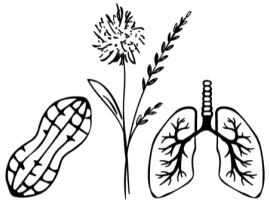
Elements of Consent and Pre-Day 1 Prep



KENILWORTH
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ASSOCIATES

FOOD • ALLERGY • ASTHMA • IMMUNOLOGY

Paul Detjen MD
Kenilworth Medical Associates, Kenilworth, IL

The objective of the OIT consent process is education

- Patients and families should be fully educated as to what might be achievable goals and what the treatment involves
  - What is the problem to be solved
  - What defines a success - there are several
  - What is the likelihood of achieving success
  - What is the risk of adverse events, immediate and long term
  - How burdensome is the treatment to the family
  - Are there alternatives to be considered
- This is best done as a long process during multiple visits and, ideally, through interactions with several clinicians

OIT is a novel treatment form with inherent risk which requires a comprehensive consent process

“Despite the promise of oral immunotherapy (OIT) to treat food allergies, this procedure is associated with potential risk. There is no current agreement about what elements should be included in the consent process.”
A 36-member international panel of allergy experts was convened to develop a consensus OIT informed consent process and framework form - using the Delphi Method.
Preparing Patients for Oral Immunotherapy (PPOINT) JACI 2024

Preparing Patients for Oral Immunotherapy (PPOINT): International Delphi consensus for procedural preparation and consent

Douglas P. Mack, MD, MSc,[a] Timothy E. Dribin, MD,[b] Paul J. Turner, FRCPCH, PhD,[c] Richard L. Wasserman, MD, PhD,[d] Mariam A. Hanna, MD,[e] Marcus Shaker, MD, MSc,[f] Mimi L. K. Tang, MBBS, PhD, FRACP, FRCPA, FAAAI,[g] Pablo Rodríguez del Río, MD, PhD,[h] Brad Sobolewski, MD, MEd,[i] Elissa M. Abrams, MD, MPH,[j] Aikaterini Anagnostou, MD, PhD,[k] Stefania Arasi, MD, PhD,[l] Sakina Bajowala, MD,[m] Philippe Bégin, MD, PhD,[n] Scott B. Cameron, MD, PhD,[o] Edmond S. Chan, MD, FRCPC,[p] Sharon Chinthrajah, MD,[q] Andrew T. Clark, MB, BS, DM,[r] Paul Detjen, MD,[s] George du Toit, MBBCh, RCPCH,[t] Motohiro Ebisawa, MD, PhD,[u] Arnon Elizur, MD,[v] Jeffrey M. Factor, MD,[w] Justin Greiwe, MD,[x] Jonathan O'B Hourihane, MB, DM,[y] Sarah W. Hughes, MPAS, PA-C,[z] Douglas H. Jones, MD,[aa] Antonella Muraro, MD, PhD,[bb] Anna Nowak-Wegrzyn, MD, PhD,[cc] Nandinee B. Patel, MD, PhD,[dd] Amy M. Scurlock, MD,[ee] Atul N. Shah, MD, FACAAI, FAAAAI,[ff] Sayantani B. Sindher, MD,[gg] Stephen Tilles, MD,[hh] Brian P. Vickery, MD,[ii] Julie Wang, MD,[jj] Hugh H. Windom, MD,[kk] and Matthew Greenhawt, MD, MBA, MSc[ll]

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The Delphi Method seeks expert consensus

The Delphi process, also known as the Delphi method, is a structured communication technique used to gather expert opinions and reach a consensus on a particular topic. It involves multiple rounds of anonymous questionnaires and controlled feedback, allowing experts to refine their views based on the input of others. This iterative process aims to reduce bias and achieve a more reliable group opinion or decision.

The Delphi Method starts by eliciting statements

- OIT-consent related statements were elicited from the 36 member panel
- 322 statements were identified from the initial process
- Statements were then sorted into procedural themes and consent themes
- A writing group edited and refined the statements
- The statements were then subject to a modified Delphi process

The Delphi Method quantifies expert consensus

- Panelists vote anonymously on each statement
  - strongly disagree, disagree, neutral, agree, strongly agree
- Consensus was defined as 75% agreement
- Statements not achieving consensus - Re-worded for a new vote
- After three rounds of voting
  - 265 statements achieved consensus for inclusion in consent
- Some statements reached consensus for exclusion from OIT
  - Contraindications from OIT were subject to another round of voting as to whether contraindication is absolute or relative

Statements that should be included in process

Statement	Agreement
Discuss natural history of food allergy without OIT	100%
Detailed discussion of the steps involved in OIT	97.2%
OFC for diagnosis prior to OIT should be prioritized	88.9%
Patient/caregivers' roles should be prioritized	97.2%
Robust education of patient and all caregivers	100%
All caregivers must understand the process/precautions	100%
OIT is not a cure	88.9%
OIT may be disease modifying	91.7%
OIT dosing may be lifelong	94.4%

Medical and other factors in consent process

Statement	Agreement
Comorbid atopic conditions that have to be well controlled:	
○ Asthma	100%
○ Allergic rhinitis	86.1%
○ Atopic dermatitis	91.7%
○ Chronic urticaria	94.4%
Baseline GI symptoms should be evaluated and treated	91.7%
Address OIT-related anxiety and provide counseling, if appropriate	94.4%
Availability of adult supervision for home dosing	100%
Ability to comply with safe dosing rules, especially activity restriction	100%
Separated or divorced parents must agree on the therapy	86.1%

Conditions favorable for initiating OIT

Condition	Agreement
Age <18 yrs	77.1%
Age 1-4 yrs	83.3%
Age 4-17 yrs	88.9%
Age > 18 yrs	No consensus
Multiple food allergies	77.1%
Food allergies unlikely to be outgrown spontaneously	91.7%
Food allergies likely to be outgrown spontaneously	No consensus
Impaired QoL because of reaction anxiety	80.0%
Impaired nutrition	80.6%
Previous anaphylaxis	80.6%
Unsuccessful food avoidance	75%

Absolute and Relative Contraindications for OIT

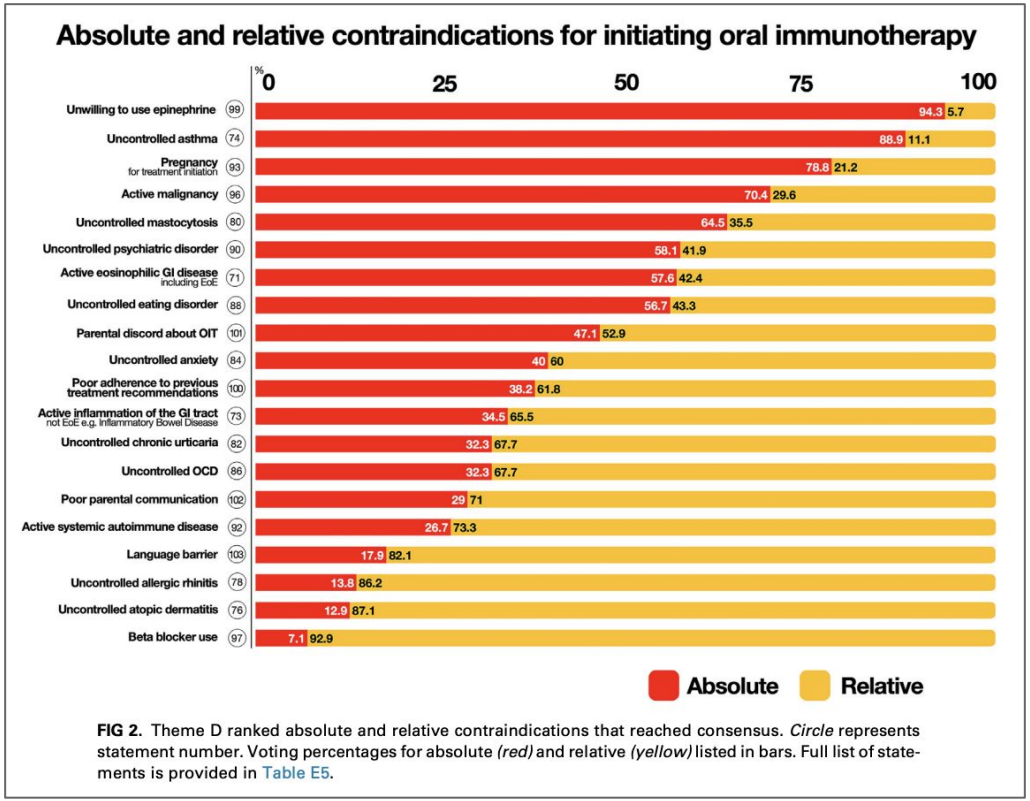

FIG 2. Theme D ranked absolute and relative contraindications that reached consensus. *Circle* represents statement number. Voting percentages for absolute *(red)* and relative *(yellow)* listed in bars. Full list of statements is provided in Table E5.

Absolute and Relative Contraindications for OIT

Absolute Contraindications	Voting Percentage
Unwilling to use epinephrine	94.3
Uncontrolled asthma	88.9
Active malignancy	70.4
Uncontrolled mastocytosis	64.5
Uncontrolled psychiatric disorder	58.1
Active eosinophilic GI disease	57.6
Parental discord about OIT	56.7
Uncontrolled anxiety	40
Poor adherence to previous treatment recommendations	38.2
Active inflammation of the GI tract	34.5
Uncontrolled chronic urticaria	32.3
Uncontrolled OCD	32.3
Poor parental communication	29
Language barrier	17.9
Uncontrolled allergic rhinitis	13.8
Uncontrolled atopic dermatitis	12.9
Beta blocker use	7.1

71 statements to be included on a Consent Form

Statements that reached consensus were then subject to an additional round of voting as to whether they should be included specifically on a physical consent form to be signed

Potential Benefits listed on Consent form

- OIT lowers risks of reaction on accidental exposure
- OIT results in less severe reaction on accidental exposure
- OIT increases threshold required to elicit a reaction
- OIT allows ingestion of foods despite precautionary allergen label - “may contain, made in facility with, made on shared equipment”

Potential Risks listed on consent form

- Oral itch
- Abdominal pain
- Mild allergic reaction such as rash or hives
- Anaphylaxis
- Rarely, fatal allergic reactions
- Reactions in clinic or at home
- Reactions may occur at any time although they are less likely on maintenance
- Epinephrine may be needed for an allergic reaction
- Eosinophilic GI disorders may occur
- EoE responsive to dose reduction may occur

Potential Outcomes listed on consent form

- Patient response may be variable and poorly predictable, and may depend on patient and food being treated.
- OIT effectiveness may be lost if the food is not eaten regularly or is discontinued.
- Patients should expect to eat the allergenic food with some frequency indefinitely.

Alternative strategies listed on consent form

- Continued food avoidance is a reasonable alternative
- OIT may be discontinued at any time

Risk Mitigation Strategies listed on Consent form

- Dosing errors may cause reactions so care must be taken to administer the correct dose
- An adult should supervise dosing administration
- There should be no active infection or signs of illness at the time of dosing
- Doses should be reduced or deferred if the patient is febrile, during an asthma exacerbation, during a vomiting illness, or for dental work
- Avoid exercise before and soon after dosing
- Avoid alcohol, NSAIDs, and hot showers or baths before or soon after dosing
- Avoid dosing while sleep deprived
- Female patients might be at increased risk for reaction during menses

Medical Reasons to Discontinue OIT Listed on Consent form

- Recurrent systemic reactions despite adherence to precautions
- Medical team judges the balance of reactions is too high
- Recurrent abdominal symptoms
- Confirmed eosinophilic esophagitis
- Eosinophilic GI symptoms that do not resolve with management
- Uncontrolled asthma
- Development of another medical condition that is a contraindication for OIT

Social/Behavioral Reasons to Discontinue OIT Listed in Consent form

- Failure to adhere to the protocol
- Failure to adhere to the safety precautions
- Epinephrine not administered when indicated despite appropriate training and education
- Side effects not reported
- Family refuses to treat asthma despite physician recommendation
- Patient requests to stop treatment
- Medical team feels it is in the best interest of the patient to stop treatment

Office policies listed on consent form

- Unscheduled clinic visits may be necessary for dose adjustments.
- Buildup phase may last 4 to 12 months, or even longer.
- Patients and caregivers are provided with guidance on how to contact health care providers with OIT-related questions, both during and outside of office hours and via phone, text, pager, or email.
- Treating physicians must be notified of cases of significant adverse effects.
- Patients and caregivers are expected to follow the allergist's guidance in the event of an OIT-related reaction.
- Any prolonged OIT dose deferral should be promptly communicated to the health care provider.
- Patients are required to bring their epinephrine autoinjector to all dosing visits.
- At least one adult per child is required during OIT visits.
- Patients and caregivers agree not to share dosing protocols that may be used by individuals to attempt OIT without medical supervision

Options for long-term management listed on consent form

- Dose and frequency should not be modified without medical advice.
- Epinephrine auto injector carriage may still be required even when receiving maintenance dosing.
- Adverse events might occur even after years of treatment and should be reported.
- Changes to patient health status may affect OIT safety and should be reported to the treatment team.
- Treatment decisions should be made in partnership and consultation with an allergist.
- Recommendations for OIT treatment may change as experience with OIT grows and as additional food allergy treatments become available

Pre-Day 1 Visit

Review of all of the above

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