Pre-Day 1 Education and Consent Process

Anaphylaxis Prevention and Management

KENILWORTH
MEDICAL
ASSOCIATES

FOOD • ALLERGY • ASTHMA • IMMUNOLOGY

Paul Detjen MD
Kenilworth Medical Associates, Kenilworth, IL

Anaphylaxis Prevention and Management
Risk Factors

Risk factors for anaphylaxis in OIT

Augmenting factors lower threshold for reactions

- infection, exercise, body temperature, extreme fatigue, vaccination, menstruation, NSAID

Concomitant diseases increase risk or severity of anaphylaxis

- asthma (alb use?), cardiac disease, mastocytosis, EoE, primary GI

Co-factors, non-immunologic risk factors in OIT

- adolescence, beta-blocker, psychiatric factors
- dental work, empty stomach (surgery/NPO), tonsillectomy
- rhinitis, CSU

Niggemann B, Beyer K. Factors augmenting allergic reactions.
Allergy. 2014 Dec;69(12):1582-7. doi: 10.1111/all.12532. PMID: 25306896

Anaphylaxis Prevention and Management Recommendations

Physical exercise	Rest period 2 hrs post-dose (and pre-dose)
Acute infection	Dose reduction during acute illness
Gastroenteritis, NPO	No dose if stomach empty
Menses (in some)	If so, dose reduction x 3d at menses onset
NSAIDs, Alcohol	Limit
Vaccination	Dose deferral or reduction (no dose, 1/2 dose, full dose)
Asthma	Good control (alb use in setting of anaphylaxis?)
CSU/MCAS	Good control of spontaneous hives
Seasonal allergen exposure	Good control of rhinitis symptoms
Gum mucosa injury / dental work	Dose deferral until healed (no dose, 1/2 dose, full dose)
Empty stomach	Dose with full meal
Sleep deprivation	No dose late in evening
Adolescence	Good control of adolescence (!) – Adults observe dosing for teens

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Anaphylaxis Prevention and Management Outside of clinic hours

Non-OIT PN accidents reportedly occur at >10% per year - 2/3 being moderate to severe

Epinephrine-Treated-Reactions in OIT have been shown to occur in the range of 1 per 1,000 doses

- more frequently in Escalation phase but Maintenance reactions occur
- more frequently with higher baseline specific IgE

24 hour availability is considered a necessary part of providing OIT

Emergency anaphylaxis management calls have 3 objectives

1. was the reaction fully reversed
2. was the reaction fully reversed quickly (should the patient be observed in a medical setting)
3. was the reaction No Cause or For Cause (illness, empty stomach, overheated, lost tooth, vaccine, etc)

Anaphylaxis Prevention and Management
Epi = ED re-considered? AAP

The unintended consequences of “If you use Epi, go to the Emergency Room”

1. Delayed use of epinephrine - Families don’t want to go to the ED
   “It’s not bad, breathing ok, let’s give it a little time” “All my other reactions went away eventually”

2. Anaphylaxis can progress quickly from 2 mild symptoms to multiple severe symptoms
   To the point where epinephrine is less effective
   Most food fatalities are a consequence of delayed use of epinephrine

First minor symptom give Zyrtec and call the 24hr number

If a second symptom develops while waiting for the call-back - add epinephrine

Need for ED monitoring is assessed during the call-back

Anaphylaxis Prevention and Management
AuviQ/Epipen dosing may be on the low end

AuviQ 0.1mg	7.5kg to 15kg
AuviQ/Epipen Jr 0.15mg	15kg to 30kg
AuviQ/Epipen 0.3mg	> 30kg

The accepted dosing schedule for epinephrine is .01 mg/kg (max 0.5mg)

The AuviQ/Epipen Jr at .15mg initially seems correctly dosed for a 15kg patient

For every kg above 15kg is the patient actually outgrowing the Jr?

Some OIT practices advance to higher epinephrine doses earlier than the PI recommendations

AuviQ 0.1mg	to 10kg
AuviQ/Epipen Jr 0.15mg/Neffy 1mg	to 20kg

Anaphylaxis Prevention and Management
Travel tips

Camp	Most camps are now familiar with OIT Camp schedule can impact best time for OIT dosing
Travel	Dose minimum 3 hrs pre-flight Skip dose that morning or ½ dose with first meal at destination May need TSA letter for liquid OIT preparations Prednisone for travel
Vacation dosing	Beach activities Ski trips
International	Depends on family's risk tolerance Depends on countries visited – remote locations/ED access Jet lag

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“There is no current agreement about what elements should be included in the OIT consent process.”

Novel treatment with inherent risk requiring a comprehensive consent process

Preparing Patients for Oral Immunotherapy (PPOINT) JACI 2024

International panel of 36 experts developed consensus on an OIT informed consent process and a framework for a consent form - the Delphi Method

Multiple rounds of anonymous questionnaires and feedback

Experts refined their views based on the input of others, re-voted until consensus

What statements should be included in the OIT consent process

What statements should be included in the OIT consent form

PPOIT: Preparing Patients for Oral Immunotherapy: International Delphi consensus for consent. D Mack, R Wasserman, D Jones, H Windom, P Detjen. J Allergy Clin Immunol. Apr 2024; 153:1621-1633

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

Check for updates

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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Issues that should be addressed in the Process

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

Medical and other factors included in the process

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

Conditions favorable for initiating OIT – *2024

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

Absolute and Relative Contraindications for OIT

Absolute Contraindications	Agreement
• Unwilling to use epinephrine	94.3
• Uncontrolled asthma	88.9
• Uncontrolled mastocytosis	64.5
• Uncontrolled psychiatric disorder	58.1
• *Active eosinophilic GI disease	57.6
• *Parental discord about OIT	56.7

*Uncontrolled anxiety
Active inflammation of GI tract
Uncontrolled OCD
Uncontrolled allergic rhinitis

*Poor adherence to prior recommendations
Uncontrolled chronic urticaria
*Poor parental communication
Uncontrolled atopic dermatitis

71 statements to be included on consent Form

Consensus statements then evaluated re inclusion on a signed consent form

Potential Benefits on consent form:

OIT lowers risks of reaction from accidental exposure

OIT results in less severe reaction from accidental exposure

OIT increases threshold required to elicit a reaction

OIT allows ingestion despite precautionary allergen label

(may contain, made in a facility with, shared equipment)

Potential Risks listed on Consent form

- Oral itch (transient) with dose
- Abdominal pain
- *Allergic reaction such as rash or hives
- *Anaphylaxis
- *Potential for fatal allergic reaction
- Reactions may occur in clinic or at home
- *Reactions may occur at any time including maintenance phase
- Epinephrine may be needed for an allergic reaction
- *Eosinophilic GI disorders may occur
- EoE may be responsive to dose reduction

Alternatives and Outcomes listed on Consent form

Alternatives:

Continued food avoidance is a reasonable alternative

Outcomes:

Patient response may be variable and is poorly predictable

*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

*OIT may be discontinued at any time

Risk mitigation strategies listed on Consent form

- Dosing errors may cause reactions, care must be taken with administration
- *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 ill, during an asthma exacerbation, during a vomiting illness, or for dental work
- Avoid exercise before and soon after dosing
- Avoid alcohol, NSAIDs, hot showers or baths before, soon after dosing
- Avoid dosing while sleep deprived
- Female patients might be at increased risk for reaction during menses

Medical reasons to stop OIT on Consent form

- *Medical team judges the frequency of reactions is too high
- Recurrent systemic reactions despite adherence to precautions (reactions can be divided into For Cause and Not For Cause)

- *Recurrent abdominal symptoms
- Confirmed eosinophilic esophagitis
- Eosinophilic GI symptoms that do not resolve with management
- *Uncontrolled asthma
- Development of another contraindicating medical condition

Behavioral reasons to stop OIT on Consent form

- *Failure to adhere to the protocol
- Failure to adhere to the safety precautions
- *Epinephrine not administered when indicated or recommended
- 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 to stop treatment

Office policies listed on Consent form

- Unscheduled clinic visits may be necessary for dose adjustments.
- Escalation phase may last 4 to 12 months, or longer.
- Patients and caregivers are provided with guidance on how to contact health care providers with OIT-related questions, outside of office hours via phone, text, or email.
- *Treating physicians must be notified of cases of significant adverse effects.
- *Patients and caregivers are expected to follow allergist's guidance for reactions.
- Prolonged OIT dose deferrals should be 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 agree not to share protocols to individuals attempting OIT w/o supervision.

Long-term management rules on Consent form

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

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