Active Food Allergy Treatment in 2025

Marcus S. Shaker, MD, MSc, FAAP, FAAAAI, FACAAI
Professor of Medicine and Pediatrics
Dartmouth Geisel School of Medicine

Food Allergy: Active Treatment

(some questions)

Why start active treatment?

What are the options?

Who benefits?

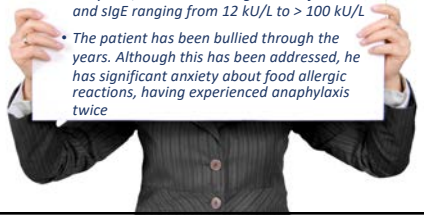
Learning Objectives

Upon completion of this activity, participants should be able to…

- Discuss how active treatment may lesson the burden of disease in IgE mediated food allergy
  - Family, community, society
  - Food allergy severity
  - Food allergy anxiety
  - Bullying & Quality of life
- Appreciate how food allergy and anxiety interact
  - Implement screening tools and risk framing for anxiety
- Consider innovative approaches to management

Dartmouth

- *M.K. is a 11 year old child with clinical food allergies to milk, egg, soy, peanut, cashew, pistachio, walnut, pecan, sesame, and mustard*
- *Markers of sensitization have increased over the years, with 3-4+ testing to most foods and sIgE ranging from 12 kU/L to > 100 kU/L*
- *The patient has been bullied through the years. Although this has been addressed, he has significant anxiety about food allergic reactions, having experienced anaphylaxis twice*



Questions:

1. How severe is his food allergy?
2. How would you assess this patient's anxiety?
3. What treatment options would you consider for food allergy?

Patient, Family, Community, Society

…nomic cost of food allergy …n USD in children alone,

Original Investigation
The Economic Impact of Childhood Food Allergy in the United States
2013

Original Article | Quick note

The Impact of Allergy Specialty Care on Health Care Utilization Among Peanut Allergy Children in the United States

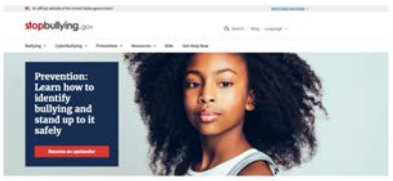
Matthew Greenhawt, MD, MBA, MSc[a], Elissa M. Abrams, MD, MPH[b], Joseph M. Chalil, MD, MBA[c], Oth Tran, MA[d], Todd D. Green, MD[e,a], and Marcus S. Shaker, MD, MS[f,g] *Aurora, Colo; Winnipeg, MB, Canada; Montrouge, France; Cambridge, Mass; Pittsburgh, Pa; and Lebanon and Hanover, NH*

J Allergy Clin In Pract 2022

- **Claims analysis of over 200,000 patients with food allergies from 2010-2019**
- **Allergist involvement**
  - ✓**Reduced costs ($7863 vs $7261 per patient, p<0.001)**
  - ✓**Improved epinephrine prescribing (RR 1.67, p< 0.001)**
  - ✓**Despite higher rates of anaphylaxis in the allergist group**

Bullying

EDUCATION
COMMUNICATION
ENGAGEMENT



About one-third of children with food allergies have been bullied due to their food allergy

Shemesh E, et al 2013
Annunziato et al 2014
Lieberman, Weiss et al 2010

WAO consensus on DEfinition of Food Allergy SEverity (DEFASE)

WORLD ALLERGY ORGANIZATION JOURNAL
Open Access

- Symptoms / signs of most severe prior reaction
- Minimum therapy to treat most severe reaction
- Individual minimal eliciting dose
- **Current food allergy quality of life**
- **Current health-economic impact**

DEFASE Domains (1-3 points each)
-mild, moderate, or severe-

DEFASE Score
- Mild: ≤6 points
- Moderate: 7-12 points
- Severe: ≥ 13 points

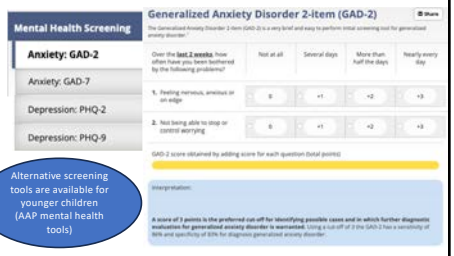
Holistic view

Arasi S, Nurmatov U, Dunn-Galvin A, et al. World Allergy Organization Journal 2023

Food Allergy and Anxiety

Conway AE, Verdi ML, Kartha N, et al. Allergic Diseases and Mental Health. JACI In Practice. 2024

- Impacts both parents and children
- In one study, 19% of parents felt their child had a moderate to high risk of food allergy fatality



Alternative screening tools are available for younger children (AAP mental health tools)

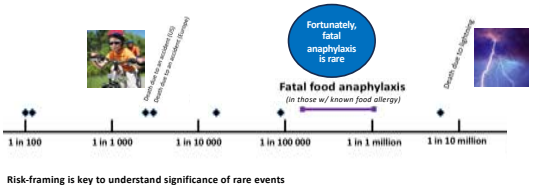
Westwell-Roper et al. Pediatr Allergy Immunol 2022; Ogg et al. Asthma & Allergy Proc. 2017; Shaker et al. Curr Opin Pediatric. 2017

https://www.hiv.uw.edu/page/mental-health-screening/gad-2

Clinical Commentary Review

Fatal Anaphylaxis: Mortality Rate and Risk Factors

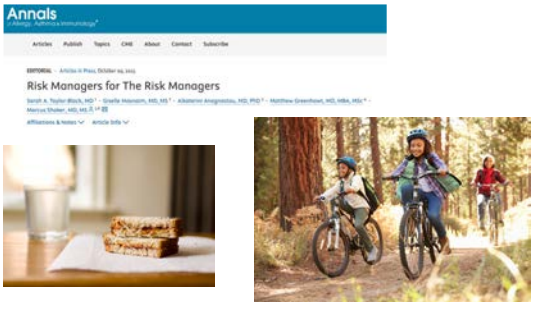
Paul J. Turner, MD, PhD[a,b], Elina Jerschow, MD[c], Thisanayagam Umasunthar, MD[a], Robert Lin, MD[d], Dianne E. Campbell, MD, PhD[b,e], and Robert J. Boyle, MB, ChB, PhD[a] *London, United Kingdom; Bronx, New York, NY; and Sydney, Australia*



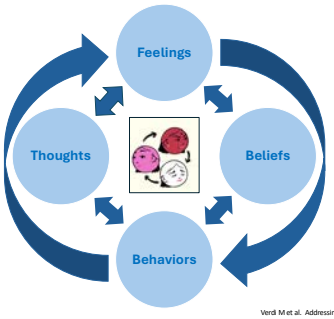
Risk-framing is key to understand significance of rare events

Turner, Jerschow et al, Fatal Anaphylaxis: Mortality and Risk Factors. JACI In Practice 2017

The Elephant in the Room: Fear

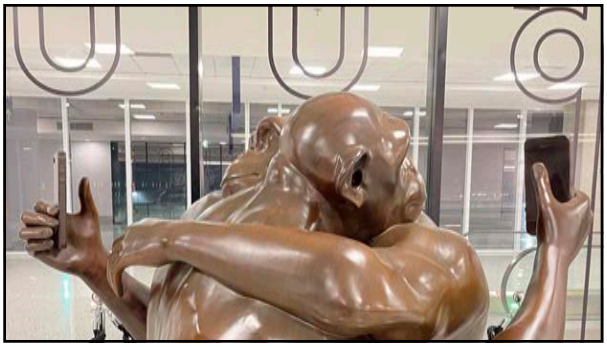


Cognitive Behavioral Therapy Through Curious Questions



- Help patients realize feelings are not facts
- The *listening self* can choose to let go of disturbing thoughts from the *commenting self*
- Risk framing can help to challenge false beliefs

Verdi M et al. Addressing Anxiety & Depression Through Brief CBT. JACI IP 2025



Compassionomics

- Compassionomics explores the return on investment of human connection in medicine
- Recommendations are of little value unless they are incorporated into the lives of individuals who benefit from them
- A lack of connection between clinicians and patient partners is a leading reason for non-adherence to medical recommendations.

Buckstein et al. JACI IP 2025

Communicating Compassion

(pause)

40 Seconds

2. Partnership

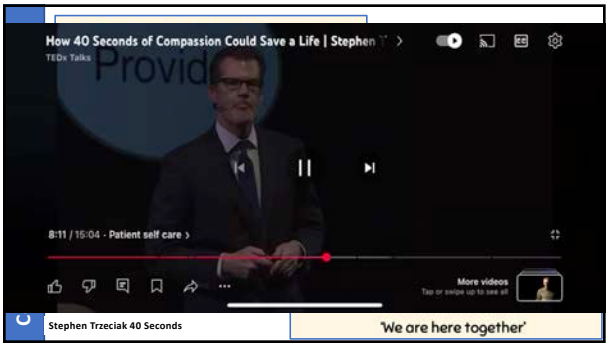
'I am here with you'

3. Empowerment

4. Repeated expression of partnership & commitment

'We are here together'

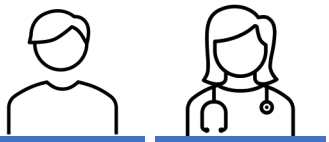
Buckstein et al. JACI IP 2025



Management Options

Shared Decision-Making

- Risk Framing ✓
- Ladders
- Food oral immunotherapy
- Sublingual immunotherapy
- Omalizumab
- EPIT?
- OMIT?



Patient/Family Expertise in their Values and Preferences

Clinician Expertise and Experience in Clinical Science

Ladders

Are we simply providing a structure to a naturally occurring process?

Thank you Doug Mack, MD

Mack et al, JACI-I, 2023

How Effective?

World Allergy Organization Journal

ORIGINAL RESEARCH Open Access

Randomised controlled trial of a baked egg intervention in young children allergic to raw egg but not baked egg

- 43 BE-tolerant egg-allergic 2 y.o. (range 6mo – 5 yrs) consumed 1.3 g protein 2 - 3 times per week for 6 months
- Raw egg OFC 1 month after discontinuation
- After the intervention, there was no difference in raw egg tolerance between groups (23.5% (4/17) intervention group and 33.3% (6/18) control group).

Netting et al, WAOJ, 2017

Allergic Living

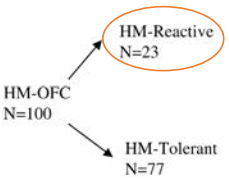
Not Without Risk

Girl with Milk Allergy Dies of Severe Reaction Related to Desensitization

- 9-year old child receiving an OIT/milk ladder approach
- Uncontrolled/suboptimally treated asthma with exacerbation
- Prior reactions treated with diphenhydramine
- Exercise, possible delay in presentation and and treatment

https://www.allergicliving.com/2021/12/20/girl-with-milk-allergy-dies-of-severe-reaction-related-to-desensitization/

Higher sensitization equals greater risk



- Reactive patients had higher baseline casein and milk-specific IgE and larger SPT size
- More likely to require epinephrine

Nowak-Wegrzyn et al, JACI 2008

Epinephrine more likely with baked

TABLE E2. Symptoms and treatments administered during oral food challenges

	Heated milk-reactive	Heated milk-tolerant, unheated milk-reactive	
Total subjects (%)	23 (23)	41 (41)	
Severity of symptoms, median anaphylaxis grade (range)*	2 (1-5)	2 (1-3)	
Symptoms observed			
Skin‡ (%)	21 (91)	35 (85)	
Upper respiratory§ (%)	17 (74)	26 (63)	
Lower respiratory‖ (%)	4 (17)	2 (5)	
Gastrointestinal¶ (%)	8 (35)	9 (22)	
Cardiovascular# (%)	1 (4)	1 (2)	
Treatments received			
Diphenhydramine (%)	22 (96)	41 (100)	
Epinephrine (%)†	8 (35)	0 (0)	P <.001
Methylprednisolone, intravenous (%)	6 (26)	2 (5)	
Albuterol, nebulized (%)	2 (9)	0 (0)	
Intravenous fluids (%)	2 (9)	0 (0)	
Cetirizine (%)	1 (4)	0 (0)	
Ranitidine (%)	1 (4)	0 (0)	

Nowak-Wegrzyn et al, JACI 2008

Lower respiratory tract and delayed symptoms more likely with baked

Original Article

Delayed and Severe Reactions to Baked Egg and Baked Milk Challenges

DISCUSSION

In our cohort, significant differences in the clinical characteristics of OFC reactions emerged for individual foods. Nearly half of BE and BM reactions lacked mucocutaneous abnormalities, and lower respiratory tract manifestations were significantly increased among BM reactors (Figure 1). Significantly higher proportions of patients reacting to BE and BM developed new symptoms 60 minutes or later after the end of the OFC (Figure 4).

Yonkof et al, JACIP, 2021

What Can We Learn From Severe Reactions?

Age	Food	Approach	Asthmatic	Disposition	Other risk factors	Country	Date
14	Milk	OIT- Induction	Yes –uncontrolled	Near-fatal	Casein sIgE 195 Poor compliance	Spain	2014
13	Egg	OIT-Induction	Yes –uncontrolled	Near-fatal	Egg white sIgE 75 Poor compliance	Spain	2014
15	Milk	OIT-Maintenance	Yes - uncontrolled	Near-fatal	Casein sIgE > 100 Poor compliance	Spain	2014
5	Milk	OIT-Maintenance	Yes	Near-fatal Profound hypoxic brain injury	Not known	Japan	2017
Boy	Milk	OIT-Maintenance	Yes - exacerbation	Near-fatal	Milk sIgE >500	Finland	2019
11	Baked Milk	Oral Food Challenge	Yes	Near-fatal Profound hypoxic brain injury	High milk-specific IgE	Israel	2020
3	Baked Milk	Oral Food Challenge	Yes	Fatal	Not known	USA	2017
9	Baked Milk	OIT-Milk Ladder	Yes - uncontrolled and exacerbation	Fatal	Delayed epinephrine Large SPT Exercise	Canada	2021

Mack et al, JACI-IP, 2023

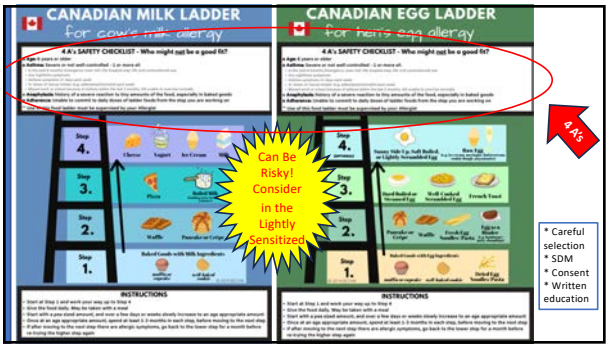
Where can baked products and ladders go wrong?

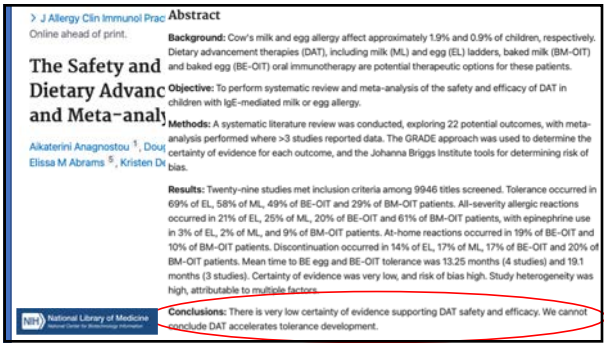
Table 3 **Potential sources of variation in baked products and ladders**

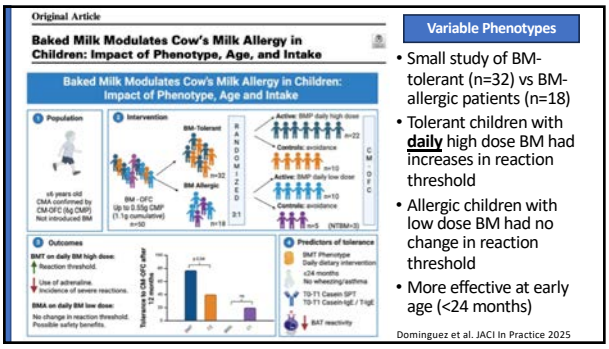
Differences in heating time and temperature
Different recipes (including commercial variation)
Differences in matrix
Differences in dispersion
Differences in cultural foods
Differences in total amount of added milk or egg protein
Differences in total allergenic amount of milk or egg protein

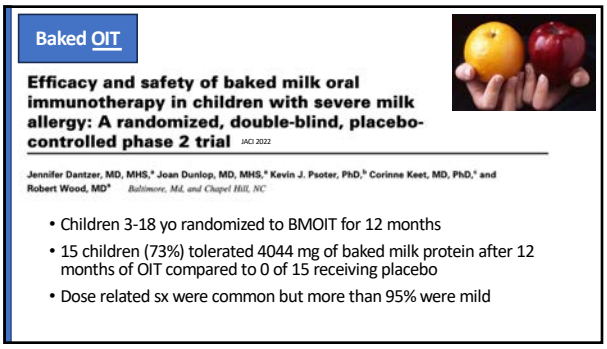
Less of an issue amongst low-risk phenotype

Mack DP, J Food Allergy, 2023









Management Options

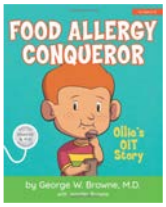
Shared Decision-Making

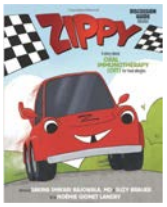
- Risk Framing ✓
- Ladders ✓
- Food oral immunotherapy
- Sublingual immunotherapy
- Omalizumab
- EPIT?
- OMIT?

Patient/Family Expertise in their Values and Preferences

Clinician Expertise and Experience in Clinical Science

Benefits of Active Treatment: Empowerment?





PACE

- Systematic review and meta-analysis of 12 trials
  - n=10,041
  - Median age 8.7 yrs
    - IQR, 5.9-11.2 years
- OIT increased
  - Anaphylaxis risk
    - RR 3.12 (95% CI, 1.75-5.55)
  - Epinephrine use
    - RR 2.21 (95% CI, 1.27-3.83)

NIH National Library of Medicine
National Center for Biotechnology Information

Oral immunotherapy for peanut allergy (PACE): a systematic review and meta-analysis of efficacy and safety

Derek K Chu [1], Robert A Wood [2], Shannon French [3], Alessandro Fiocchi [4], Manel Jordana [5], Susan Waserman [6], Jan L Brożek [7], Holger J Schünemann [8]

Affiliations + expand

PMID: 31030987 DOI: 10.1016/S0140-6736(19)30420-9

Interpretation: In patients with peanut allergy, high-certainty evidence shows that available peanut oral immunotherapy regimens considerably increase allergic and anaphylactic reactions over avoidance or placebo, despite effectively inducing desensitisation. Safer peanut allergy treatment approaches and rigorous randomised controlled trials that evaluate patient-important outcomes are needed.

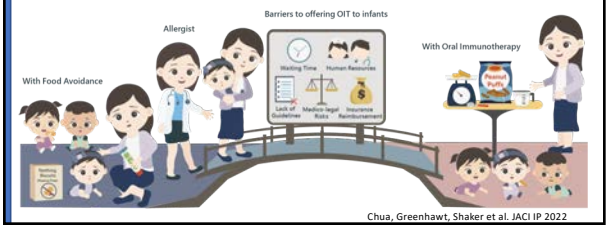
Lancet 2019

Long Term Models

- Systemic reactions to OIT were less common than anaphylaxis from accidental reactions without OIT when considered from a longer-term horizon
- With early OIT, cost savings reached $12.3 to $47 billion in the US and $10.4 to $13.6 billion in Canada
- Not only did OIT save money, at the same time it improved quality-adjusted life years

NIH National Library of Medicine
National Center for Biotechnology Information

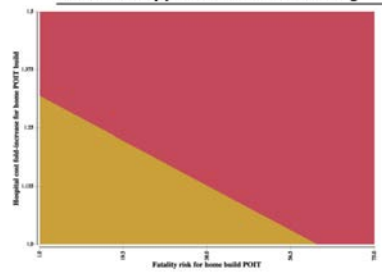
Barriers to Active Treatment



Chua, Greenhawt, Shaker et al. JACI IP 2022

Original Article

The Cost-Effectiveness of Preschool Peanut Oral Immunotherapy in the Real-World Setting



- In the US context, home immunotherapy without required clinic visits was the optimal strategy below a 62-fold increase in fatality risk

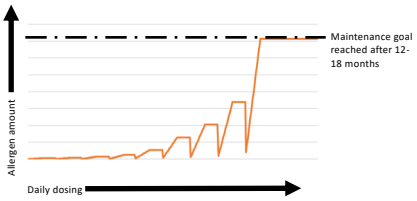
Shaker et al. JACI IP 2021

Spoon Sheets

Each year 3.6 million people in the United States do not obtain medical care due to transportation issues

American Hospital Association. www.aha.org

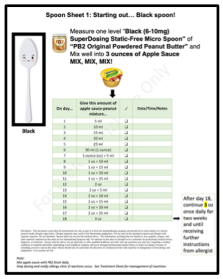
- Steps must be very small
  - Less than 1 mg or 10% of the daily dose
- Tiny steps every day may pose no greater risk than larger steps administered every two weeks



Marcus.S.Shaker@Hitchcock.org

Home Multifood Oral Immunotherapy with Dartmouth Spoon Sheets

- Retrospective chart review
  - n=100 (index anaphylaxis in 35%)
  - Average age 4.31 years (8 months – 16.7 years)
- Maintenance reached in 45%,
  - 15% discontinued
- Average duration to date 1.3 years
- Foods Treated:
  - Peanut: 57%
  - Tree nuts: 34%
  - Milk: 16%
  - Egg: 26%
  - Multi-OIT: 46%
- 41% with immediate OIT reactions
- 6% of patients experienced any reaction greater than grade 1
  - Epinephrine use: 1%



Hughes et al. JACI IP 2024

Received: 18 July 2022 | Revised: 24 August 2022 | Accepted: 6 September 2022
DOI: 10.1111/ina.14235

Review

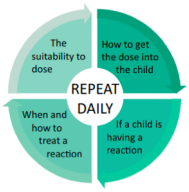
WILEY

Information needs of patients considering oral immunotherapy for food allergy

Douglas Paul Mack[1] | Matthew Greenhawt[2] | Paul J. Turner[3] | Richard L. Wasserman[4] | Mariam A. Hanna[1] | Marcus Shaker[5] | Sarah W. Hughes[4] | Pablo Rodríguez del Río[7]

Key messages

- Oral immunotherapy is an elective, rarely curative procedure with inherent risks and challenges.
- This procedure requires families and patients to assume the role of amateur medical professionals.
- Thorough counselling and shared decision-making approaches are required to prepare families for this role.



Key elements in counseling and consent

- Alignment of goals of therapy
- Current food allergy management options
- Expected outcomes of OIT
- Potential risk of OIT
- Contraindications
- Practical elements
- Risk mitigation approaches
- Long term discussion

Shared Decision-Making

A lot needs to be discussed...

The Journal of Allergy and Clinical Immunology: **In Practice**

Original Article

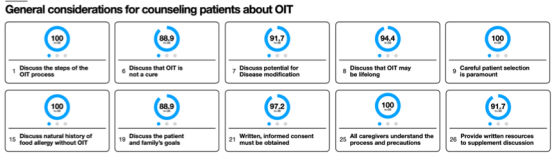
PPOINT: Preparing Patients For Oral Immunotherapy

Mack D, Dribin T, Wasserman R, Hanna M, Shaker M, et al. February 2024

- Global Delphi study
- 36-member expert panel representing US, Canada, UK, Europe, Asia, and Australia

Theme

General considerations for counseling patients about OIT

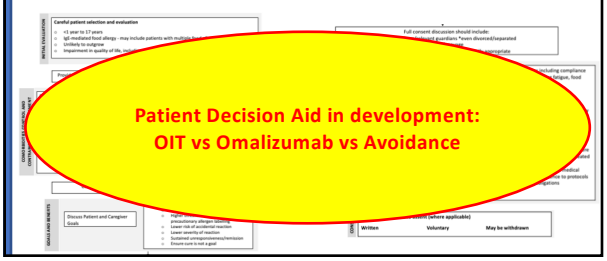


Original Article

PPOINT: Preparing Patients For Oral Immunotherapy

Mack D, Dribin T, Wasserman R, Hanna M, Shaker M, et al. February 2024

The Journal of Allergy and Clinical Immunology: **In Practice**



Patient Decision Aid in development: OIT vs Omalizumab vs Avoidance

Food allergy and gastrointestinal disease

SLIT

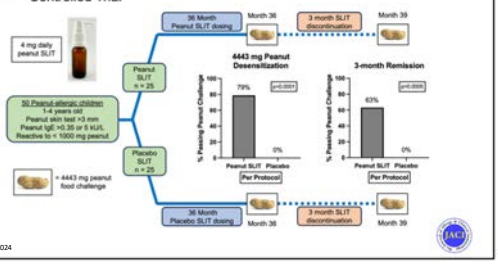
Desensitization and remission after peanut sublingual immunotherapy in 1- to 4-year-old peanut-allergic children: A randomized, placebo-controlled trial

Edwin H. Kim, MD, MS,[a] J. Andrew Bird, MD,[c] Corinne A. Keet, MD, PhD,[a] Yamini V. Virkud, MD, MPH,[a] Lauren Herlihy, DNP,[a] Ping Ye, PhD,[a] Johanna M. Smeekens, PhD,[a] Rishu Guo, PhD,[a] Xiaohong Yue, MS, DDS,[a] Anusha Penumarti, PhD,[a] Bahjat Qaqish, PhD,[b] Quefeng Li, PhD,[b] Michael D. Kulis, PhD,[a] and A. Wesley Burks, MD[a]
Chapel Hill, NC, and Dallas, Tex

- Small study (n=25 in active treatment) showing high safety and benefit with as little as **4mg of sublingual peanut**
- Highest rates of desensitization in the youngest patients
- While local oropharyngeal dosing symptoms were common, no participant received epinephrine

Kim et al 2024

Desensitization and Remission after Peanut Sublingual Immunotherapy in 1-4 year-old Peanut Allergic Children: a Randomized, Placebo-Controlled Trial

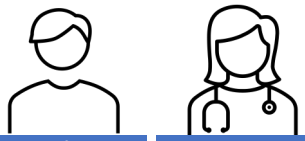


Kim et al 2024

Management Options

- Avoidance ✓
- Ladders ✓
- Food oral immunotherapy ✓
- Sublingual immunotherapy ✓
- Omalizumab

Shared Decision-Making



Patient/Family Expertise in their Values and Preferences

Clinician Expertise and Experience in Clinical Science

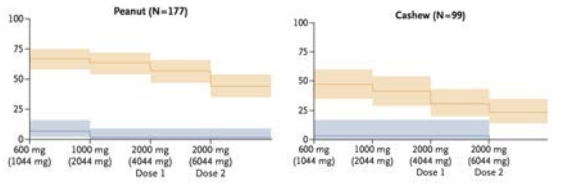
2024

The NEW ENGLAND JOURNAL of MEDICINE

Wood RA, Togias A, et al. NEJM 2024

ORIGINAL ARTICLE

Omalizumab for the Treatment of Multiple Food Allergies



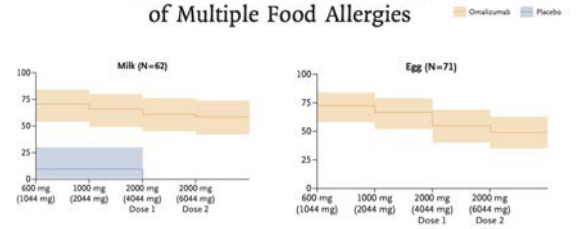
2024

The NEW ENGLAND JOURNAL of MEDICINE

Wood RA, Togias A, et al. NEJM 2024

ORIGINAL ARTICLE

Omalizumab for the Treatment of Multiple Food Allergies



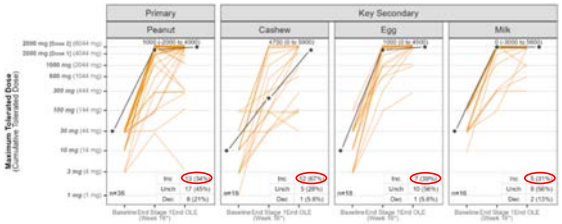
2024

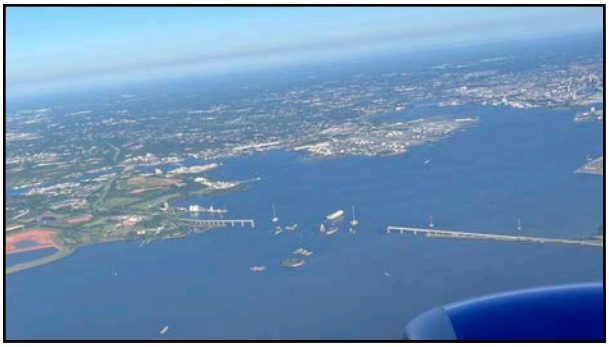
The NEW ENGLAND JOURNAL of MEDICINE

Wood RA, Togias A, et al. NEJM 2024

ORIGINAL ARTICLE

Open Label Extension to 40-44 weeks





Omalizumab: Approved for FA in February 2024

- **Entry DBPCFC's**
- **Dose limiting (mod-severe) sx to PN protein at <u>≤</u>100 mg**
- **Dose limiting sx to other foods (x2) at <u>≤</u>300mg of protein**
- **N=165, ages 1-17y**
- **Endpoint: DBPCFC's without dose limiting (mod-severe) sx after 16-24 weeks of therapy**

Prescribing Information

Food, Challenge Dose	Response Rate[a] (%) (n/N)	
	X[redacted]	Placebo
Peanut, ≥600 mg	68% (75/110)	5% (3/55)
Peanut, ≥1000 mg[b]	65% (72/110)	0% (0/55)
Cashew, ≥1000 mg	42% (27/64)	3% (1/30)
Milk, ≥1000 mg	66% (25/38)	11% (2/19)
Egg, ≥1000 mg	67% (31/46)	0% (0/19)

From Outmatch:
- For consumption of 3 foods (cumulative dose):
  - 47% were able to consume 1,044 mg
  - 37% were able to consume 2,044 mg
  - 31% were able to consume 4,044 mg
  - 24% were able to consume 6,044 mg

https://www.gene.com/download/pdf/[redacted]prescribing.pdf

Omalizumab: Approved for FA in February 2024

"To be used in conjunction with food avoidance"

Prescribing Information

Pretreatment Serum IgE (IU/mL)	Dosing Freq.	Body Weight (kg) ≥10-12	>12-15	>15-20	>20-25	>25-30	>30-40	>40-50	>50-60	>60-70	>70-80	>80-90	>90-125	>125-150
		Dose (mg)												
≥30 - 100	Every 4 Weeks	75	75	75	75	75	75	150	150	150	150	150	300	300
>100 - 200		75	75	75	150	150	150	300	300	300	300	300	450	600
>200 - 300		75	75	150	150	150	225	300	300	450	450	450	600	375
>300 - 400		150	150	150	225	225	300	450	450	450	600	600	450	525
>400 - 500		150	150	225	225	300	450	450	600	600	375	375	525	600
>500 - 600		150	150	225	300	300	450	600	600	375	450	450	600	
>600 - 700		150	150	225	300	225	450	600	375	450	450	525		
>700 - 800	Every 3 Weeks	150	150	150	225	225	300	375	450	450	525	600		
>800 - 900		150	150	150	225	225	300	375	450	525	600			
>900 - 1000		150	150	225	225	300	375	450	525	600				
>1000 - 1100		150	150	225	225	300	375	450	600					
>1100 - 1200		150	150	225	300	300	450	525	600					
>1200 - 1300		150	225	225	300	375	450	525						
>1300 - 1500		150	225	300	300	375	525	600						
>1500 - 1850			225	300	375	450	600							

Insufficient data to Recommend a Dose

https://www.gene.com/download/pdf/[redacted]prescribing.pdf

Certainty in Patient Outcome

- **Entry DBPCFC's**
- **Dose limiting (mod-severe) sx to PN protein at <u>≤</u>100 mg**
- **Dose limiting sx to other foods (x2) at <u>≤</u>300mg of protein**
- **N=165, ages 1-17y**
- **Endpoint: DBPCFC's without dose limiting (mod-severe) sx after 16-24 weeks of therapy**

Prescribing Information

Food, Challenge Dose	Response Rate[a] (%) (n/N)
	X[redacted]
Peanut, ≥600 mg	68% (75/110)
Peanut, ≥1000 mg[b]	65% (72/110)
Cashew, ≥1000 mg	42% (27/64)
Milk, ≥1000 mg	66% (25/38)
Egg, ≥1000 mg	67% (31/46)

- Need to identify responders?
- Role of SDM
- Patient goals and preferences are key
- Some patients may choose 'off-label' threshold challenges
- Others may choose to follow labeled indication
- Durability of response assumed?

https://www.gene.com/download/pdf/[redacted]prescribing.pdf

Clinical Commentary Review

Fatal Anaphylaxis: Mortality Rate and Risk Factors

Paul J. Turner, MD, PhD[a,b], Elina Jerschow, MD[c], Thisanayagam Umasunthar, MD[a], Robert Dianne E. Campbell, MD, PhD[b,e], and Robert J. Boyle, MB, ChB, PhD[a] *London, United Kingd Sydney, Australia*

What are patient/family goals of therapy?

Fortunately, fatal anaphylaxis is rare

Fatal food anaphylaxis *(in those w/ known food allergy)*

1 in 100 | 1 in 1 000 | 1 in 10 000 | 1 in 100 000 | 1 in 1 million | 1 in 10 million

Omalizumab

Risk-framing is key to understand significance of rare events

Turner, Jerschow et al, Fatal Anaphylaxis: Mortality and Risk Factors. JACI In Practice 2017

> Ann Allergy Asthma Immunol. 2024 Aug 24:S1081-1206(24)00494-0.
doi: 10.1016/j.anai.2024.07.034. Online ahead of print.

Food allergy yardstick: Where does omalizumab fit?

Aikaterini Anagnostou [1], Matthew Greenhawt [2], Marcus Shaker [3], Brian P Vickery [4], Julie Wang [5]

Affiliations + expand

PMID: 39182580 DOI: 10.1016/j.anai.2024.07.034

"In respecting patient autonomy, healthcare delivery must allow flexibility in patient care"

Abstract

Food allergy management has greatly evolved in the last several years, moving from passive approaches, such as strict food allergen avoidance, to more active treatments, including regulatory approval of the first specifically indicated immunotherapy product (for peanut) in 2020. In 2024, a second therapy, omalizumab, received regulatory approval for the treatment of 1 or more IgE-mediated food allergies, providing clinicians with multiple treatment options to offer patients and families. With this expanded armamentarium of food allergy treatment options, the practicing clinician requires detailed knowledge of benefits and risks of omalizumab, how omalizumab fits into the management landscape, and how to use shared decision-making to optimize therapy. This yardstick aims to provide the clinician with a review of data leading to omalizumab's food allergy indication and an evidence-based expert opinion approach regarding on how best to use this and other therapies available to optimize patient management.

Omalizumab is a treatment option for IgE mediated food allergy…

- Without restriction based on disease severity or prior treatment failure
- For patients in dosing range with likely allergy
- OFC not required, either for diagnosis or threshold

Practice Guideline · J Allergy Clin Immunol. 2025 Jan;155(1):62-69.e1. doi: 10.1016/j.jaci.2024.09.031. Epub 2024 Nov 22.

The use and implementation of omalizumab as food allergy treatment: Consensus-based guidance and Work Group Report of the Adverse Reactions to Foods Committee of the American Academy of Allergy, Asthma & Immunology

Aikaterini Anagnostou [1], J Andrew Bird [2], Sharon Chinthrajah [3], Timothy E Dribin [4], David M Fleischer [5], Edwin Kim [6], Anna Nowak-Wegrzyn [7], Rima Rachid [8], Marcus S Shaker [9], Wayne Shreffler [10], Scott Sicherer [11], Jonathan Tam [12], Brian P Vickery [13], Yamini V Virkud [8], Julie Wang [11], Michael Young [8], Matthew Greenhawt [14]

Affiliations + expand

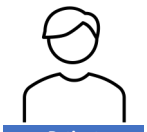
PMID: 39580718 DOI: 10.1016/j.jaci.2024.09.031

- Treatment outcomes should be individualized, an OFC may be considered after 16-20 weeks if desired
- Off-label use with OIT an option
- Vaccines not contraindicated
- Option of home dosing

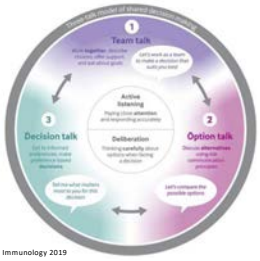
"In respecting patient autonomy, healthcare delivery must allow flexibility in patient care"

Shared Decision Making

Shared Decision Making and Risk



Patient Expertise in their Values and Preferences



Clinician Expertise and Experience in Clinical Science

Blaiss et al. Annals of Allergy, Asthma, and Immunology 2019

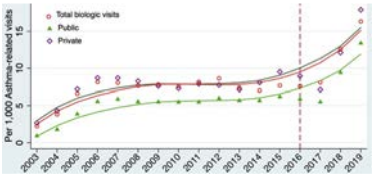
Social Determinants of Health

www.healthy.gov

Multilevel Determinants of Pharmacoequity

Chalasani et al. J Health Policy Law 2022

Pharmacoequity and race



Akenroye et al. JACI IP 2021

- In a 2021 evaluation of the IQVIA (a sample of 3,700-4,100 office-based physicians) national database no biologics were recorded for those without insurance
- Biologic use is lower in those publicly insured
- Among the publicly insured, Black patients are particularly under-represented compared to White patients

Cost-Effectiveness of Biologics for Allergic Diseases

Ann Chen Wu, MD, MPH[a], Anne L. Fuhlbrigge, MD, MSc[b], Maria Acosta Robayo, BA[a], and Marcus Shaker, MD, MSc[c,d]
Boston, Mass; Aurora, Colo; and Lebanon and Hanover, NH

Agent	Price*	Value-based*
Reslizumab	$28,900	$6,500-10,400
Benralizuamb	$27,800	$8,300-$11,900
Omalizumab	$28,900	$9,000-$13,300
Mepolizumab	$29,500	$9,200-$13,400
Dupilumab	$31,000	$10,100-$14,300

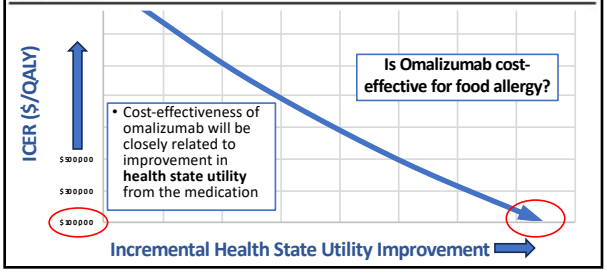
*Annual estimates by the Institute for Clinical & Economic Review 2018. ICERs $100k-$150k/QALY

Even value-based costs are too high!

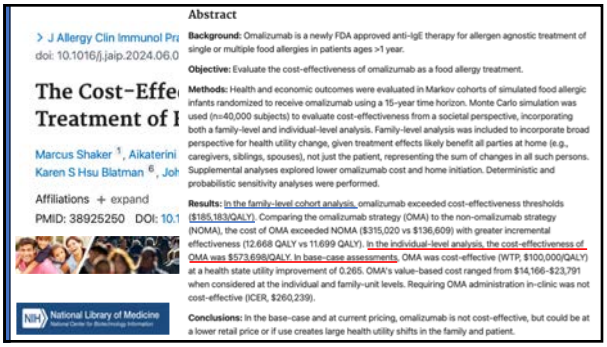
*"Ultimately, critical medications must be **affordable** and available to patients who need them, and if this cannot be achieved, then the tremendous investment to discover specific pathways and develop safe and effective medications represents a failure to achieve our common goal to provide the right care, for the right patient, at the right time, every time."*

JACI In Practice 2021

Cost-Effectiveness of Biologics for Allergic Diseases



Burden of Illness for Patient, Family, Community, Society



> J Allergy Clin Immunol Pr
doi: 10.1016/j.jaip.2024.06.0

The Cost-Effe
Treatment of I

Marcus Shaker [1], Aikaterini
Karen S Hsu Blatman [6], Joh

Affiliations + expand
PMID: 38925250 DOI: 10.1

National Library of Medicine

Abstract

Background: Omalizumab is a newly FDA approved anti-IgE therapy for allergen agnostic treatment of single or multiple food allergies in patients ages >1 year.

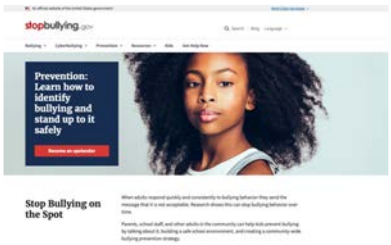
Objective: Evaluate the cost-effectiveness of omalizumab as a food allergy treatment.

Methods: Health and economic outcomes were evaluated in Markov cohorts of simulated food allergic infants randomized to receive omalizumab using a 15-year time horizon. Monte Carlo simulation was used (n=40,000 subjects) to evaluate cost-effectiveness from a societal perspective, incorporating both a family-level and individual-level analysis. Family-level analysis was included to incorporate broad perspective for health utility change, given treatment effects likely benefit all parties at home (e.g., caregivers, siblings, spouses), not just the patient, representing the sum of changes in all such persons. Supplemental analyses explored lower omalizumab cost and home initiation. Deterministic and probabilistic sensitivity analyses were performed.

Results: In the family-level cohort analysis, omalizumab exceeded cost-effectiveness thresholds ($185,183/QALY). Comparing the omalizumab strategy (OMA) to the non-omalizumab strategy (NOMA), the cost of OMA exceeded NOMA ($315,020 vs $136,609) with greater incremental effectiveness (12.668 QALY vs 11.699 QALY). In the individual-level analysis, the cost-effectiveness of OMA was $573,698/QALY. In base-case assessments, OMA was cost-effective (WTP, $100,000/QALY) at a health state utility improvement of 0.265. OMA's value-based cost ranged from $14,166-$23,791 when considered at the individual and family-unit levels. Requiring OMA administration in-clinic was not cost-effective (ICER, $260,239).

Conclusions: In the base-case and at current pricing, omalizumab is not cost-effective, but could be at a lower retail price or if use creates large health utility shifts in the family and patient.

What is the Burden of Illness?



Shemesh E, et al 2013
Annunziato et al 2014
Lieberman, Weiss et al 2010

Patient Selection is critical

Variation will exist in burden of illness for the patient after non-pharmacologic interventions

One last update...

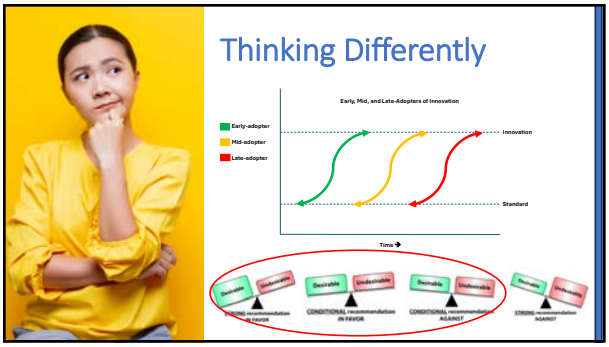
Beyond IgE...

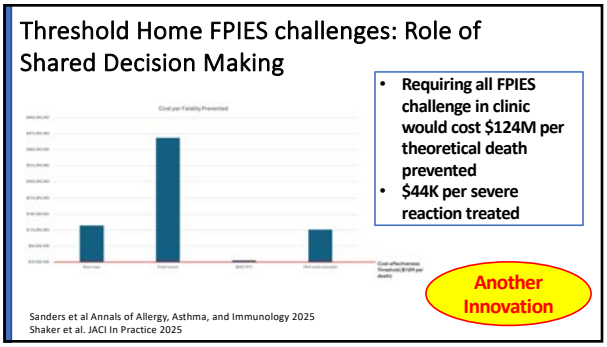
Thinking Fast, Thinking Slow...

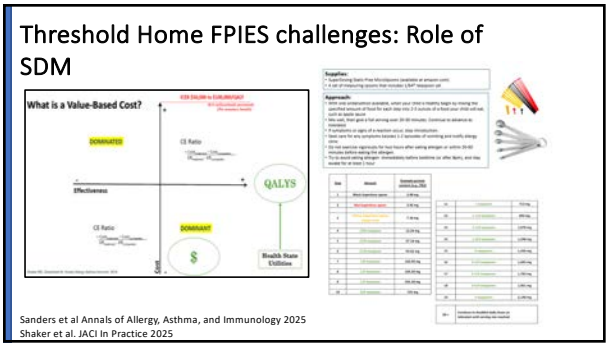
System 1 — Quick, Intuitive, Heuristic

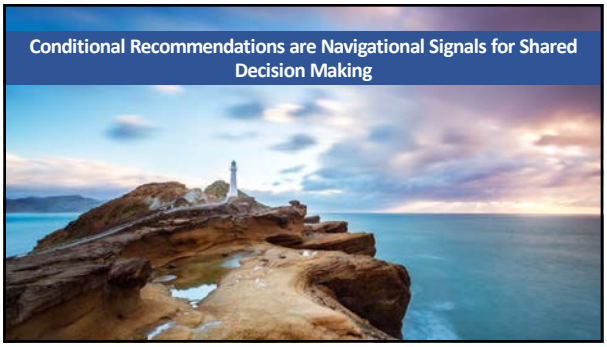
System 2 — Analytical, Deliberate, Reasoned

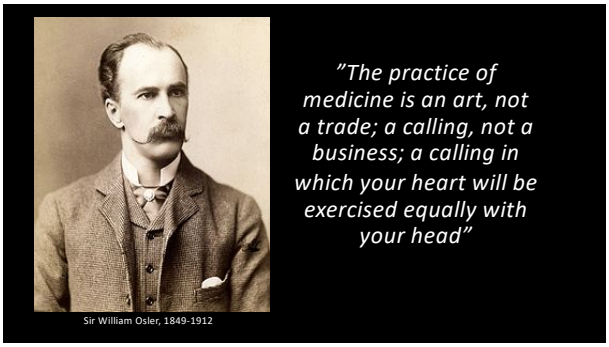
Conway A et al. Pharmacoequity and Biologics in the Allergy Clinic: Providing the Right Care, At the Right Time, Every Time. J Allergy Clin Immunol In Pract. 2024


Thinking Differently
Early, Mid, and Late-Adopters of Innovation
Early-adopter
Mid-adopter
Late-adopter
Innovation
Standard
Time
Desirable
Undesirable
CONDITIONAL recommendation IN FAVOR
CONDITIONAL recommendation AGAINST
STRONG recommendation AGAINST


Threshold Home FPIES challenges: Role of Shared Decision Making
Requiring all FPIES challenge in clinic would cost $124M per theoretical death prevented
$44K per severe reaction treated
Another Innovation
Sanders et al Annals of Allergy, Asthma, and Immunology 2025
Shaker et al. JACI In Practice 2025


Threshold Home FPIES challenges: Role of SDM
What is a Value-Based Cost?
DOMINATED
CE Ratio
Effectiveness
QALYS
DOMINANT
$
Health State Utilities
Sanders et al Annals of Allergy, Asthma, and Immunology 2025
Shaker et al. JACI In Practice 2025


Conditional Recommendations are Navigational Signals for Shared Decision Making


Sir William Osler, 1849-1912
"The practice of medicine is an art, not a trade; a calling, not a business; a calling in which your heart will be exercised equally with your head"


Take Home Points
Food allergy impacts patients, family, community, and larger society
Risk framing can help
The benefits of effective & safe food allergy therapy must be considered from individual & societal perspectives
Active treatment can be safe & effective for many patients – but patient identification is complex
Innovative approaches can improve value

Thank You