OIT is it right for you and me: how to identify potential patients?

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OIT Key Concepts

Desensitization to food allergen

OIT has been used in research and clinical practice since mid-2000s

1st FDA product approved in 2020

Goal: protect food allergic individual from reacting to accidental exposures

Sustained unresponsiveness- only occurs in a small percentage= not goal of OIT
US knowledge of OIT

• Overall, 72% did not know what OIT was prior to the survey.
• Respondents from households earning over $100,000/year or with a college degree each had significantly greater odds of reporting any OIT awareness compared to lower-income and non-college-educated respondents.
• Among respondents familiar/unfamiliar with OIT, 54%/34% reported their expected treatment outcome was to obtain protection against accidental exposure.
• Among expected treatment outcome to be curing the allergy.
• Furthermore, 55% of OIT unfamiliar respondents said they would not be comfortable initiating a conversation with their healthcare provider about their suitability for OIT.

Who is the right patient for OIT?
The answer is....

- Shared decision making

1. Creating choice awareness
   - Identify all possible options without a priori assumption for preferences
   - Adjust or elaborate new options based on mutual understanding

2. Discussing relevant options
   - Provide a detailed description of each clinical option and what it entails
   - Present current medical evidence in an unbiased manner
   - Put emphasis on aspects « that matters most » to patient

3. Exploring patient preferences
   - Determine "what matters most" to patient
   - Discuss patient's experience with past management strategy
   - Clarify goals and expectations with treatment
   - Explore fears

Knowledge of OIT

Goal of treatment

• Reduce risk of fatal food reaction
• Reduce hassle of strict avoidance
• Increase social options
• Incorporate food into diet (not goal of Palforzia)

Start the conversation

The Basics

• History of IgE mediated allergy
  • Clinical reaction
  • Testing
  • Oral Challenge
  • Previous history of anaphylaxis
• Co-morbidities under control
• Understanding of risk and benefits of OIT
Other considerations

- Family and patient motivation
- Family dynamics
- Activities/Sports
- Ability to come to clinic every 2 weeks
- Ability to adhere to schedule at home
- Cost/insurance
- Fears/Anxiety

Clearly defined goals and process

- Time commitment
- Indefinite nature of treatment
  - Possibility of reactions
  - Knowledge of emergency plan and use of Epinephrine
- Symptom development may require stoppage of treatment
- Is avoidance best treatment option
Case Study #1

• KC is a 5-year female
• PMH:
  • 1st reaction occurred at 11 months age
  • Developed generalized hives and vomiting treated with epinephrine in ED
  • History of eczema and mild intermittent asthma
  • Peanut IgE 25 and Ara h2 4.6
• SH:
  • Will be starting kindergarten in the fall
  • Lives at home with parents and 1 sibling
  • Involved in gymnastics and soccer
• Thoughts on OIT for this patient?

Case Study #2

• LA is a 13-year-old boy
• PMH
  • 1st reaction to peanuts at 1 year of age with development of hives, lip swelling and vomiting
  • Last year had an accidental exposure at school resulting in anaphylaxis. Treated with Epinephrine by school nurse and required 2nd dose of Epinephrine in ED
  • History of seasonal allergic rhinitis
• SH:
  • Splits time between mother and father’s home
  • Plays competitive soccer and basketball
  • LA is very nervous to do OIT
• Thoughts on OIT for this patient?
Helpful resources

Integrating oral immunotherapy into clinical practice


An approach to the office-based practice of food oral immunotherapy


Practice pearls

There are options for food allergies

Incorporate OIT education into clinic visits

Open dialogue and shared decision making can make OIT right for your patient
Thank you for attending

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READY FOR PRIME TIME: GETTING YOUR PRACTICE AND PATIENT READY FOR OIT

Cindy Bandelier RN, BSN, CPN
Children’s Mercy Hospital

OVERVIEW: PREPARING YOUR CLINIC

- Safety
- FDA approved product vs off label
- Clinic flow
EMERGENCY PREPAREDNESS

• Know what your clinic will do in case of anaphylaxis
• Epi, oxygen, suction
• Having a standard work for anaphylaxis and other reactions
• Calling for help:
  • 911
  • Code Blue, emergency response
  • Transferring patient if needed
  • BLS- all staff

PRODUCTS

• FDA approved product
• Peanut- flour, peanut fragments, peanut M&Ms, peanut butter
• Tree nuts- flour, fragments, tree nut butters, milk
• Milk
• Egg
FDA

- Insurance approval and age restrictions
- PA process and documentation
- Communication between parents/staff and insurance/specialty pharmacy
- Set up delivery
- No product preparation
- Clinic storage of product

Off Label

- What type of product will you use
- Who will prepare
- Accurate equipment for measuring
- Time/space/staff to prepare product
- Teach family how to prepare
- Usually no insurance approval needed
- Cash pay
- Clinic storage of product
SUPPLIES FOR PREPARATION

- Scale
- Peanut flour
- Peanut Fragments
- Pill Cutter
- Bottle
- Syringe

CLINIC FLOW

- SCHEDULING
  - 1st day is usually multiple doses - 3-4 hours in clinic
  - Pt will need to come back every 2 weeks to increase dosage
  - What days work best for you clinic
  - Which providers will be supervising OIT
  - What’s your clinic space like
  - How long will pts stay in clinic
  - Rescheduling due to illness or other issues
  - Differences since covid
CLINIC FLOW

• Staffing Considerations
  • How many nurses do you have on staff on a given day
  • Nurse to patient ratio
  • What other responsibilities do the nurses have in clinic
  • Calling specialty pharmacies to dispense doses.
  • If a reaction occurs who will assist you
  • Use of standard work is helpful
  • Education of product and process

DISCHARGE

• Review daily dosing with family
• Review how family will receive dosing for the next 2 weeks
• For some families review how to mix or make the doses.
• Review S/S of reaction
• Epi autoinjectors
• Review when to hold daily dose
• Provide clinic numbers and instructions on how to reach on call provider in case of a problem.
TAKE AWAY POINTS

• Safety is key - be prepared
• Using standard work to guide your practice
• Know your clinic limitations
• Education for families goes a long way.

HELPFUL RESOURCES

• An Approach to the Office-Based Practice of Food Oral Immunotherapy
• Wasserman et al. J Allergy Clin Immunology Practice May 2021:9(5) 1826-1838
Thank you for attending
Cindy Bandelier RN, BSN, CPN

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Objectives

1. Explore commonly used selection criteria for patient selection in OIT

1. Examine other possible selection criteria and scales to consider for patient selection in OIT

1. Identify resources for navigating the psychosocial impact of OIT (and life with FA in general)
AN EXAMPLE OF RECOMMENDED CONSIDERATIONS FOR PATIENT SELECTION in OIT:

Two main goals of patient selection: to identify good candidates with actual food allergy while minimizing dependence on OFCs.

- The history of reaction to the allergenic food is critical in this selection:
  - Scenario 1: Recent history with unequivocal, objective signs of anaphylaxis
  - Scenario 2: Distant history of objective allergic reaction
  - Scenario 3: Vague / subjective / no signs or symptoms

- In Scenario 1, any positive test result (SPT, specific- or component-IgE test) is essentially diagnostic.
  - These individuals could be considered candidates for therapy without an OFC
  - Warnings: severe/life-threatening anaphylaxis, severe/poorly controlled asthma, and EGID

- In the other scenarios, further evaluation is warranted before determining whether therapy can be recommended.
  - A reliable biomarker that accurately predicts allergy would be immensely helpful
Recommended Selection Considerations Did Not Include Mention of:

1. Food Allergy Anxiety Data of Patient and/or Caregiver
2. Quality of Life (QoL) Data of Patient and/or Caregiver

How Do We Obtain this Data?

- Scale of Food Allergy Anxiety (SOFAA)
- Other QoL Questionnaires
Scale of Food Allergy Anxiety (SOFAA)

- SOFAA-C
  - self-rated 21-item questionnaire for children and adolescents ages 8–18
  - assesses food allergy-related anxiety and related anxious avoidance behaviors over the past week.

- SOFAA-P
  - corresponding parent-rated version
  - parents rate their perceptions of their child’s food allergy-related anxiety and anxious avoidance over the past week.

- Condensed versions available for both SOFAA-C and SOFAA-P

Recent Validation of SOFAA

- The 21-item SOFAA-C and 21-item SOFAA-P
  - good-to-excellent validity
    - evaluated for construct, convergent, and divergent effects
  - excellent reliability
    - both for internal consistency and under test-retest conditions

- 14-item SOFAA-C-brief and 7-item SOFAA-P-brief
  - valid and reliable (see Dahlsgaard et al., 2021).

Katherine K. Dahlsgaard, Leah K. Wilkey, Shana D. Stites, Megan O. Lewis, Jonathan M. Spergel, Development of the Child- and Parent-Rated Scales of Food Allergy Anxiety (SOFAA), The Journal of Allergy and Clinical Immunology: In Practice, 2021,
What Does this Mean?

• May be used to screen children at risk for
  • excessive food allergy-related anxiety
  • guide behavioral health interventions in this population
  • aid mental health providers in the efficient construction of exposure hierarchies
  • establish a severity threshold for eligibility and evaluated outcome in a clinical trial.

Other Available QoL Questionnaires to Consider

• Food Allergy Quality of Life Questionnaire-Parent Form (FAQLQ-PF) Children aged 0-12 years
• FAQLQ-CF Food Allergy Quality of Life Questionnaire – Child Form (8-12 years)
• Food Allergy Quality of Life Questionnaire FAQLQ for young people (aged 12-17 years)
• Food Allergy Quality of Life Questionnaire – Adult Form ( ≥18 years)

FAQLQ Short forms
• The Food Allergy Quality of Life Questionnaire, Parent Impact 10 (FAQLQ-PF10) for parents of children with food allergy
• The Food Allergy Quality of Life Questionnaire, Proxy Parent Form 10
• (FAQLQ-PF10) for children aged 0-12 years
• The Food Allergy Quality of Life Questionnaire, Child Form 10
• (FAQLQ-CF 10) for children aged 0-12 years
• The Food Allergy Quality of Life Questionnaire, Teen/Adult Form 10 (FAQLQ-TF/AF 10)

• Self-efficacy in Food Allergy Questionnaire (SEFAQ) Parent Proxy
• Food Allergy Self-Efficacy Questionnaire (SEFAQ) Teens Self-Report

For Use: Contact Dr. Audrey DunnGalvin a.dunngalvin@ucc.ie
What Do We DO with this Data?

• If patient is “high” on the anxiety scales prior to and/or during OIT:
  • Empower them with:
    • Valid and reliable psychoeducation resources about ways to safely LIVE with food allergies
      • Ensure appropriate health literacy levels
    • Resources for strategies to manage behavioral health anxiety symptoms
      • Apps (Calm, Headspace, etc)
      • Reliable websites (Child Mind Institute, Good Therapy, Very Well Mind, etc.)
    • Referrals to food-allergy knowledgeable behavioral health clinicians
      • Food Allergy Counselor (FAC) Directory
Evidence that Mindset Matters......

• Perceived mild reactions to the treatment as useful
  • less anxious about symptoms
  • less likely to skip doses
  • less likely to experience side effects at the end of their treatment when real
    peanuts were introduced.

• “a simple change in the way we frame and discuss side effects of a
  treatment can have a meaningful impact not only on anxiety and
  adherence but also on the physiological benefits of that treatment”

  - Alia Crum, PhD, assistant professor of psychology and senior author of the study.


Summary:

1. Food allergies have a documented impact on psychosocial functioning and Quality
   of Life for patients and caregivers

1. BUT....current OIT patient selection processes do not often include baseline
   measures of the psychosocial functioning/quality of life for patients/caregivers.

1. There are validated scales that can be used for this assessment in your OIT practice.

1. If a patient/caregiver is identified as “not being a good candidate” for OIT based
   upon psychosocial assessment outcomes, be sure to provide appropriate resources
   to patient/caregiver to address these concerns with the goal of eventually
   increasing their chances of becoming appropriate OIT candidates if they so desire.