

# Oral Food Challenges: *A Practical Approach*

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# Learning Objectives

***Upon completion of this learning activity, participants should be able to:***

1. Identify clinical scenarios requiring oral food challenges (OFCs).
2. Perform OFCs in their practice setting.
3. Interpret OFC results and provide patients and their families with appropriate dietary guidance.



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# Introduction

- OFCs: medically supervised feeding test
- Types: open, single-blind, double-blind placebo-controlled food challenges (DBPCFC)
- **Only 1/3 of suspected culprit foods are confirmed allergens during DBPCFC**



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# Indications

1. Gold standard for **diagnosis** of food allergy, especially when history and SPT/sIgE testing are inconclusive
2. Assess **tolerance, resolution, desensitization, remission**
3. Determine **threshold** for allergic reaction



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## Patient Selection & Other Considerations

- Importance of food in the family's diet
- Nutritional value of food
- Likelihood of incorporating food in diet after OFC
- Social burden of avoidance
- Quality of life implications
- Low risk for FA but patient/family too nervous to try highly allergenic food at home and there is a clear benefit (eg, FA prevention)



# What scenarios might you consider challenging patients with serum IgE and/or SPT results that suggest 95% likelihood of a positive OFC?

Food	Serum food-IgE (kU/L)		SPT Wheal (mm)	
	~ 95% Positive OFC	~ 50% Negative OFC	~ 95% Positive OFC	~ 50% Negative OFC
Cow's milk	$\geq 15$ $\geq 5$ if younger than 1 y	$\leq 2$	$\geq 8$	
Egg white	$\geq 7$ $\geq 2$ if younger than 2 y	$\leq 2$	$\geq 7$	$\leq 3$
Peanut	$\geq 14$	$\leq 2$ with and $\leq 5$ without history of peanut reaction	$\geq 8$	$\leq 3$
Fish	$\geq 20$			

Bird et al., J Allergy Clin Immunol, 2020

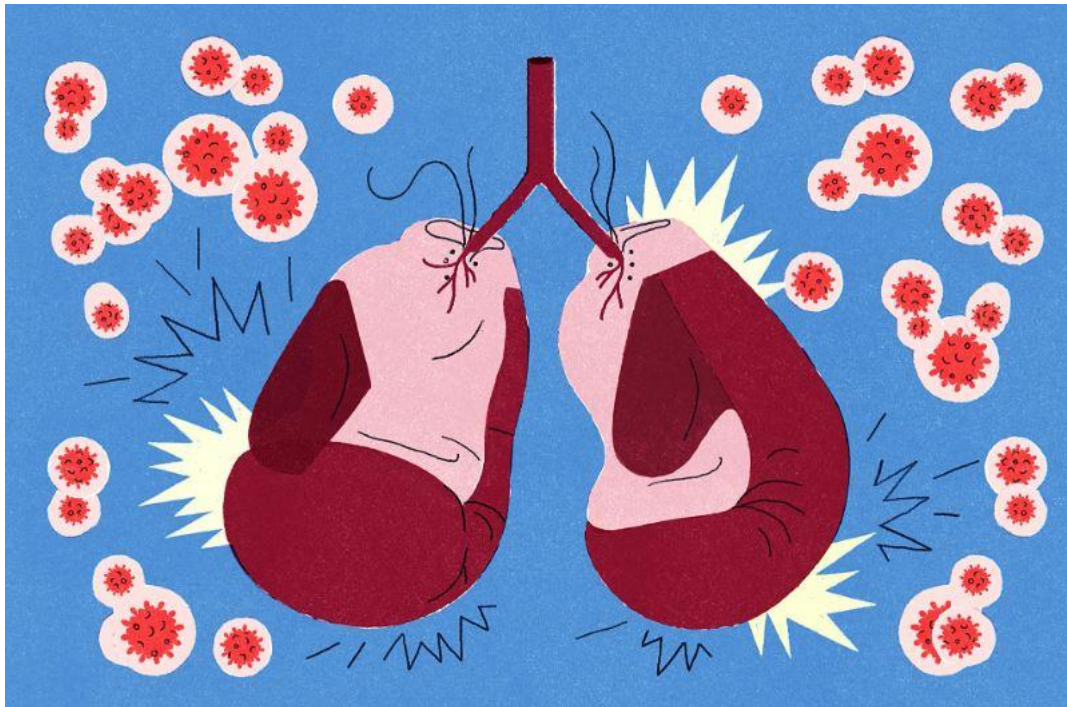


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# Contraindications

- Uncontrolled asthma, atopic dermatitis, and/or allergic rhinitis
- Recent severe reaction
- Active infection



# High-Risk OFC Patients

- History of severe reactions/anaphylaxis
- Asthma (regardless of severity)
- Very low threshold (ie, reactive to trace amounts)
- Allergen being challenged -> milk, peanut, tree nuts, fish, shellfish
  - Foods frequently associated with fatal/near-fatal reactions
- Difficult vascular access
- Treatment with beta-blockers or ACE inhibitors

## UPDATE from AAAAI-EAACI PRACTALL Guidelines:

Mitigate risks using step-wise dosing protocols tailored to specific IgE levels and history of anaphylaxis



# Patient Preparation Pre-OFC

- Optimize allergic co-morbidities
- Hold medications that may interfere with outcome of OFC (eg, antihistamines)
- Fast 4 hours before OFC, light meal 2 hours prior okay for young children
- Informed consent: review risks (anaphylaxis), potential benefits (improvement in quality of life, reduction in anxiety, expand diet, nutritional gains), alternatives (continue avoidance)



# Informed Consent Template

PATIENT:

MR NO.:

DATE OF BIRTH:

DATE OF VISIT:

Consent for OFC

You/your child has been offered a medically supervised diagnostic feeding test (oral food challenge). This test is considered the best way to determine whether there is an allergy to the tested food. For the remainder of this consent form “you” will refer to you or your child.

The food challenge involves eating the food in gradually increasing amounts (doses) over time and a period of observation. The amounts offered and timing between the doses may vary depending on your doctor’s assessment. The test may take several hours or longer. If your doctor determines that you are having an allergic reaction, feeding will stop and treatment for the allergic reaction will be given. If you have a reaction, you may be watched for additional time.

*Benefits and risks of food challenges.* The oral food challenge is an accepted medical test. The benefit includes finding out if you have an allergy and understanding your reaction to the food. Your doctor will explain the specific risks for a feeding test to this food. Eating a food to which there is a possible allergy can result in a reaction. Reactions can be mild or severe, including anaphylaxis, a severe, potentially life-threatening allergic reaction. Possible symptoms include throat/mouth itching, swelling, hives, worsening of eczema, nausea, vomiting, stomach pain, diarrhea, wheezing, fainting, and/or a drop in blood pressure. Death is a risk. If a reaction occurs, treatment could include an antihistamine, an injection of epinephrine, an inhaled bronchodilator, steroids, and other medications and treatments. Payment for treatment of adverse events related to this food challenge will occur in the manner you routinely pay for health care.

If an allergic reaction should occur during a food challenge, you will be required to remain under care until the physician believes it is safe for you to go home. In unusual circumstances, you may need to be transferred to an emergency room or hospital unit for further observation/treatment.

Alternatives to an oral food challenge: If you choose to not have an oral food challenge, the safest thing to do is restrict the food in question from your diet. Signing this consent form indicates that you have read this form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this food challenge.

\_\_\_\_\_  
Subject or legally authorized representative

\_\_\_\_\_  
Date

\_\_\_\_\_  
Physician/medical representative

\_\_\_\_\_  
Date

\_\_\_\_\_  
Witness (if applicable)

\_\_\_\_\_  
Date



# Infant OFC

## Before the challenge

1. Assess feeding concerns with the family, such as oral-motor skill deficits, and determine whether the infant is eating solid foods. If there are feeding concerns or the infant is not eating solid foods, it may be appropriate to wait until feeding concerns are addressed by an occupational/speech therapist or the parents have introduced other solid foods.
2. Have an open discussion with the family with particular emphasis on plans following the challenge. For instance, if the family states they will not be able to feed the child peanut products after the challenge, then reconsider the necessity of performing the challenge.
3. Optimize control of atopic dermatitis (AD) and asthma. Do not perform the challenge in a child with poorly controlled AD, wheezing, coughing, URI symptoms, or febrile illness.
4. Remind parents that the child may have a light meal (eg,  $\frac{1}{2}$  of the usual serving) 2 h before the challenge.
5. Remind the family to bring entertainment, toys, music, etc during the challenge and multiple forms of the target food.
6. Structure the timing and environment of the OFC to be as similar to the home meal environment as possible (ie, avoid scheduling the challenge during the infant's nap time; have a high chair available).

## Day of the challenge

1. Ensure medications have been discontinued as outlined in [Tables I and II](#).
2. Obtain the child's weight, temperature, heart rate, respiratory rate, blood pressure, and oxygen saturation level.
3. Perform a thorough physical examination including examination of ears (do not perform challenge if the child has evidence of an ear infection), oropharynx and nose (getting baseline visualization of uvula and tongue, rhinorrhea, congestion, etc), lungs (listen for wheezing, crackles, or coarse breath sounds), and skin (looking for any rashes, urticaria, birth marks, etc).
4. Calculate doses of emergency medications.
5. Prepare the food challenge product.
6. Administer doses. Give each dose 15-20 min apart. Perform a brief physical examination including visualization of the oropharynx, auscultation of the lungs, and visualization of the skin between each dose.



# Timing for discontinuation of commonly used antihistamines

Medication class	Medication name	Approximated recommended last dose (# days)
<b>Oral antihistamines</b>	Diphenhydramine	2-5
	Hydroxyzine	5-8
	Cetirizine	3-5
	Desloratadine	7
	Fexofenadine	2-5
	Levocetirizine	Unknown
	Loratadine	3-7
	Famotidine (H2 blocker)	0-2
<b>Intranasal antihistamines</b>	Azelastine	2
	Olopatadine	Unknown



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## Office Preparation Pre-OFC

- Immediate access to emergency medications
- Resuscitation equipment / code cart, pulse oximeter, sphygmomanometer, nasal cannula
- Train personnel to carry out in office emergency action plan

## Emergency Medications to Stock for OFC

Cetirizine: 1mg/ml PO liquid

Diphenhydramine: 12.5mg/5ml PO liquid

Epinephrine: 1 mg/ml, 1:1000 for IM injection, IM auto-injector, intranasal device

Ondansetron: 2mg/1ml IV/IM, orally disintegrating tablets 4mg per tablet

Prednisolone Oral Solution: 60mg/20ml PO liquid

Albuterol nebulizer: 2.5mg/3ml normal saline; nebulizer machine, tubing, mask

Supplemental oxygen

# Sample flow sheet

PATIENT NAME \_\_\_\_\_

Date \_\_\_\_\_

OFC type: Open \_\_\_\_\_ Single blind \_\_\_\_\_ Double-blind \_\_\_\_\_

Location: Office \_\_\_\_\_ ED \_\_\_\_\_ Inpatient \_\_\_\_\_

Food provided by: Patient \_\_\_\_\_ Physician/dietitian \_\_\_\_\_

Challenge food \_\_\_\_\_ Masking food \_\_\_\_\_ Placebo food \_\_\_\_\_

Total dose of challenge food \_\_\_\_\_ Total weight of challenge food mixed with masking food: \_\_\_\_\_

Time	Dose	Symptom score													
		Rash % body area	Pruritus	Urticaria	Rash	Sneezing /itching	Nasal congestion	Runny nose	Larynx	Wheeze	GI subjective	GI objective	Cardio- vascular	Total score	Comments stop/continue
Base	0														

Total dose ingested (%): \_\_\_\_\_ Time stopped: \_\_\_\_\_ Outcome: Passed \_\_\_\_\_ Failed \_\_\_\_\_

## TREATMENT

Time	Symptoms	Treatment	Vital signs	Comment

Discharge home: Time \_\_\_\_\_ Discharge instructions: \_\_\_\_\_

Physician's signature \_\_\_\_\_ Date/time \_\_\_\_\_

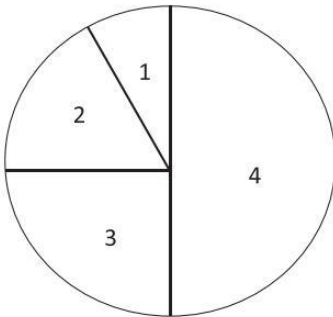


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# OFC Procedure

1. Baseline patient examination and verbal/written consent
2. Food is given in several incremental doses at 15-minute intervals over 1 hour
3. Patient is evaluated for any allergic symptoms before each dose
4. For objective symptoms or prolonged subjective symptoms, feeding is stopped and reaction treated
5. Patient is observed for 2 hours after finishing the serving of food if tolerated or for at least 2 hours after resolution of allergic symptoms

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



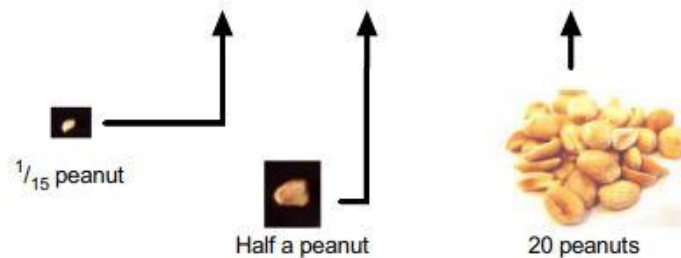
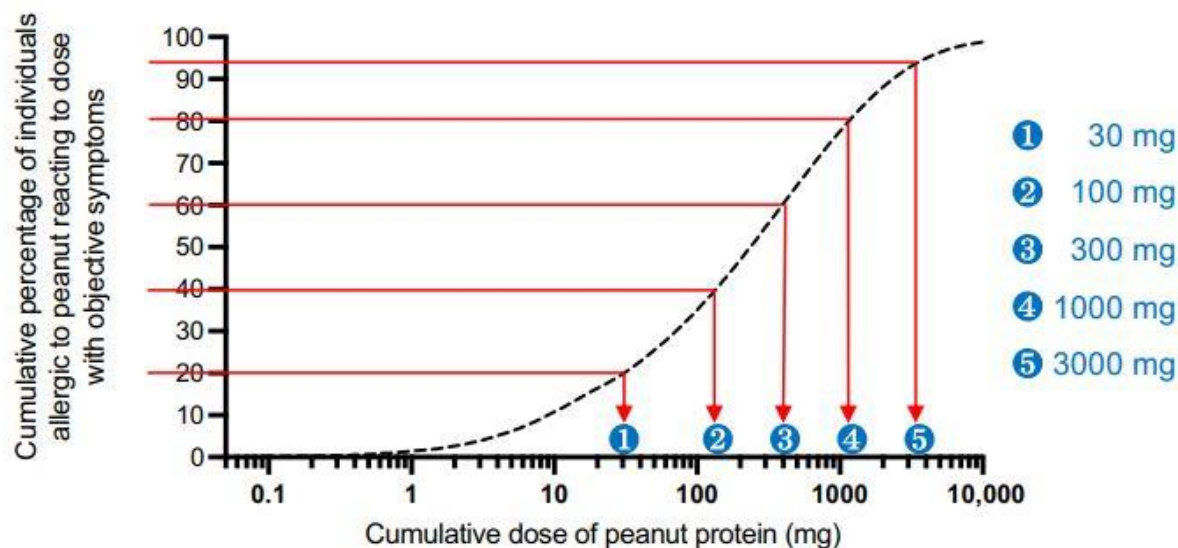
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## UPDATE from AAAAI-EAACI PRACTALL Guidelines:

- Intervals between doses should be every **20-30 minute intervals** between semi-logarithmic incremental doses
- When mild objective or subjective symptoms occur:
  - Stop the challenge
  - Wait longer for next dose
  - Repeat dose

Sampson et al., Pediatr Allergy Immunol, 2024



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# Age-specific portion sizes for common food allergens

Allergen	Food	Food protein per serving	4–11 months	1–3 years	4–8 years	>9 years
Egg	French toast (1 egg per 1 slice of bread)*	6 g if made with 1 large egg	½–1 slice	½–1 slice	1 slice	1–2 slices
	Hard-boiled or scrambled egg	6 g/1 large egg	½–1 egg	½–1 egg	1 egg	1–2 eggs
Milk	Infant formula	2–3 g/140 mL (5 oz)	4–8 oz			
	Milk	8 g/220 mL (8 oz)		110–220 mL (4–8 oz)	110–220 mL (4–8 oz)	220 mL (8 oz)
	Cottage cheese	10–14 g/4 oz	¼–½ cup	¼–½ cup	½–1 cup	½–1 cup
	Hard cheese	6–8 g/28 g (1 oz)	7–14 g (¼–½ oz)	14 g (½ oz)	28 g (1 oz)	28 g (1 oz)
	Yogurt (NOT Greek style)	8 g/226 g (8 oz)	60–120 g (¼–½ cup)	60–120 g (¼–½ cup)	120–240 g (½–1 cup)	120–240 g (½–1 cup)
Peanut	Peanut (whole)	2 g/w8 peanuts			16 pieces	16 pieces
	Peanut butter	3 g/1 tbsp	1 rounded tbsp	1–2 tbsp	1–2 tbsp	2 tbsp
	Peanut flour or peanut butter powder	3 g/1 tbsp original or 2.25 g/1 tbsp chocolate flavor	1 rounded tbsp	1–2 tbsp	1–2 tbsp	2 tbsp
Tree nut	Almond	3 g/11 whole nuts			11 pieces	11 pieces
	Cashew	3 g/10 whole nuts			10 pieces	10 pieces
	Hazelnut	3 g/3 tbsp hazelnuts or hazelnut meal			3 tbsp	3 tbsp
	Pecan (halves)	3 g/25 halves			10–25 halves	25 halves
	Pine nuts	3.5 g/3 tbsp pine nuts			3 tbsp	3–4 tbsp
	Pistachio	3 g/20 whole nuts			20 pieces	20 pieces
	Walnut (halves)	3 g/10 halves			10 halves	10 halves

Bird et al., J Allergy Clin Immunol Pract, 2020  
 Sampson et al., Pediatr Allergy Immunol, 2024

# Stopping Criteria for OFC

The OFC should be stopped if any **1** of the following symptoms is present during the OFC:

## Skin

- $\geq 3$  urticarial lesions
- Angioedema
- Confluent erythematous, pruritic rash

## Respiratory

- Wheezing
- Repetitive cough
- Difficulty breathing/increased work of breathing
- Stridor
- Dysphonia
- Aphonia

## Gastrointestinal

- Vomiting alone not associated with gag reflex
- Severe abdominal pain (such as abnormal stillness, inconsolable crying, or drawing legs up to abdomen) that persists for  $\geq 3$  min

## Cardiovascular

- Hypotension for age not associated with vasovagal episode

If 2 or more of the following are present, the OFC should be stopped:

## Skin

- Persistent scratching for  $\geq 3$  min

## Respiratory

- Persistent rubbing of the nose or eyes for  $\geq 3$  min
- Persistent rhinorrhea for  $\geq 3$  min

## Gastrointestinal

- Diarrhea

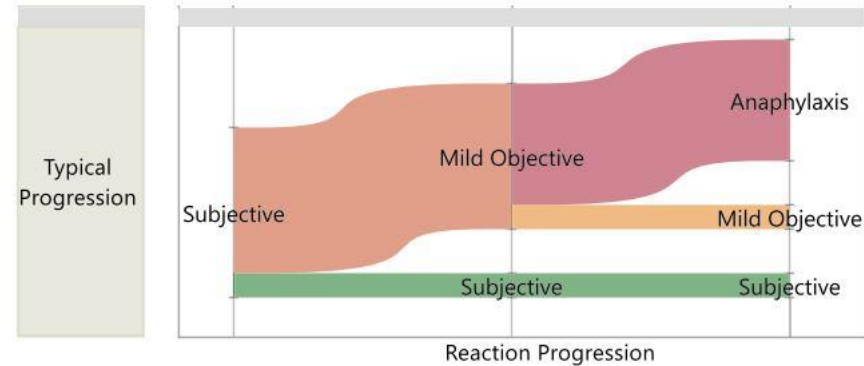


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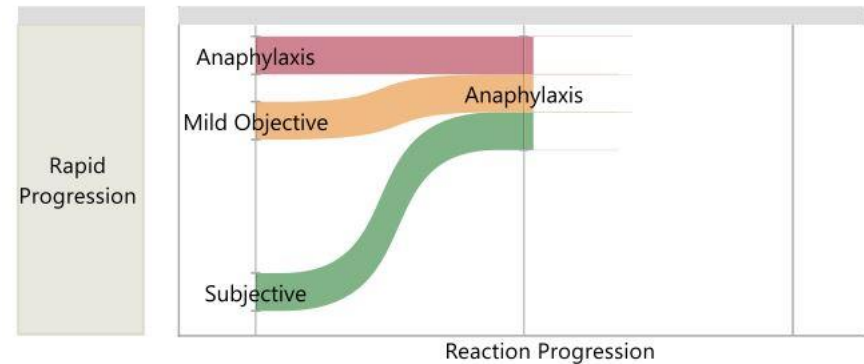
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# Variations in Clinical Reactivity

(A)



(B)



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# Stopping Criteria for OFC

## UPDATE from AAAAI-EAACI PRACTALL Guidelines

### I. Skin

Rash: erythema	<b>Few areas of faint erythema</b> <i>&lt;50% of body surface area</i> <b>Generalized (&gt;50% body surface area)</b>
Rash: urticaria	<b>Limited to perioral region or due to contact</b> <i>1-2 lesions (not perioral or due to contact)</i> <b>≥3 lesions (not perioral or due to contact)</b>
Angioedema	<i>Prominent lip or ear edema</i> <b>Facial edema (and new-onset uvula edema)</b> <b>Generalized edema</b>
Pruritus	<b>Scratching (any)</b>



### II. Eyes/Upper respiratory

Eyes	<b>Minimal reddening, rubbing of eyes</b> <i>Conjunctival hyperemia (without prior rubbing)</i>
Nasal	<b>Mild, infrequent rhinitis</b> <i>Persistent<sup>a</sup> and significant rhinorrhea/sneezing/rhinitis</i>

### III. Respiratory

Cough <sup>b</sup>	<b>Intermittent cough associated with throat clearing</b> <i>Frequent cough without respiratory compromise</i> <b>Cough with respiratory compromise*</b> <i>*Manage as anaphylaxis</i>
Wheezing	<b>Any wheeze*</b> <i>*Manage as anaphylaxis</i>
Chest tightness	<b>Isolated chest tightness</b> <b>Chest tightness with fall in peak flow of ≥20%* (with good technique)</b> <i>*Manage as anaphylaxis</i>



# Stopping Criteria for OFC

## IV. Oropharyngeal

Oral cavity	Itchy mouth
Throat/Laryngeal	Itchy throat, intermittent throat clearing Persistent <sup>a</sup> throat tightness or pain Non-transient hoarseness/stridor

## V. Gastrointestinal

Abdominal discomfort	Nausea (any severity/frequency) Mild abdominal pain Persistent <sup>a</sup> non-distractable abdominal pain (usually with a decrease in activity level in children) Persistent <sup>a</sup> severe abdominal pain
Vomiting	Vomit due to gag or taste aversion 1+ episode (where investigator considers this is due to allergic reaction)
Diarrhea	1 episode 2+ episodes

## VI. Cardiovascular

Cardiovascular	Mild tachycardia Clinically significant hypotension Cardiovascular shock/collapse
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## VII. Neurological

Neurological	Feeling weak, tired, upset/agitated Significant change in cognition or GCS* Loss of consciousness* *Manage as anaphylaxis
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# Management of Anaphylaxis

## 1. Initial steps

- Assess appearance, breathing, circulation, mentation
- Give epinephrine 1:1000 at a dose of 0.01 mg/kg intramuscular in the lateral thigh (maximum 0.5 mg). Appropriate epinephrine autoinjectors may alternatively be used
- Lie patient flat with legs elevated unless this causes increased respiratory distress, in which case the patient may prefer to sit up. Return the patient to the supine position if there is any deterioration in consciousness
- Airway management (according to skills and equipment) if required
- Obtain BP
- Gain IV access, if necessary
- Give oxygen for respiratory distress and/or hypotension
- If the patient is hypotensive, also give IV normal saline bolus 20 mL/kg
- Inhaled short-acting  $\beta_2$ -agonists may be needed to relieve symptoms of bronchoconstriction
- For upper airway obstruction/stridor, also consider giving continuous nebulization of epinephrine (5 mL of 1 mg/mL)
- H1 and H2 antihistamines may be considered as supportive therapy but should not be given in lieu of epinephrine

## 2. If there is inadequate response, an immediate life-threatening situation, or deterioration,

- Repeat intramuscular epinephrine injection every 3-5 min as needed or start an IV epinephrine infusion as per hospital guidelines/protocol. Monitor BP closely
- If the patient remains hypotensive, additional normal saline fluid boluses (up to 50 mL/kg in total) may be required
- When indicated at any time, prepare to initiate cardiopulmonary resuscitation including standard IV epinephrine dosing if the patient goes into cardiac arrest
- Consider calling a code team or Emergency Medical Services

## 3. Disposition

- Duration of observation after a reaction should be based on clinical judgment following symptom resolution with treatment. It is typical to observe 2-4 h after resolution of symptoms
- If the patient remains unstable they should be transported to a higher acuity medical facility for further care and monitoring



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# Post-Challenge Observation

- 1-2 hours if no reaction
- Up to 4 hours if symptoms occurred
- Overnight observation for severe systemic reactions requiring extensive treatment

Code	Description for ingestion challenge	Relative value units	Notes
95076	First 2 h (at least 61 min)	3.39	Includes pretest and posttest evaluation
95079	Each additional hour (at least 31 min)	2.38	May be charged more than once per challenge

Bird et al., J Allergy Clin Immunol, 2020



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# Recommendations after positive OFC

You/your child had a reaction during a food challenge—Recommendations from your doctor

You/your child did not tolerate the challenge food today. This means you/your child is still allergic to the food.

Activity level should be minimal for the rest of the day. Resume normal activity tomorrow.

You/your child's next meal should consist of foods unlikely to cause stomach discomfort because this may be confused with a delayed allergic reaction.

Please make sure you/your child has epinephrine available for the rest of the day.

Please monitor yourself/your child for the rest of the day. Rarely, you/your child may develop a delayed allergic reaction hours after eating the food. If you/your child has symptoms of an allergic reaction such as hives, cough, breathing problems, vomiting, or diarrhea later today, treat according to your emergency action plan first and go to the emergency department.

You/your child must continue to avoid the challenge food and carry epinephrine autoinjectors at all times.

Reminders about epinephrine:

Always have 2 epinephrine injectors available at all times.

Practice how to use epinephrine.

Make sure the school or day care has 2 epinephrine autoinjectors.

Resume any medications held for the food challenge. Return for Allergy follow-up as instructed by your doctor.

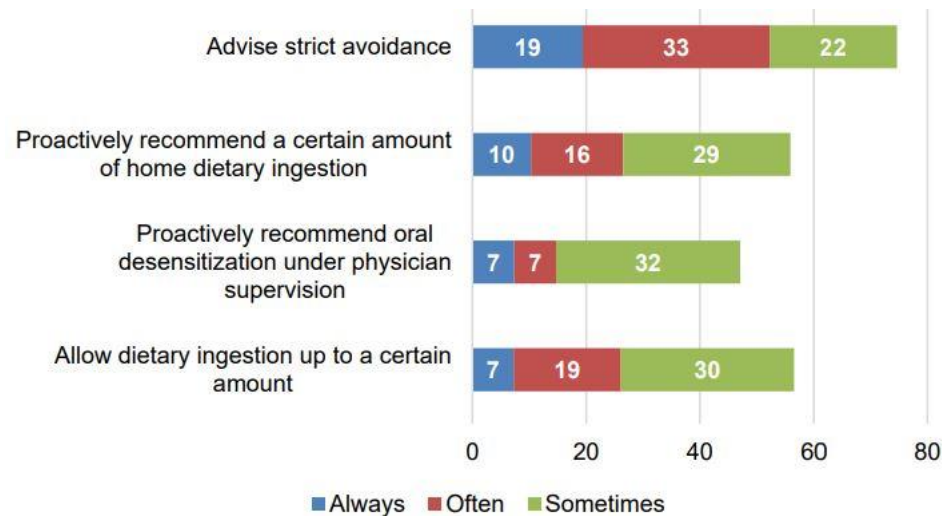
It is normal to feel disappointed after experiencing a reaction during a food challenge. However, it also can be a valuable learning experience in helping you/your child recognize symptoms of an allergic reaction and experience the effectiveness of immediate treatment with epinephrine. For parents, try to be as encouraging as possible when discussing the experience with your child. Please do not use the word "fail" in front of your child. Rather, praise your child for participating in the food challenge and helping to answer the question of whether or not he/she is allergic to the food. It is also possible that you/your child will experience increased worry about food allergy after an allergic reaction. This is also normal, and most patients typically feel better in a few days. If you/your child continue to feel more worry than is typical for you/your child, contact your doctor or mental health professional.

If you have any questions or concerns, please call \_\_\_\_\_.



# Emerging approach

- Subthreshold consumption following positive OFC -> requires further research



# Recommendations after negative OFC

You/your child did not have a reaction during a food challenge—Recommendations from your doctor

Congratulations! You/your child did not have a reaction during your OFC. This means you/your child does not have an allergy to the food tested. You/your child may eat this food in any amount in the future.

Do not eat/feed additional servings of the challenge food on the day of the challenge.

You/your child may start eating the food tomorrow.

You/your child's next meal should consist of foods unlikely to cause stomach discomfort because this may be confused with a delayed allergic reaction.

Please carry epinephrine autoinjectors twin pack today in the rare chance of delayed symptoms. Call your doctor if you/your child develop symptoms after discharge.

If there are no symptoms, begin regular consumption of the food starting the day after the challenge as directed by your doctor. This food should be reincorporated as a normal part of your/your child's diet. Some patients continue to experience worry about eating the food that they ate in the food challenge. This is normal and typically subsides after eating the food a few times after the food challenge. Remember that you/your child tolerated the food during the food challenge, which means that you/your child is no longer allergic to the food. It is also normal to not immediately like the taste of the food that you/your child ate during the food challenge. If you have concerns about incorporating the food into you/your child's diet, contact your doctor.

If you/your child notice an increase in allergy symptoms over the next few weeks, please call your doctor to discuss whether this may be related to ingesting the new food.

If you/your child do not have other food allergies, your doctor may advise you to carry your epinephrine autoinjector twin pack for 1 y or until the expiry date. Make sure to continue carrying your epinephrine autoinjector twin pack if you have other food allergies.

Continue to use caution to avoid cross-contact if you have other food allergies.

Resume any medications held for the food challenge. Return for Allergy follow-up as instructed by your doctor.

If you have any questions or concerns, please call \_\_\_\_\_.



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# Recommendations for infant OFC

## POSTCHALLENGE INSTRUCTIONS

☐ **CHILD INGESTS FULL AMOUNT AND DOES NOT HAVE A REACTION**

1. Instruct family to reintroduce the food as a normal part of the child's diet.

☐ **CHILD INGESTS MORE THAN HALF OF THE CHALLENGE BUT REFUSES THE REMAINDER.**

1. Instruct the family to give an equivalent amount at home and if tolerated, increase serving to an **age-appropriate, serving of the food.**

☐ **CHILD DOES NOT COMPLETE DOSE 3 BUT TOLERATES DOSES 1 AND 2.**

1. Results are inconclusive. Continue avoidance and return for challenge at another time (eg, in 1-2 wk or longer depending on family preference).

☐ **CHILD HAS A REACTION DURING THE CHALLENGE AND IS CONSIDERED ALLERGIC.**

1. Instruct family on allergen avoidance.
2. Provide food allergy action plan and discuss the signs and symptoms of a food-induced allergic reaction.
3. Provide a prescription for 2 autoinjectable epinephrine devices and demonstrate appropriate use with a trainer device.



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# Conclusions

- OFCs are time-intensive procedures but essential for accurate diagnosis and management of FA
- Requires careful selection of patients and families
- Medical team offering OFC must be able to manage anaphylaxis quickly and effectively
- Discuss and individualize post-challenge care plans, irrespective of outcome (ie, positive or negative OFC)



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# Questions?

## Email

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