM, Lambrecht DM, Sicherer SH. Food allergen advisory labeling and product contamination with egg, milk, and peanut. J Allergy Clin Immunol 2010;126:384-5.
2. Robertson ON, Hourihane JO, Remington BC, Baumert JL, Taylor SL. Survey of peanut levels in selected Irish food products bearing peanut allergen advisory labels. Food Addit Contam Part A Chem Anal Control Expo Risk Assess 2013;30:1467-72.
3. Remington BC, Baumert JL, Blom WM, Houben GF, Taylor SL, Kruizinga AG. Unintended allergens in precautionary labelled and unlabelled products pose significant risks to UK allergic consumers. Allergy 2015;70:813-9.

What about cross contact?
Choose those from dedicated facilities*

*Risk of cross contact may change and frequent contact with the manufacturer is required!

Nuts	Brands
Almonds	Barney Butter™, Barney Bakery™ flour and almonds, Wonderful™ brand almonds
Cashews	Sunshine nut co.™ brand
Macadamia	Hamakua™ brand
Pine Nuts	Wholesale Pine Nuts (wholesalepinenuts.com)
Pistachio	Wonderful™ brand pistachios, Santa Barbara Pistachios™, Pistachio Factory butter
Walnuts	Crazy Go Nuts™ Walnut Butters, Derby Walnuts
Sesame	Kevala™ brand tahini

Who should avoid products with PAL?

- Patients with food protein-induced enterocolitis syndrome (FPIES)?
  - Not typically
- Patients with eosinophilic esophagitis (EoE)?
  - Maybe
- Patients tolerating baked milk or baked egg?
  - Depends on the product
- Patients with high threshold?
  - Not easy to define
- The food allergy guidelines suggest avoiding *any product* with a precautionary label for your allergen (IgE-mediated food allergy)

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Boyce JA, Assa'a A, Burks AW, et al. Guidelines for the diagnosis and management of food allergy in the United States: summary of the NIAID-Sponsored Expert Panel Report. Nutrition 2011;27:253-67.

Box 1. Examples of 'snack'[1] items which have been reported to have a higher risk of allergen cross-contamination

- Chocolates and chocolate-based foods, for example chocolate spreads
- Cookies/Biscuits
- Muesli bars/Cereal bars/'Trail' bars/Dried fruit bars/Nutrition bars
- Nut mixes
- Baked goods/baking mixes (cakes, pastries, scones)
- 'Confectionery' (such as sweets and candies)
- Ice cream

There is anecdotal data suggesting the seeded ('speciality') breads may also have a high risk of allergen cross-contamination. We would suggest that these items should always be avoided by nut-allergic individuals.

[1]We acknowledge that 'snack' foods might be defined differently by different consumers and in diverse countries.

Table 1. Factors associated with life-threatening reactions to peanut [8, 9, 38]

Factors associated with increased risk	Factors associated with low risk
Prior anaphylaxis to the same food	?
Teenagers and younger adults [110, 115]	?
Comorbidities (asthma, cardiovascular disease, mastocytosis) [110, 116]	?
Concurrent use of medications (e.g. non-selective beta-blockers and non-steroidal anti-inflammatory) drugs	?
Exercise	?

What should we avoid?

Brough HA, Turner PJ, Wright T, Fox AT, Taylor SL, Warner JO, et al. Dietary management of peanut and tree nut allergy: what exactly should patients avoid? Clin Exp Allergy. 2015;45(5):859-71.

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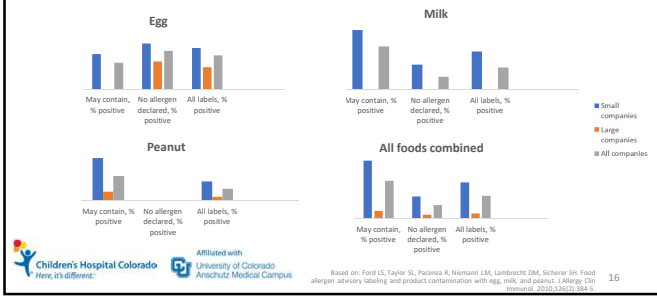
Smaller vs. larger companies



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Based on: Ford LS, Taylor SL, Pacenza R, Niemann LM, Lambrecht DM, Sicherer SH. Food allergen advisory labeling and product contamination with egg, milk, and peanut. J Allergy Clin Immunol. 2010;126(2):384-5.

16

Is this peanut oil highly refined?

The way an oil is processed (highly refined or expeller pressed) is not required to be listed on the product label.

FALCPA Exempts

- **Foods that are placed in a wrapper or container or prepared on a made-to-order basis.**
- FALCPA does not cover foods "served in restaurants or other establishments in which food is served for immediate human consumption".
- Alcoholic beverages, medications, anything regulated by the USDA (U.S. Department of Agriculture) (fresh meat, poultry, eggs fruits and vegetables).

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https://www.fda.gov/food/food-allergensgluten-free-guidance-documents-regulatory-information/food-allergen-labeling-and-consumer-protection-act-2004-questions-and-answers

FALCPA exemptions

- Are there any other areas not covered by FALCPA?
- Yes, there are quite a few areas where the law does not apply:
  - Prescription drugs
  - Over-the-counter drugs
  - Personal care items such as cosmetics, shampoo, mouthwash, toothpaste or shaving cream.
  - Any food product regulated by the USDA, which includes meat, poultry, or certain egg products.
  - Any product regulated by the Alcohol, Tobacco Tax and Trade Bureau (ATTB). This includes alcoholic drinks, spirits, beer and tobacco products.
  - Any restaurant foods or foods that are placed in a wrapper or container in response to a person's order for that food. This includes street vendors, festival foods, fast food restaurants.
  - Pet: foods, supplements, and supplies
  - Kosher labeling (not related to FALCPA)
- More information on FALCPA: https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Allergens/ucm106890.htm

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The thing about COVID - FDA labeling "Temporary Flexibility Policy"

What has changed:

- The FDA is allowing manufacturers to use minor formulation changes without full disclosure on a food product label.
- All major allergens must continue to be fully disclosed.

What has not changed:

- Manufacturers **must** continue to completely abide by the Food Allergen Labeling and Consumer Protection Act.
- Mandatory identification of major allergens is still required.
- The use of vague ingredient terms such as spices can contain hidden spice ingredients that are not considered major allergens. Items using terms such as "spices" may swap out different spice ingredients without any notification. **This is not a change and has always been the case.** The FDA is reminding manufacturers of this rule.
- Precautionary allergen labeling (such as "May contain...") is still voluntary.

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https://www.fda.gov/regulatory-information/search-fda-guidance-documents/temporary-policy-regarding-certain-food-labeling-requirements-during-covid-19-public-health?eType=EmailBlastContent&eId=4ed3c997-9e1b-45d4-8542-71186aa6051d

20

COVID and food labeling

The good news is:

- This temporary policy does not impact mandatory food allergen labeling.

Use caution:

- If you use a special product because you have verified in the past that it does not contain sesame, garlic, mustard, rice starch, etc., in the "natural flavor" or "spice" or "starch" you may want to confirm with the manufacturer to see if there have been any formulation changes.
  - Manufacturers are asked to avoid substitutions that could result in a safety concern without making a label change or inform consumers of the change. **However, is NOT mandatory.**

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COVID

Questions you might get:

- Patients have mostly been concerned about issues such as PAL - a company may swap out almond for peanut in a product (for example a chocolate bar) that is run on the same line as a plain product but the PAL still says "may contain almond."
- If patients are concerned they can use products from allergen "free-from" companies.

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When we start to travel again

- Food allergen labeling laws differ around the world
- Major food allergens differ
- Products/ingredients that are "exempted differ"
- Look out for paper: Dietary management of food allergies later this year
  - Raquel Durban, Marion Groetch, Sherry Collins, Wendy Elverson, Alyssa Friebert, Jamie Kabourek, Stephanie M Marchand, Vicki McWilliams Rosan Meyer, Merryn Netting, Isabel Skypala, Taryn Van Brennan, Emillia Vassilopoulou, Berber Vlieg – Boerstra, Carina Venter

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Any questions?

- Thank you
- Marion Groetch

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FPIES: A Difficult Disease During Uncertain Times

Food Allergy University 2020
October 23, 2020

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Disclosures: Marion Groetch

Financial
- Royalties from UpToDate
- Royalties from AND and FARE

Volunteer Advisory
- Medical Advisory Board of I-FPIES
- Senior Advisor to FARE
- Health Sciences Advisory Council for APFED

Commercial
- None

The opinions reflected in this presentation are those of the speaker and independent of Nutricia North America.

Food Protein-Induced Enterocolitis Syndrome (FPIES)

- A non IgE-mediated, cell-mediated food allergy
- Typically presents in infancy
- **Delayed** onset of repetitive, protracted **VOMITING** that begins approximately 1 to 4 hours after food ingestion.
- Vomiting is often accompanied by lethargy and pallor.
- Delayed onset and absence of cutaneous and respiratory symptoms suggest a systemic reaction different from anaphylaxis.

FPIES reactions required a high degree of health care utilization:

- 56% (N = 220 of 393) were evaluated in the hospital
- 35.1% (N = 138 of 393) were managed solely in the emergency department
- 20.9% (N = 82 of 393) were admitted to the hospital

Maciag et al. A slice of FPIES: Insights form 441 Caregivers. J Allergy Clin Immunol Pract. 2020

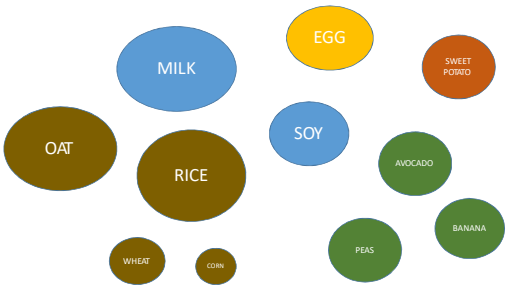
Marion Groetch, MS, RDN2020

Objectives

- List common trigger foods for FPIES in published case series
- Discuss the risk for multiple food FPIES and the potential impact on complementary feeding
- Explain dietary management, nutritional risks, and nutritional approach to the patient with FPIES during the COVID pandemic

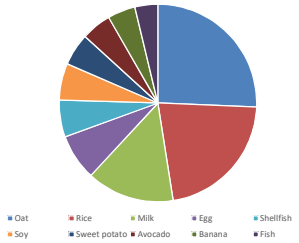
Marion Groetch, MS, RDN2020

Objective: List common trigger foods for FPIES in published case series



Marion Groetch, MS, RDN2020

Foods causing acute FPIES, expressed as a percentage of patients with FPIES reaction to the trigger food



Based on: Su, Patil, Stockbridge, et al. J Allergy Clin Immunol. 2020

Marion Groetch, MS, RDN2020

Grains

Trigger food	No. (%) of patients (N = 74)
Grains	65 (88)
Rice	39 (53)
Oats	26 (35)
Wheat	4 (5)
Quinoa	3 (4)

Blackman AC, et al. Ann Allergy Asthma Immunol. 2019

- Wang *et al.* reported no patient (n=13) challenged to wheat due to oat or rice triggered FPIES had a positive challenge
- Blackman *et al.* (4) also reported low cross reactivity with wheat (5%) in those with rice FPIES (n=39)
- Mehr *et al* (7) with a cross reactivity of 5% for wheat and 1% for corn

Marion Groetch, MS, RDN2020

Vegetables	32 (43)
Sweet potato	16 (22)
Squash	9 (12)
Potato	6 (8)
Corn	5 (7)
Carrots	5 (7)
Green beans	4 (5)
White potato	3 (4)
Pea	3 (4)
Beet	1 (1)

Fruits	30 (40)
Banana	18 (24)
Avocado	12 (16)
Apple	8 (11)
Pear	7 (9)
Blueberry	2 (3)
Mango	2 (3)
Peach	1 (1)
Strawberry	1 (1)
Plum	1 (1)

Blackman AC, et al. Ann Allergy Asthma Immunol. 2019

Meat	10 (13)
Chicken	5 (7)
Turkey	2 (3)
Beef	1 (1)
Pork	1 (1)
Bison	1 (1)

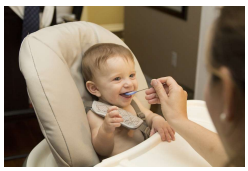
Blackman AC, et al. Ann Allergy Asthma Immunol. 2019

Su, *et al.* found that chicken and turkey had a strongly positive association, whereas wheat and barley had a moderately positive association

Su, Patil, Stockbridge, et al.
J Allergy Clin Immunol. 2020

Marion Groetch, MS, RDN2020

Objective:
Discuss the risk for multiple food FPIES and the potential impact on complementary feeding



Marion Groetch, MS, RDN2020

Multiple Food Triggers and Avoidance

- ~50% - 80% in the established literature have FPIES to a single food
- Blackman *et al.* (Texas) >50% had recorded more than 3 triggers
- In a recent Australian cohort, infants with FPIES to multiple foods were younger at time of initial episode [4.6 v. 5.8 mo (*P*=.001)]
- Maciag *et al.* (Boston) 69.4% avoided at least 2 food groups

- A. Nowak-Węgrzyn, M. Chehade, M. Groetch, et al. J Allergy Clin Immunol 2017
- Caubet JM FL, et al. J Allergy Clin Immunol 2014
- Ruffner MA, et al. J Allergy Clin Immunol In practice 2013
- Mehr S, Frith K, Barnes EH, et al. J Allergy Clin Immunol. 2017
- Blackman AC, et al. Ann Allergy Asthma Immunol. 2019
- Maciag, Bartnikas, Sicherer, *et al.* J Allergy Clin Immunol Pract. 2020

Marion Groetch, MS, RDN2020

The Psychosocial Impact of FPIES

Compared to published cohorts of caregivers of children with IgE-mediated food allergy*

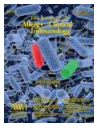
- The burden of FPIES on caregivers was significantly higher (mean=3.4 versus 3.0, p<0.001)
- Self-efficacy was significantly lower (mean=63.9 versus 76.1, p<0.001)

*Based on surveys completed by caregiver-members of the International FPIES Association at a conference (n=42) and online (n=368).

Marion Groetch, MS, RDN2020 Maciag et al. J Allergy Clin Immunol Pract. 2020

International Consensus Guidelines

- Infants with FPIES are at heightened risk of nutritional inadequacy during the introduction of complementary foods…
- They therefore need a well-managed weaning process
- Elimination and Guidance on Food Introduction
  - Risk
  - Nutrition
  - Feeding skill development



A. Nowak-Węgrzyn, M. Chehade, M. Groetch, et al. Journal of Allergy and Clinical Immunology 2017

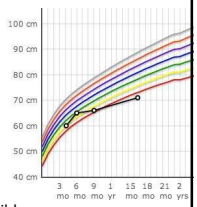
Marion Groetch, MS, RDN2020

Objective:
Explain nutritional risks, dietary management, and nutritional approach to the patient

Marion Groetch, MS, RDN2020

What is the cause of nutritional problems?

•Meyer *et al*. found children particularly at risk of poor growth are those with non-IgE and mixed IgE- and non-IgE-mediated allergies, and those with cow milk allergy (CMA)



- Blackman *et al.* reported from their cohort of 74 children:
  - Malnutrition noted in 16 patients (23%)
- Cause of malnutrition noted by dietitian in subset of patients
  - Suboptimal oral intake and limited food choices
  - Knowledge deficit related to how to introduce safe foods.

Meyer, *et al.* J Hum Nutr Diet 2019
Blackman AC, *et al*. Ann Allergy Asthma Immunol. 2019

Marion Groetch, MS, RDN2020

Food aversion and poor weight gain in FPIES: A retrospective study Su, et al. JACI 2020

Food aversion
- Multiple triggers (≥3)
- FPIES to wheat
- Family history of food allergy

Poor weight gain
- Multiple triggers (≥3)
- FPIES to cow milk
- FPIES to banana
- Chronic FPIES

Logistic regression analysis for patients with FPIES with food aversion and poor body weight gain

Dietary Management

- Introduce solid foods by 6 months of age.
- Start with one or two fruits and/or vegetables, red meats and grains including ancient/pseudo grains, fortified corn products and even wheat can be considered.
- Foods should be offered in age-appropriate forms and textures.

- While there are no US recommendations to guide selections from food groups, the US Dietary Guidelines Advisory Committee Report (DGAC) recommends including 0.5 ounce of fortified infant cereal in the early complementary diet for the breastfed infant

https://www.dietaryguidelines.gov/sites/default/files/2020-07/ScientificReport_of_the_2020DietaryGuidelinesAdvisoryCommittee_first-print.pdf

Marion Groetch, MS, RDN2020

Lower risk	Moderate risk	Higher risk
Vegetables		
Broccoli, cauliflower, parsnip, turnip, pumpkin	Squash, carrot, white potato, green bean (legume)	Sweet potato, green pea (legume)
Fruits		
Blueberries, strawberries, plum, watermelon, peach	Apple, pear, orange	Banana, avocado
High iron foods		
Lamb, fortified quinoa cereal, millet	Beef, fortified grits and corn cereal, wheat (whole wheat and fortified), fortified barley cereal	Fortified, infant rice and oat cereals
Other		
Tree nuts and seed butters* (sesame, sunflower, etc.) *Thinned with water or infant puree to prevent choking	Peanut, other legumes (other than green pea)	Milk, soy, poultry, egg, fish

Marion Groetch, MS, RDN2020

Nowak-Węgrzyn, Chehade, Groetch, et al. Journal of Allergy and Clinical Immunology 2017

Objective: How does the global pandemic change our nutritional approach?

- Families may not have access to preferred brands
- Families may be less interested in introducing new foods and risking an emergency department visit

Provide tools to feed in this environment

Marion Groetch, MS, RDN2020

Do not avoid precautionary allergen labeling (PAL) unless in the rare circumstance patient has reacted to trace/invisible amounts in the past.

Generally safe ingredients: refined oils like soy and corn oil, soy lecithin, corn syrup, corn syrup solids, leavening agents such as ammonium or sodium bicarbonate, baking soda, enzymes, spices, salts, sugars, preservatives, artificial flavorings or colorings, gums like guar gum, xanthan gum, cellulose gel or gum, carrageenan, silicon dioxide, calcium carbonate or other vitamins or minerals

Introduce new foods gradually- discuss with the MD!

Serve 1 new food over 5-10 days. Start with a ¼ tsp and double amount with each serving. Serve twice per day (separated by 6 hours). Stop feeding if any symptoms.

Example: Day one: ¼ tsp at 9 AM and ½ tsp at 5PM

Day two: 1 tsp at 9AM and 2 tsp at 5PM

Continue increasing until reaching an infant serving size

Infant serving size: 1-3 Tablespoons meat, 2 ounces fruit or vegetable, 1/4 - 1/2 cup grains

Multiple servings (1-3) may be needed per day depending on age and nutritional needs.

Supplementation may be needed:

1 mg/kg/day elemental iron for breastfed infants without a dietary source of iron

400 IU vitamin D /day for breastfed infants and for formula-fed infants receiving <1 liter infant formula/day

Continued supplementation >1yr may be required for cow's milk allergy

International consensus guidelines for the diagnosis and management of food protein–induced enterocolitis syndrome: Executive summary—Workgroup Report of the Adverse Reactions to Foods Committee, American Academy of Allergy, Asthma & Immunology

Anna Nowak-Węgrzyn, MD, Mirna Chehade, MD, Marion E. Groetch, MS, RDN, Jonathan M. Spergel, MD, PhD, Robert A. Wood, MD, Katrina Allen, MD, PhD, Dan Atkins, MD, Sami Bahna, MD, PhD, Ashis V. Barad, MD, Cecilia Berin, PhD, Terri Brown Whitehorn, MD, A. Wesley Burks, MD, Jean-Christoph Caubet, MD, Antonella Cianferoni, MD, PhD, Marisa Conte, MLIS, Carla Davis, MD, Alessandro Fiocchi, MD, Kate Grimshaw, PhD, RD, RNutr, Ruchi Gupta, MD, Brittany Hofmeister, RD, J.B. Hwang, MD, Yitzhak Katz, MD, George N. Konstantinou, MD, PhD, MSc, Stephanie A. Leonard, MD, Jennifer Lightdale, MD, Sean McGhee, MD, Sami Mehr, MD, FRACP, Stefano Miceli Sopo, MD, :10.1016/j.jaci.2016.12.966

- Journal of Allergy and Clinical Immunology 2017
- Available through open access and is a comprehensive review of the literature, using GRADE evaluation and was authored by the world's leading FPIES experts including allergists, gastroenterologists, pediatricians, nurses, dietitians, and 281 representatives from lay patient organizations from the USA, UK, Australia, Italy, Switzerland, Japan, Korea, and Greece.

Questions?

Making food fun! Practical tips for your patients with food allergies

Raquel Durban MS, RD, LD/N
Asthma & Allergy Specialists, PA
Charlotte, NC
October 23, 2020

Disclosures

Employer: Asthma & Allergy Specialists, PA
Voluntary Board Member/Advisory Panel
International FPIES Association
American College Allergy, Asthma and Immunology: Food Allergy and Allied Health Committee
American Academy Allergy, Asthma and Immunology: Eosinophilic Gastrointestinal Diseases and Adverse Reaction to Food Committee
Consultant
Mead Johnson Nutrition
AstraZeneca
Allakos
Speaker's Bureau
Mead Johnson Nutrition
Nutricia North America
Abbott Nutrition

Speaker honorarium provided by Nutricia

The opinions reflected in this presentation are those of the speaker and independent of Nutricia North America

Objectives

Understand	Understand challenges of food procurement
Discover	Discover tips to prepare available foods in creative ways
Ensure	Ensuring adequate nutrition despite adversity

Considerations for the Implementation of ANY Elimination Diet

Potential Barriers to Implementation	First Steps	Resolve
Patients may present with nutritional deficits	• Screen for nutritional risks by carefully assessing growth - both weight and height/length • Take a detailed diet history • Nutrition labs if needed	Correct nutritional deficits while implementing diet or delay dietary management until nutritional needs can be met
Eating/feeding problems may impact the ability of the patient to accept substitute foods.	• Assess eating and feeding skills and behaviors • Assess food preferences	Recommend alternative sources of nutrition that the patient can tolerate and is willing to eat
Other dietary implementation needs	• Screen for additional barriers such as social, financial, behavioral	Ensure that families can safely implement the diet

RDN – Really Darn Nourishing

Push towards opportunity

Tips and tricks from a food allergy RDN

Practical approach to making food fun!

Food procurement	• Access to grocer • Dining out • School
Label reading	• Empowering opportunity for options • Educating patient or other caregivers
Budget	• Prioritize • Plan • Perimeter
Versatility of food	• Building a plate • Jam, jelly, preserves, fruit • Hash it or smash it, just devour it!

Groetch M, et al. Ann Allergy Asthma Immunol. 2020.

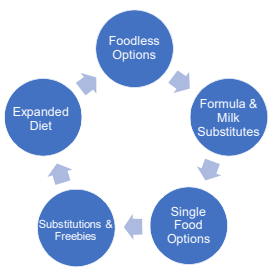
Raquel's Rule of 3

- Safety, always, in all ways
- Stop and smell the roses
- Find a common ground

SAFETY	ENJOYMENT	INCLUSION
Label reading	What can I have?	What can I pack?
When in doubt, ask!	How can I prepare it?	Consideration
Alternative options	Social event empowerment	Confidence

Think in steps

- What do I want to eat?
- What can I eat?
- What tools do I have?



When we can, I'd rather be proactive than reactive

- Phone alarms
  Friendly reminders
- Even the best of plans are not fool proof
  Anticipate it!
- Accidents happen,
  But please tell your team
- If you have a question,
  JUST ASK!
- Vitamins and mineral
  Supplement should be individualized – ask, read, adhere
- There's an app for that
  Most carriers have an app store - symptom tracking, label reading

Success is not measured in pass/fail

- Food trials/oral food challenge (OFC) - brave
- Recipes – willingness to learn
- Acceptance of a new food - adventurous
- Grocery shopping – thrill seeking!
- Dining out – prepared and confident

Success is measured in resiliency!

Pearls and takeaways

You CAN make food allergies FUN

RDNs provide a valuable patient and clinician resource for optimizing patient outcomes

References and Resources

Publications:

- Wang R, Hirano I, Doerfler B, Zalewski A, Gonsalves N, Taft T. Assessing Adherence and Barriers to Long-Term Elimination Diet Therapy in Adults with Eosinophilic Esophagitis. *Dig Dis Sci*. 2018;63(7):1756-1762. doi:10.1007/s10620-018-5045-0
- Jones CJ, Llewellyn CD, Frew AJ, Du Toit G, Mukhopadhyay S, Smith H. Factors associated with good adherence to self-care behaviours amongst adolescents with food allergy. *Pediatr Allergy Immunol*. 2015;26(2):111-118. doi:10.1111/pai.12333

Websites and blogs:

- Kids with Food Allergies: Recipe Finder (https://www.kidswithfoodallergies.org/recipes-diet.aspx)
- Minimalist Baker (https://minimalistbaker.com/)
- Eating bird food (www.eatingbirdfood.com)
- The pretty bee (www.theprettybee.com)
- Allrecipes (www.allrecipes.com)

THE ROLE OF EARLY INFANT FEEDING TO PREVENT FOOD ALLERGIES

Sherry Coleman Collins, MS, RDN, LD
October 23, 2020

DISCLOSURES

- Honorarium provided by Nutricia
- Consultant to National Peanut Board

The opinions reflected in this presentation are those of the speaker and independent of Nutricia North America

OBJECTIVES

Following this presentation, attendees will be able to:

1. Incorporate the latest guidelines for early infant feeding to prevent food allergies into clinical practice;
2. Provide guidance for oral food challenges based on the latest expert consensus;
3. Recommend specific foods in age-appropriate forms to assist families with early infant feeding for food allergy prevention.

THINGS HAVE CHANGED…A LOT…IN 20 YEARS!

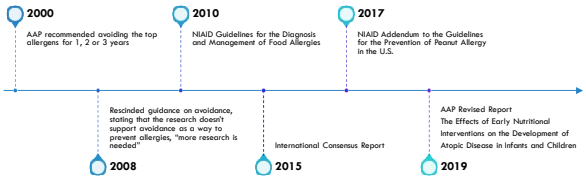
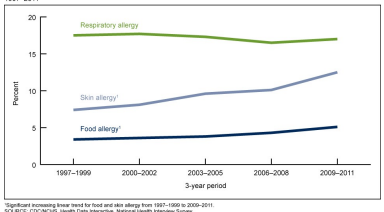


Figure 1. Percentage of children aged 0–17 years with a reported allergic condition in the past 12 months: United States, 1997–2011



*Significant increasing linear trend for food and skin allergy from 1997–1999 to 2009–2011.
SOURCE: CDC/NCHS, Health Data Interactive, National Health Interview Survey.

WHAT HAPPENED?

Significant increase in the rates of allergic disease in the United States among very young children.

SENSITIZATION ≠ CLINICAL ALLERGY

Sensitization – an individual has detectable IgE circulating to a specific protein or substance.*

Clinical Allergy – an individual experiences objective symptoms upon exposure to a specific allergenic substance every time they are exposed to the substance.**

*Sensitization can (and often does) occur in the absence of symptoms. This individual does not have clinical allergy.

**Thresholds and denaturization of protein can affect tolerance in some people.

LET'S LOOK AT SOME RESEARCH

A SURPRISING ASSOCIATION

2008 Study by Du Toit, et al found that a group of Jewish babies in the UK were 10 times as likely as their counterparts in Israel to develop peanut allergies.

What was the difference?

Du Toit, G, et al. Early consumption of peanuts in infancy is associated with a low prevalence of peanut allergy. J Allergy Clin Immunol. 2008;122:984-991.

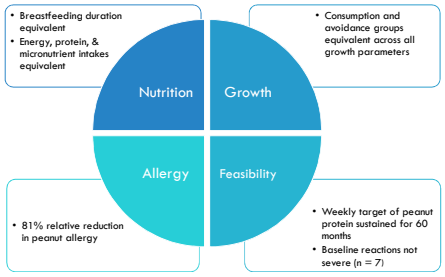
LEARNING EARLY ABOUT PEANUT ALLERGY (LEAP)

Up to an 86% reduction in peanut allergy

- UK Babies 4-11 months old at high-risk for peanut allergy
  - Severe eczema
  - Egg allergy
  - Both
- Randomized to eat peanut foods at enrollment or abstain until 5 years old

Du Toit, G, et al. Randomized trial of peanut consumption in infants at risk for peanut allergy. N Engl J Med. 2015;372:803-813.

LEAP NUTRITION



Based on: Feeney, M, et al. Impact of peanut consumption in the LEAP study: Feasibility, growth, and nutrition. J Allergy Clin Immunol 2016;138:1108-18.

ENQUIRING ABOUT TOLERANCE (EAT)

- Exclusively breastfed 3-month-old babies in UK with unknown risk for food allergies
- Randomly introduced 6 potential allergens (peanut, cooked egg, cow milk, sesame, whitefish, and wheat)
- Poor adherence
- Lower rates of all allergies in the early-intro group
- In per-protocol, lower rates of egg and peanut allergies (2g/each/week)

Perkin, MR, et al. Randomized trial of introduction of allergenic foods in breast-fed infants. N Engl J Med. 2016;374:1733-1743.

PETIT

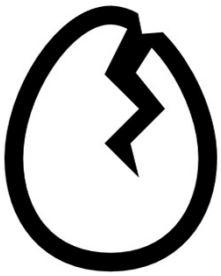
Randomized DBPC study – one group got egg and the other got placebo

4-5 month old Japanese Infants with eczema

Step-wise introduction of egg protein + aggressive eczema management

Stopped trial early because of such a significant positive response in the egg group

Huge reduction in egg allergy in the egg eating group 8% vs. 37.7% based on oral food challenge



Natsume, O, et al. Two-step egg introduction for prevention of egg allergy in high-risk infants with eczema (PETIT): a randomized, double-blind, placebo-controlled trial. Lancet. 2016.

CHILD

- General population of infants monitored every 6 months for 3 years
- Ongoing study of 2,669 participants
- At 3 years, positive "sensitization and probable clinical allergy" statistically significantly different when allergens (particularly peanut and egg) were introduced before 18 months of age

Simons, E, et al. Timing of introduction, sensitization, and allergy to highly allergenic foods at age 3 years in a general-population Canadian cohort. J Allergy Clin Immunol: In Practice. 2020;8:166-175.

THE IMPORTANT ROLE OF THE SKIN

The skin protects the body from foreign and potentially harmful substances and organisms.

Eczema provides an opportunity for allergy by triggering immune cells in the skin that may promote the development of IgE.

Managing eczema and promoting skin integrity is an evolving and important part of food allergy prevention.

ORAL FOOD CHALLENGE

STRATIFICATION OF RISK

HIGH RISK = SEVERE ECZEMA AND/OR EXISTING FOOD ALLERGY

SOME RISK = MILD TO MODERATE ECZEMA

LOW RISK = NO ECZEMA AND/OR EXISTING FOOD ALLERGY

MULTIDISCIPLINARY APPROACH

RD/RDN can help assess risk of food allergy

- Low/Moderate risk do not need pediatrician visit before introduction
- High risk infants should see pediatrician or allergist before introduction

PANDEMIC-RELATED RECOMMENDATIONS AND GUIDANCE

Telehealth services are encouraged (and could be here for the long-term!)

Risk vs. Benefit of introduction

- Low risk of serious adverse events even in allergic infants
- High risk of developing food allergies if not introduced before 12-18 months

CURRENT GUIDELINES AND RECOMMENDATIONS

NIAID GUIDELINES

Summary of Addendum Guidelines

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

National Institute of Allergy and Infectious Diseases-Sponsored Expert Panel. 2017 Addendum guidelines for the prevention of peanut allergy in the United States. Version current 24 October, 2018.

AAP GUIDANCE ON EARLY NUTRITIONAL INTERVENTIONS ON THE DEVELOPMENT OF ATOPIC DISEASE IN INFANTS AND CHILDREN

There is no evidence that delaying the introduction of allergenic foods, including peanuts, eggs, and fish, beyond 4-6 months prevents atopic disease.

There is now evidence that the early introduction of infant-safe forms of peanuts reduces the risk for peanut allergies. Data are less clear for timing of introduction of eggs; and

The new recommendations for the prevention of peanut allergy are based largely on the LEAP trial and are endorsed by the AAP.

Greer, FR, et al. The effects of early nutritional interventions on the development of atopic disease in infants and children: The role of maternal dietary restriction, breastfeeding, hydrolyzed formulas, and timing of introduction of allergenic complementary foods. Pediatrics. 2019;121:346.

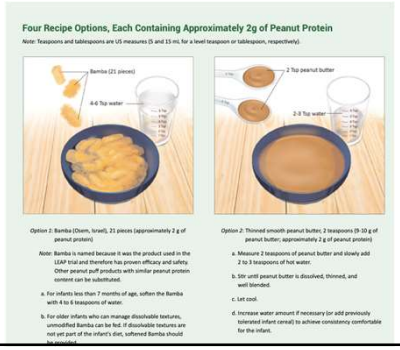
DGA 2020 SCIENTIFIC REPORT ISSUED JUNE 2020

HOW TO INTRODUCE COMMONLY ALLERGENIC FOOD

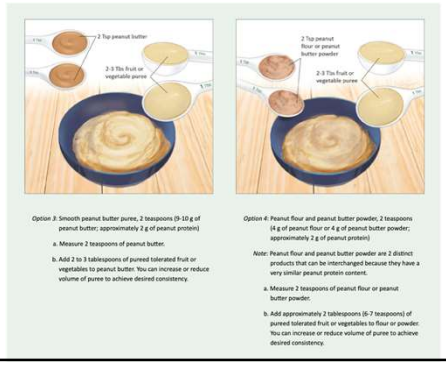
TO BEGIN

- Consider developmental readiness.
- Start with a well baby, no fever, vomiting, diarrhea, etc.
- Give peanut or other allergen at home, not in a restaurant, at daycare, etc.
- Feed early in the day, when 2 hours are available to observe.
- Start with a small amount on the tip of a spoon and wait 10 minutes before continuing.
- Stop if baby has a reaction; if no reaction continue until a full portion has been eaten.

RECIPES



RECIPES



NEW CATEGORIES OF INFANT FOODS

Purees that contain one or more allergen

Puffs made with peanut powder

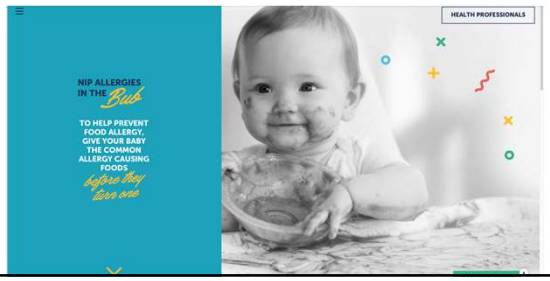
Powders that include peanut and/or egg

Dietary supplements with up to 16 allergenic proteins

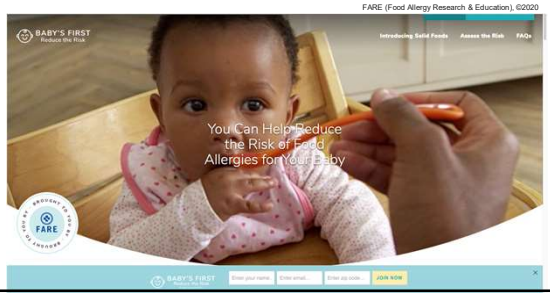
RESOURCES AND WEBSITES

NIAID ADDENDUM

PREVENTALLERGIES.ORG.AU



BABYSFIRST.ORG



PREVENTPEANUTALLERGIES.ORG

IN SHORT…

THANK YOU

QUESTIONS?

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@DietitianSherry

HOW TO GET STARTED WITH VIRTUAL DIETETICS

Alexia Beauregard, MS, RD, CSP, LD
Chief, Clinical Dietetics Branch, Winn Army Community Hospital
Faculty, Ellyn Satter Institute
October 23, 2020

Disclosure

The information provided in this webinar does not reflect the views of the U.S. Army Medical Department Activity, Winn Army Community Hospital, or Fort Stewart-Hunter army airfield

Medical advisory board member for The FPIES Foundation

Honorarium provided by Nutricia

The opinions reflected in this presentation are those of the speaker and independent of Nutricia North America

Objectives

- Explain the benefits of telemedicine for registered dietitians (RDs) and patients
- Identify platforms available for telemedicine
- Illustrate patient education techniques to help connect to patients virtually

Telehealth or Telenutrition

"Use of electronic information and telecommunications technologies to support long-distance clinical health care, patient and professional health-related education, and public health, and health administration" – Journal of the Academy of Nutrition and Dietetics (JAND)

- Video conferencing
- E-mail
- Mobile technology
- App-enabled technology
- Wearable devices

Peregrin, Tony. JAND, 2015;119(11).

Telehealth

Benefit

- RDs can provide access to nutrition care so healthcare information can be obtained at the right place and the right time regardless of socioeconomic status and physical location

Risk

- RDs may become obsolete if they do not enter the virtual healthcare space as it becomes dominated by individuals and companies that provide nutrition advice and recommendations

Maunder, K., et al. Strategic leadership will be essential for dietitian eHealth readiness: A qualitative study exploring dietitian perspectives of eHealth readiness
Peregrin, Tony. JAND, 2015;119(11).

Benefits

- High patient satisfaction
- Increased access to care
  - Allergists
  - Registered dietitians, especially those with specific food allergy training
  - Rural areas
- Decrease costs
  - Travel expenses, missed work for patients and families
  - Provider expenses (once technology has been paid for)
- Schedule flexibility for both patients and providers

What is a virtual visit?

- Synchronous – patient and provider are online at the same time
- Asynchronous – patient and provider not online at the same time
  - Store and forward information
  - Test results
- Facilitated – require a patient to travel to a facility where some type of physical examination will occur and they will use equipment at that facility to complete the appointment; sometimes referred to as Near Location
- Unfacilitated – patient will use own equipment and can be located anywhere; also referred to as Direct to Consumer

Portnoy, et al. J Allergy Clin Immunol;146(2).
Elliott, et al. J Allergy Clin Immunol Pract. Nov/Dec 2019.

- Technology infrastructure
- Access and comfort level – both provider and patient
- Ease of use, integration with an electronic medical record (EMR), forwarding information to a medical team
- Efficiency
- Licensure requirements
- Ethics
- Reimbursement
- Different type of human interaction

Challenges

Virtual Dietetics Success Studies

- Australia
  - Chronic kidney disease
  - Liver transplant
  - Malnutrition in older adults
- USA
  - Binge eating disorder
  - Weight reduction
  - Diabetes self management
  - Peanut introduction at home
- Studies varied in length and patient participation, more studies needed, but promising start
- Few telehealth intervention studies for
  - Celiac disease management
  - Pediatric malnutrition

Documentation

- Client's informed consent
  - Disclosure of protected health information (PHI) for electronic and telephonic treatment
- Client's agreement to engage in electronic communication
- How PHI will be protected and stored
- Outline management modality and expectations
- Be specific about what types of conditions or disease states you will be discussing during your appointments

Peregrin, Tony. JAND, 2019;119(11).

- Business Associate Agreement (BAAs)
  - Must be generated between a third-party entity storing patient data and the organization or provider requesting the data storage
  - This is to ensure that data is stored securely
  - Provides audit trail in the event of a data breach
- Companies such as Verizon® and Google® do not enter in BAAs with healthcare providers
  - Using this platform for patient communication could leave RDs liable for fines or civil actions if a data breach occurs
- Should your email signature include a statement that it is not a secure form of communication?

Peregrin, Tony. JAND, 2019;119(11).

Current Platforms

- Must be HIPAA (Health Insurance Portability and Accountability Act) compliant
- Free platforms will most likely NOT be HIPAA compliant
- Some states relaxed laws to allow use of FaceTime or other smart phone platforms but those changes will most likely not be permanent
- Examples:
  - Skype for Business®
  - Nutrimedy℠
  - Fruit Street℠
  - Healthie℠
  - Doxy.me℠
  - SimplePractice℠

Portnoy, et al. J Allergy Clin Immunol;146(2).

Skype for Business is a registered trademark of Microsoft Corporation. Nutrimedy is a service mark of Nutrimedy LLC. Fruit Street is a service mark of Fruit Street Health, Inc. Healthie is a service mark of Healthie Inc. Doxy.me is a service mark of Doxy.me, LLC. SimplePractice is a service mark of SimplePractice LLC.

Current Services

- Primary care gaining traction in telemedicine
- Urgent care or on-demand visits are well represented
- Usually marketed to employers and health plans
- E-consults are also gaining traction

- AmWell℠
- Teladoc℠
- MD LIVE℠
- Doctor on Demand®
- Rubicon MD
- AristaMD℠

Portnoy, et al. J Allergy Clin Immunol;146(2).

Amwell is a service mark of American Well Corporation. Teladoc is a service mark of Teladoc Health, Inc. MDLIVE is a registered trademark of MD LIVE Inc. Doctor On Demand, Inc. is a registered trademark of Doctor on Demand, Inc. AristaMD is a service mark of AristaMD Inc.

Wearable Devices

- AIBI™
  - Early detection of anaphylaxis
  - An armband that can measure histamine levels and can signal adult caregivers in the earliest stages of anaphylaxis
  - First on market in 2016; unable to locate studies that it works as advertised
- Allergy Amulet™
  - Necklace or bracelet with strips that are sensitive enough to detect very small amounts of allergens in food
  - Pre-orders are supposed to launch Fall 2020
- Devices have the potential to change the way health care is provided

This Photo by Unknown Author is licensed under CC BY

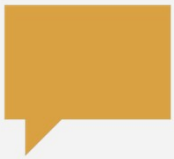
AIBI is a trademark of AIBI International Pte Ltd. Allergy Amulet is a trademark of Allergy Amulet, Inc.

Connecting on a human level

- Have real conversation
- Build rapport
  - How did they feel when the diagnosis was first made?
  - Any previous experience with a RD? What was that like?
- What are the expectations for telenutrition services?
- What are their goals for management?

Connecting on a human level

- Ask about barriers to telenutrition
  - Reliable internet connection
  - Comfortable with technology
  - Comfortable with telehealth platform
- How does a telehealth appointment feel compared to seeing a RD in person?



Connecting on a human level

- At subsequent sessions, ask
  - How comfortable are they using the technology?
  - Do they feel rushed?
  - Do they like the length of the visit?
  - How is the length between appointments?
- Is using SMS (i.e. text messages) appropriate in-between appointments to help patient feel connected? Is that TOO much connection?

Connecting on a human level

- Patient education can still be effective
  - Send handouts prior to the appointment
  - Open handouts and share your screen to discuss while looking at them at the same time
  - Find interactive patient education materials
    - Videos
    - Games
    - Sources of these materials can be patient advocacy organizations, medical journals, podcasts
  - Teach back

Patient Experiences in a 12-Week Telehealth Coaching Program to Promote Management of Chronic Kidney Disease

Appreciating Convenience
(Direct to Consumer Model)
- Integrating easily into lifestyle
- Talking in a familiar environment
- Minimizing travel and wait times

Making sense of complexity
- Contextualizing and prioritizing comorbidities
- Gaining confidence to make dietary decisions
- Setting and achieving realistic goals

Valuing Relationships
- Receiving tangible & perceptible support
- Building trust & rapport via the telehealth platform
- Motivated by accountability
- Personalized approach
- Reassured by health professional expertise

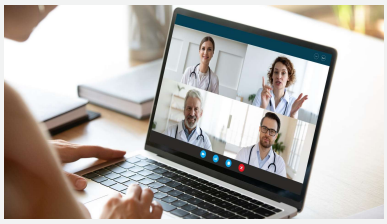
Empowered with actionable knowledge
- Comprehending diet-disease mechanisms
- Practical problem solving for sustainable dietary behavior

Increasing diet-consciousness
- Learning from ongoing feedback
- Prompted by repetition of messages

Based on: Warner, et al. JAND 2019;119(8).

Areas for growth

- Modification to state licensure laws
- Changes to reimbursement policy for ALL dietetic visits, not just telehealth visits
- New HIPAA compliant platforms



Take home thoughts

Do not discount telehealth services

Quality of the service should be the same

Hold yourself to the same professional standard

Multidisciplinary care is the gold standard, especially in food allergy

HIPAA Compliant Platform

- Ease of access by patients?
- What is the comfort level using this technology?
- Incorporate data from wearable devices?

Licensure

- Research licensure laws in the state(s) where you practice

Work Environment

- Facilitated, near care to the patient
  - Children's Healthcare of Atlanta, Medical University of South Carolina
- Unfacilitated, direct to consumer

Take home thoughts

Documentation

- Your note should include a detailed history and document medical decision making
- Informed client consent
- Privacy statement

What type of clients will you accept in your practice?

- Know where to refer if a face-to-face is more appropriate

Take home thoughts

Resources

- National Consortium of Telehealth Resource Centers
- The National Telehealth Policy Resource Center
  - Individual state pages
  - Rules for Medicaid, Medicare, Private Insurance
- American Telemedicine Association
- American Academy of Nutrition and Dietetics
  - Telehealth page

Resources

- Project ECHO
  - Seeks to increase training of PCPs in remote areas by specialists
- Dr. Rosan Meyer
  - How to Measure a Child at Home
  - Video on YouTube

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QUESTIONS?