Biologics for Food Allergy

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

Learning Objectives

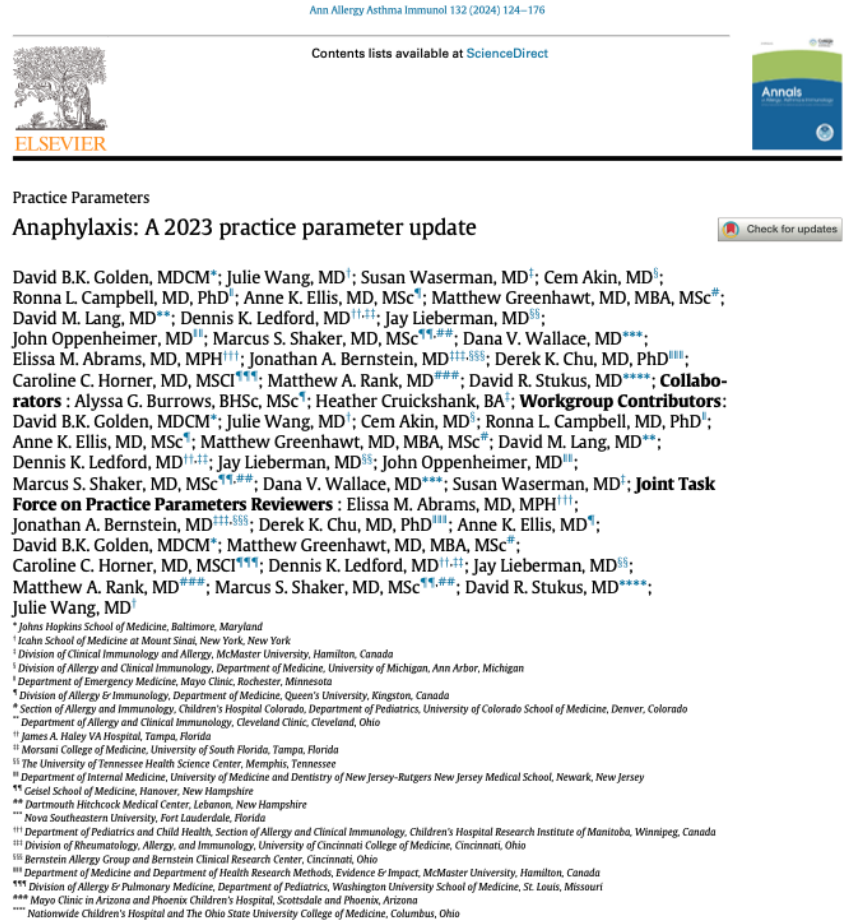
Upon completion of this activity, participants should be able to…

- Discuss how biologics 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

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?

Joint Task Force on Practice Parameters


Ann Allergy Asthma Immunol 132 (2024) 124–176
Contents lists available at ScienceDirect
ELSEVIER
Annals
Practice Parameters

Anaphylaxis: A 2023 practice parameter update

Check for updates

David B.K. Golden, MDCM[*]; Julie Wang, MD[†]; Susan Waserman, MD[‡]; Cem Akin, MD[§]; Ronna L. Campbell, MD, PhD[‖]; Anne K. Ellis, MD, MSc[¶]; Matthew Greenhawt, MD, MBA, MSc[#]; David M. Lang, MD[**]; Dennis K. Ledford, MD[††,‡‡]; Jay Lieberman, MD[§§]; John Oppenheimer, MD[‖‖]; Marcus S. Shaker, MD, MSc[¶¶,###]; Dana V. Wallace, MD[***]; Elissa M. Abrams, MD, MPH[†††]; Jonathan A. Bernstein, MD[‡‡‡,§§§]; Derek K. Chu, MD, PhD[‖‖‖]; Caroline C. Horner, MD, MSCI[¶¶¶]; Matthew A. Rank, MD[###]; David R. Stukus, MD[****]; **Collaborators** : Alyssa G. Burrows, BHSc, MSc[¶]; Heather Cruickshank, BA[‖]; **Workgroup Contributors**: David B.K. Golden, MDCM[*]; Julie Wang, MD[†]; Cem Akin, MD[§]; Ronna L. Campbell, MD, PhD[‖]; Anne K. Ellis, MD, MSc[¶]; Matthew Greenhawt, MD, MBA, MSc[#]; David M. Lang, MD[**]; Dennis K. Ledford, MD[††,‡‡]; Jay Lieberman, MD[§§]; John Oppenheimer, MD[‖‖]; Marcus S. Shaker, MD, MSc[¶¶,###]; Dana V. Wallace, MD[***]; Susan Waserman, MD[‡]; **Joint Task Force on Practice Parameters Reviewers** : Elissa M. Abrams, MD, MPH[†††]; Jonathan A. Bernstein, MD[‡‡‡,§§§]; Derek K. Chu, MD, PhD[‖‖‖]; Anne K. Ellis, MD[¶]; David B.K. Golden, MDCM[*]; Matthew Greenhawt, MD, MBA, MSc[#]; Caroline C. Horner, MD, MSCI[¶¶¶]; Dennis K. Ledford, MD[††,‡‡]; Jay Lieberman, MD[§§]; Matthew A. Rank, MD[###]; Marcus S. Shaker, MD, MSc[¶¶,###]; David R. Stukus, MD[****]; Julie Wang, MD[†]

[*] *Johns Hopkins School of Medicine, Baltimore, Maryland*
[†] *Icahn School of Medicine at Mount Sinai, New York, New York*
[‡] *Division of Clinical Immunology and Allergy, McMaster University, Hamilton, Canada*
[§] *Division of Allergy and Clinical Immunology, Department of Medicine, University of Michigan, Ann Arbor, Michigan*
[‖] *Department of Emergency Medicine, Mayo Clinic, Rochester, Minnesota*
[¶] *Division of Allergy & Immunology, Department of Medicine, Queen's University, Kingston, Canada*
[#] *Section of Allergy and Immunology, Children's Hospital Colorado, Department of Pediatrics, University of Colorado School of Medicine, Denver, Colorado*
[**] *Department of Allergy and Clinical Immunology, Cleveland Clinic, Cleveland, Ohio*
[††] *James A. Haley VA Hospital, Tampa, Florida*
[‡‡] *Morsani College of Medicine, University of South Florida, Tampa, Florida*
[§§] *The University of Tennessee Health Science Center, Memphis, Tennessee*
[‖‖] *Department of Internal Medicine, University of Medicine and Dentistry of New Jersey-Rutgers New Jersey Medical School, Newark, New Jersey*
[¶¶] *Geisel School of Medicine, Hanover, New Hampshire*
[##] *Dartmouth Hitchcock Medical Center, Lebanon, New Hampshire*
[***] *Nova Southeastern University, Fort Lauderdale, Florida*
[†††] *Department of Pediatrics and Child Health, Section of Allergy and Clinical Immunology, Children's Hospital Research Institute of Manitoba, Winnipeg, Canada*
[‡‡‡] *Division of Rheumatology, Allergy, and Immunology, University of Cincinnati College of Medicine, Cincinnati, Ohio*
[§§§] *Bernstein Allergy Group and Bernstein Clinical Research Center, Cincinnati, Ohio*
[‖‖‖] *Department of Medicine and Department of Health Research Methods, Evidence & Impact, McMaster University, Hamilton, Canada*
[¶¶¶] *Division of Allergy & Pulmonary Medicine, Department of Pediatrics, Washington University School of Medicine, St. Louis, Missouri*
[###] *Mayo Clinic in Arizona and Phoenix Children's Hospital, Scottsdale and Phoenix, Arizona*
[****] *Nationwide Children's Hospital and The Ohio State University College of Medicine, Columbus, Ohio*

https://www.allergyparameters.org

Anaphylaxis Triggers and Risks

Leading anaphylaxis triggers

- Adults: Medications
  - Antibiotics, NSAIDS, Immunomodulators, Biologics, Anesthetics
- Children/Adolescents: Foods
- All ages: Stinging Insects
- Idiopathic

Risk factors for severe anaphylaxis include

- Cardiovascular disease
- Asthma
- Older age
- Co-morbid conditions
  - Mast cell disorder, beta-blocker use, ACEi use

Shaker M, Wallace D, Golden DBK, et al. JACI 2020. PMID 32001253

Patient, Family, Community, Society

Overall economic cost of food allergy
$24.8 billion USD in children alone

Original Investigation

The Economic Impact of Childhood Food Allergy in the United States

2013

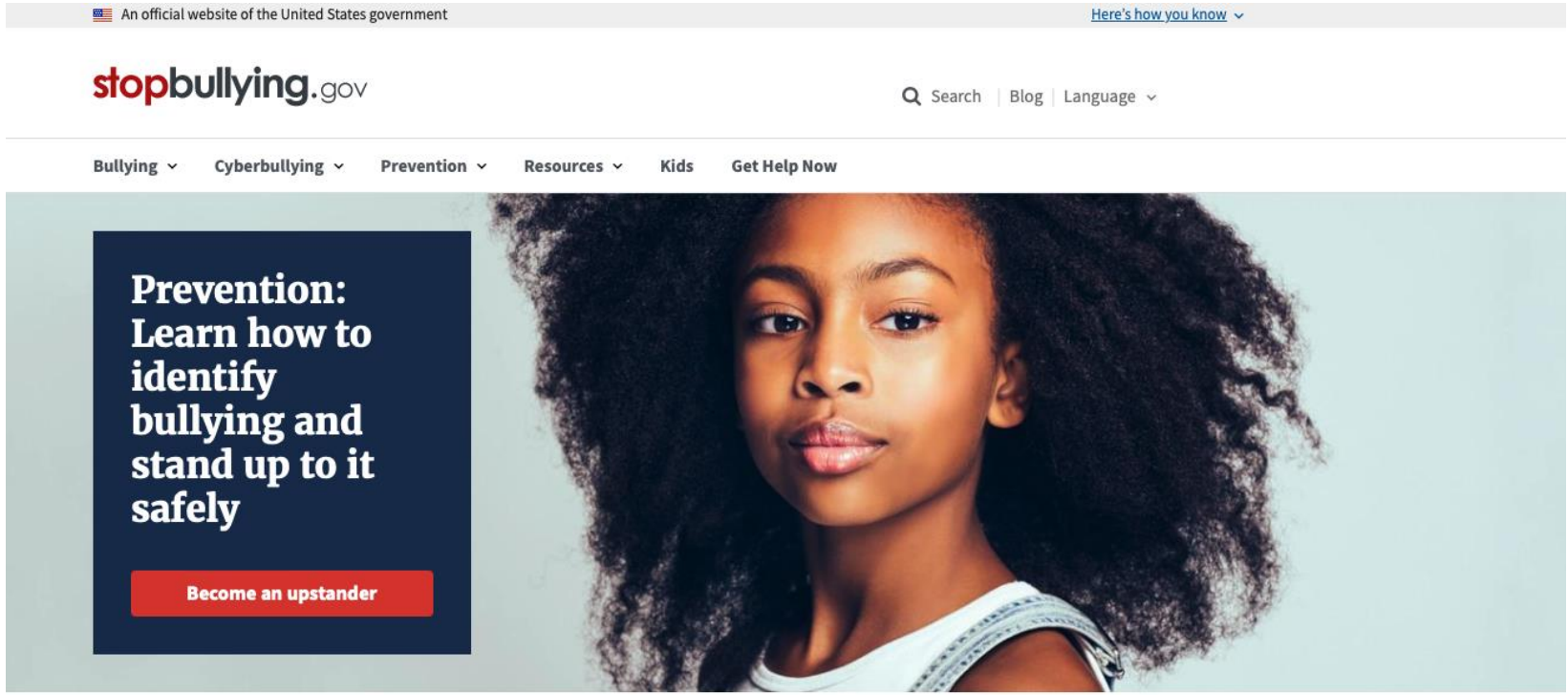
Ruchi Gupta, MD, MPH; David Holdford, RPh, PhD; Lucy Bilaver, PhD; Ashley Dyer, MPH; Jane L. Holl, MD, MPH; David Meltzer, MD, PhD

Bullying

EDUCATION

COMMUNICATION

ENGAGEMENT



Stop Bullying on the Spot

When adults respond quickly and consistently to bullying behavior they send the message that it is not acceptable. Research shows this can stop bullying behavior over time.

Parents, school staff, and other adults in the community can help kids prevent bullying by talking about it, building a safe school environment, and creating a community-wide bullying prevention strategy.

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-

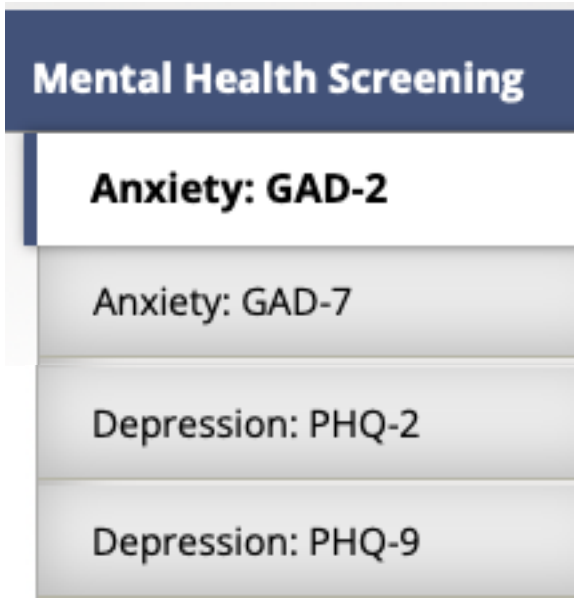
DEFASE Score
- Mild: ≤6 points
- Moderate: 7-12 points
- Severe: ≥ 13 points

Holistic view

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

Food Allergy and Anxiety

- Impacts both parents and children
- In one study, 99% of parents felt their child had a moderate to high risk of food allergy fatality



Generalized Anxiety Disorder 2-item (GAD-2)

Share

The Generalized Anxiety Disorder 2-item (GAD-2) is a very brief and easy to perform initial screening tool for generalized anxiety disorder.[1]

Over the **last 2 weeks**, how often have you been bothered by the following problems?	Not at all	Several days	More than half the days	Nearly every day
1. Feeling nervous, anxious or on edge	0	+1	+2	+3
2. Not being able to stop or control worrying	0	+1	+2	+3

GAD-2 score obtained by adding score for each question (total points)

Interpretation:

A score of 3 points is the preferred cut-off for identifying possible cases and in which further diagnostic evaluation for generalized anxiety disorder is warranted. Using a cut-off of 3 the GAD-2 has a sensitivity of 86% and specificity of 83% for diagnosis generalized anxiety disorder.

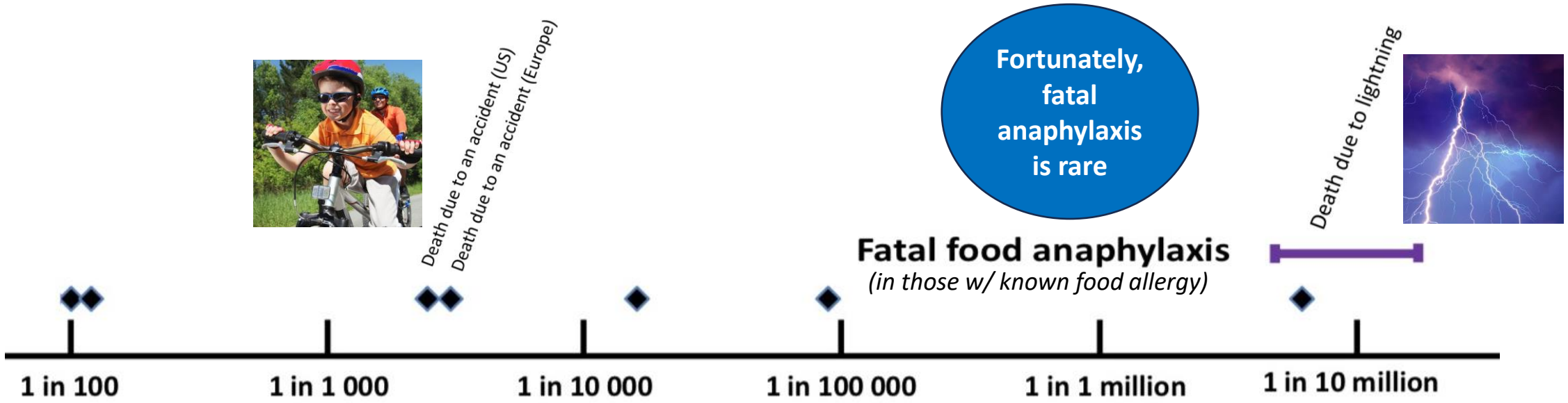
Westwell-Roper et al. Pediatr Allergy Immunol 2022; Ogg et al. Asthma & Allergy Proc. 2017; Shaker et al. Curr Opin Pediatric. 2017

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

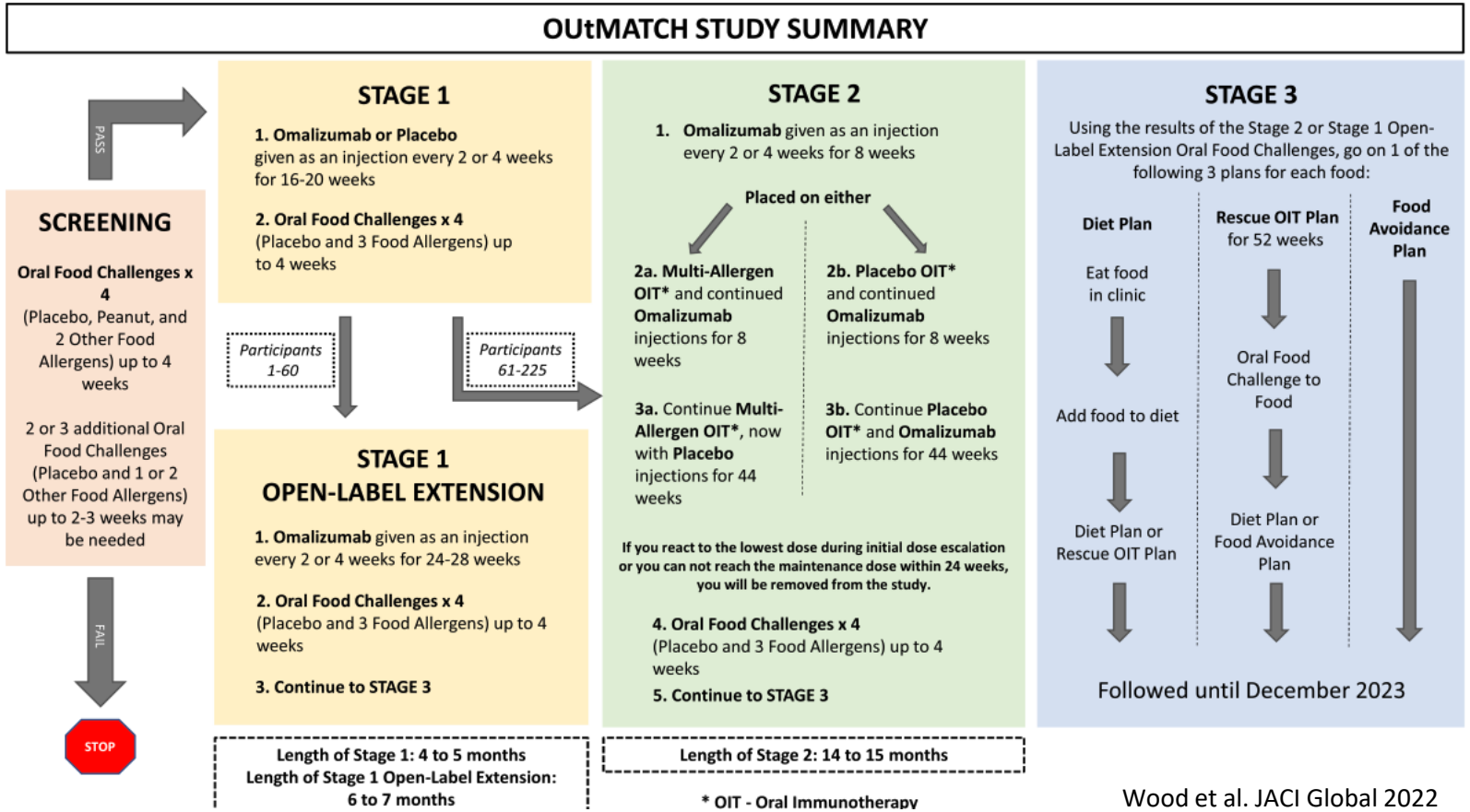
Management Options

Shared Decision-Making

- Avoidance
- Food oral immunotherapy
- Sublingual immunotherapy
- Omalizumab
- EPIT?
- OMIT?

Protocol design and synopsis: Omalizumab as Monotherapy and as Adjunct Therapy to Multiallergen OIT in Children and Adults with Food Allergy (OUtMATCH)

Check for updates



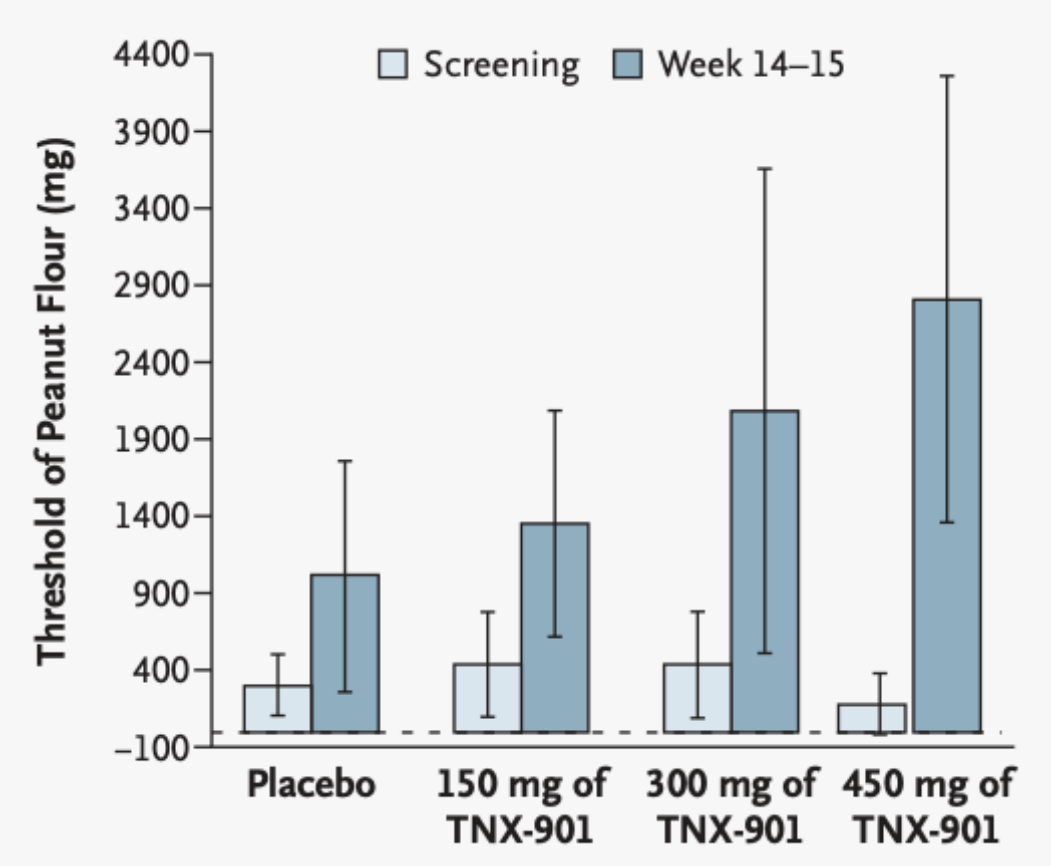
Wood et al. JACI Global 2022

Even earlier in 2003…

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Effect of Anti-IgE Therapy in Patients with Peanut Allergy



- TNX-901 was a humanized IgG1 monoclonal antibody against IgE
- In a double blind trial, challenge threshold increased significantly after treatment in the 450mg group
  - Threshold increased from 178 mg to 2805 mg in this group

Leung, Sampson, et al

Even earlier in 2003..

THE WALL STREET JOURNAL.

How [redacted], [redacted] Stifled A Promising Drug

Biotech Firm Tried to Pursue

By David P. HamiltonStaff Reporter of THE WALL STREET JOURNAL

April 5, 2005 at 12:01 am ET

Instead, the drug sits on the shelf, abandoned after Tanox's own corporate partners forced it to end development. The U.S. biotech giant [redacted] Inc. and Swiss drug maker [redacted] AG insisted that Tanox kill TNX-901 in favor of a [redacted] drug called [redacted] that has yet to prove effective against peanut allergy.

Leung, Sampson, et al

2011: Breadcrumbs of benefit

A phase II, randomized, double-blind, parallel-group, placebo-controlled oral food challenge trial of [redacted] (omalizumab) in peanut allergy

To the Editor:

The study was designed to compare changes in peanut tolerability thresholds in subjects with proven peanut allergy who were treated with either omalizumab or placebo. Although the study intended to randomize 150 subjects, it was stopped early on the basis of the recommendation of the Data Safety Monitoring Committee because of the severity of 2 anaphylactic reactions that occurred during the qualifying oral food challenges (OFCs) before the administration of the study drug

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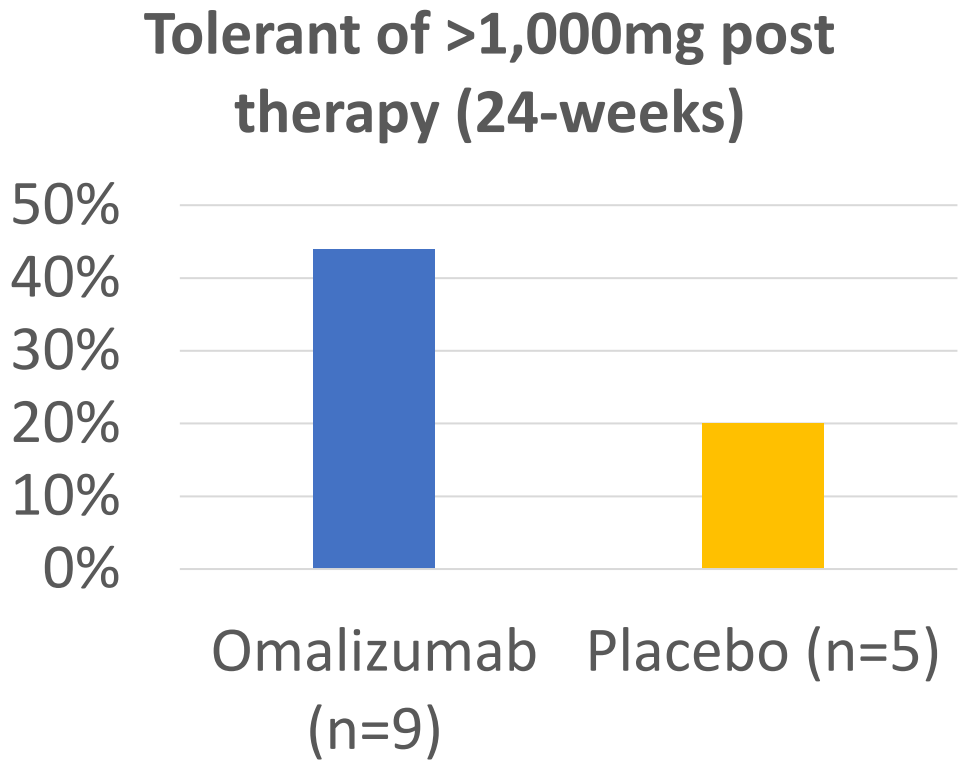


Despite early termination, 44.4% vs 20% of patients tolerated 1 g peanut flour
Omalizumab dose: 0.016 mg/kg/IgE/month (doses > 300mg/month divided q 1 weeks)

JACI 2011

2016

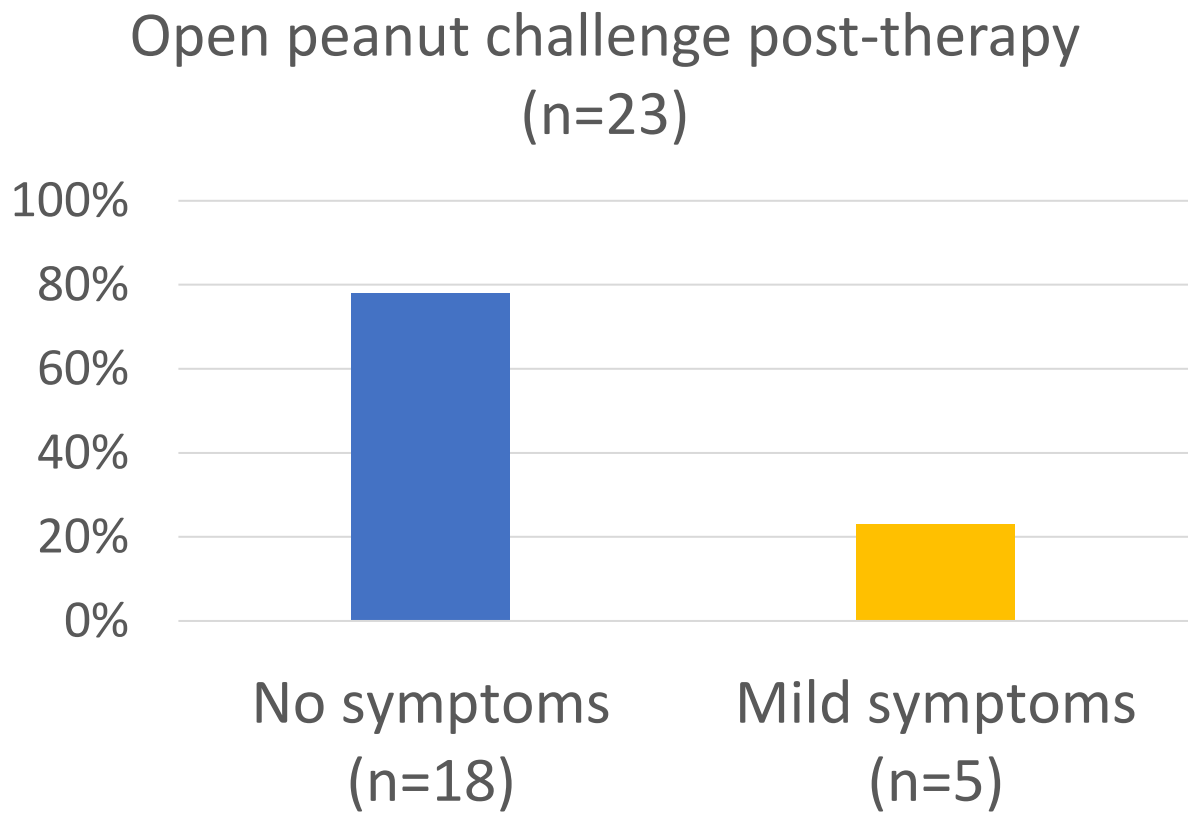
doi: 10.1111/cea.12862

ORIGINAL ARTICLE Clinical Allergy

Clinical & Experimental Allergy, **47**, 540–550

Individually dosed omalizumab: an effective treatment for severe peanut allergy

- 23 patients with severe peanut allergy
- Omalizumab for 8-24 weeks
- Basophil allergen threshold improved
- Open peanut challenges performed with no or minimal symptoms (78% vs 23%)

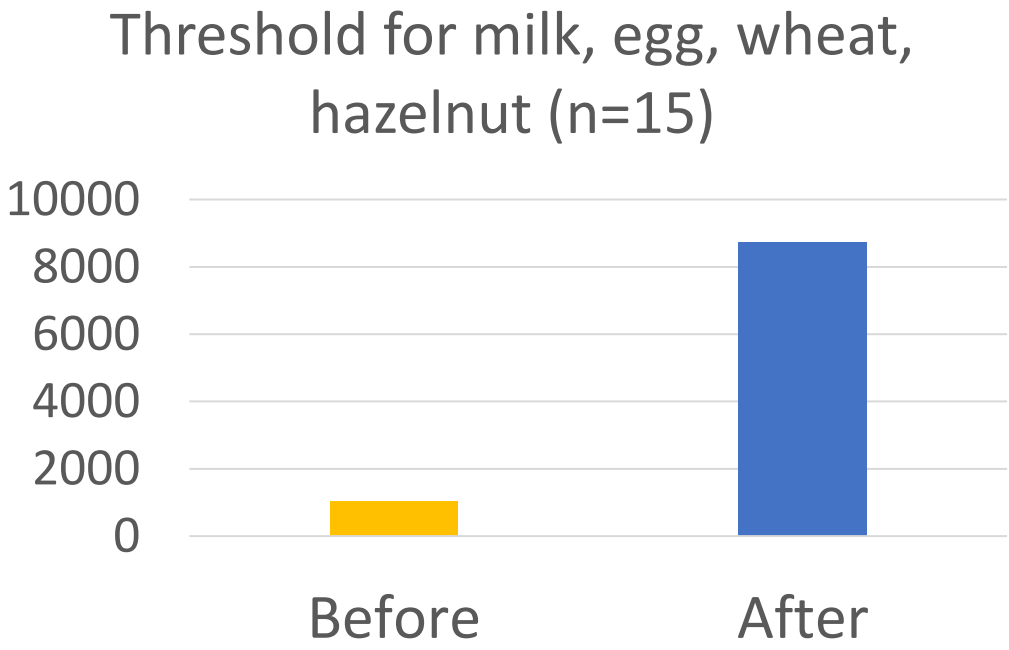


Brandstrom et al. 2016

2019

Impact of Omalizumab on Food Allergy in Patients Treated for Asthma: A Real-Life Study

- Observational study of 15 children allergic to 37 foods
- Omalizumab used for their severe asthma
- Still, 70.4% tolerated complete challenge dose after 4 months
- Number of reactions to accidental ingestions dropped from 47 to 2.
- Quality of life improved



Threshold increased from
1013 mg +/- 1465
To
8727 mg +/- 6463
($p<0.01$)

Fiocchi et al. JACI In Practice 2019

Omalizumab facilitated OIT

- Begin et al 2014 (PMID 24576338): Short term
  - Rush omalizumab for 8 weeks before & after multi-food OIT start in 25 children **allowed rapid OIT escalation**
- Wood et al 2015 (PMID 26581915): DBPC trial to open label, 2-3 years
  - 57 patients, omalizumab **decreased OIT reactions and doses to maintenance but did not impact desensitization rates or SU**
- MacGinnitie et al 2017 (PMID 27609658): Short-term study, 12 weeks
  - 37 patients randomized. Omalizumab **increased day 1 desensitization (250 mg vs 22.5mg). Benefit of omalizumab persisted 12 weeks after it was stopped**
- Andorf et al 2018 (PMID 29242014). Short term, 9 months
  - Randomized 48 (active) + 12 (placebo). 4 months of omalizumab + 7 months of OIT **improved challenge outcomes over OIT alone** (83% vs 33%, $p<0.01$)
- Yee et al 2019 (PMID 30267889): Long-term study , 6 years
  - 13 patients, POIT with an initial 12 weeks of omalizumab. **More rapid OIT but 46% discontinued within 6 years due to side effects.**

2023

Omalizumab in IgE-Mediated Food Allergy: A Systematic Review and Meta-Analysis

What is already known about this topic? Immediate-type food allergy is mediated by immunoglobulin E (IgE). Omalizumab, an anti-IgE, has potential in the treatment of this condition; however, there is a lack of clarity in the available evidence supporting its potential clinical application.

What does this article add to our knowledge? To our knowledge, this is the first meta-analysis summarizing the available data for omalizumab as monotherapy or as an adjunct to oral immunotherapy in patients with IgE-mediated food allergy. No new safety signals were identified.

How does this study impact current management guidelines? Omalizumab was beneficial as a monotherapy and as an adjunct to oral immunotherapy in patients with IgE-mediated food allergy. It represents a potential treatment modality that will be further evaluated in the phase III OUtMATCH study.

Study durations

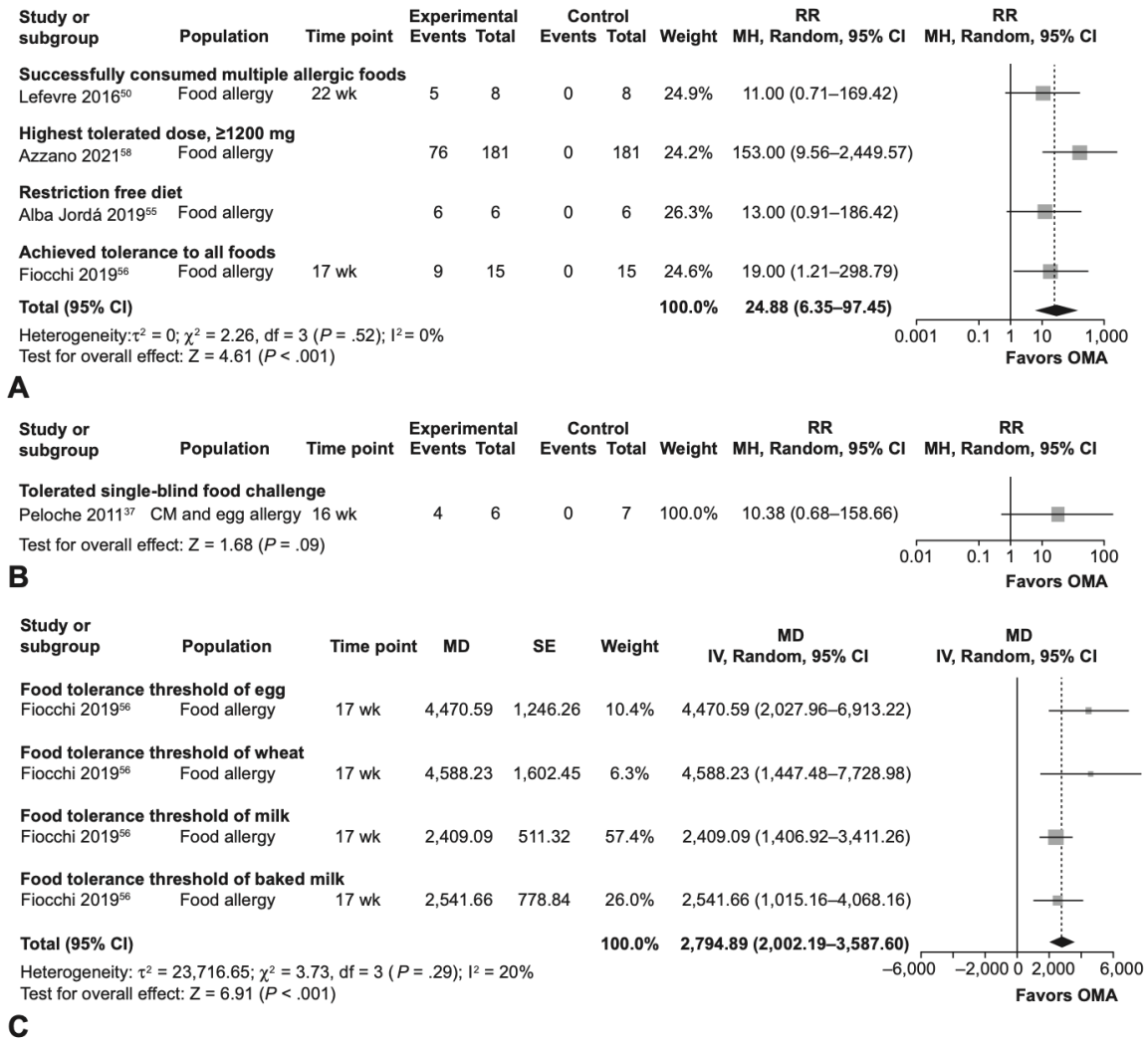
Treatment: 8 weeks – 122 weeks

Follow-up: 8 weeks - 317 weeks

Zuberbier, Wood, et al. JACI In Practice 2023

Omalizumab in IgE-Mediated Food Allergy: A Systematic Review and Meta-Analysis

- 36 studies included
- Omalizumab monotherapy increased tolerated dose of multiple foods
  - Improved QoL
  - Reduced food allergic reactions
- Omalizumab + OIT increased tolerated dose
  - Increased desensitization
  - Improved QoL
- No major safety concerns identified



Zuberbier, Wood, et al. JACI In Practice 2023

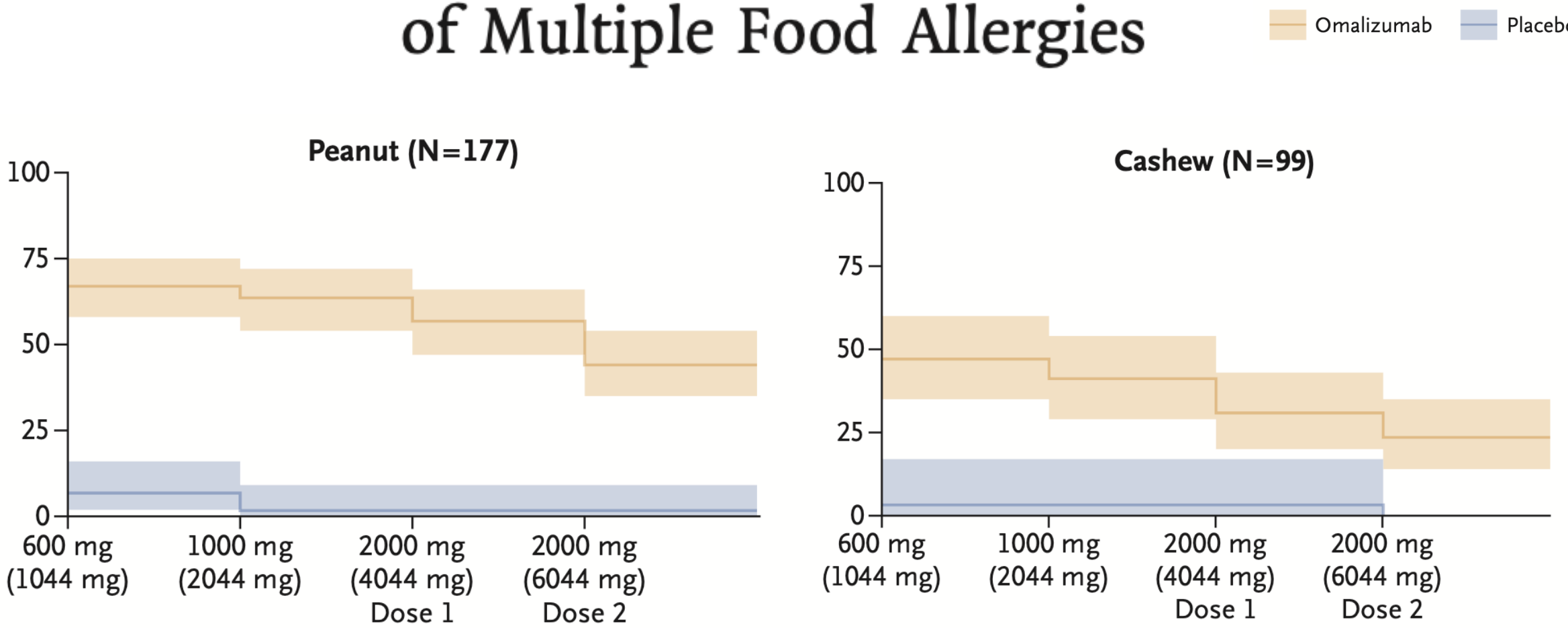
2024

The NEW ENGLAND JOURNAL of MEDICINE

Wood RA, Togias A, et al. NEJM 2024

ORIGINAL ARTICLE

Omalizumab for the Treatment of Multiple Food Allergies



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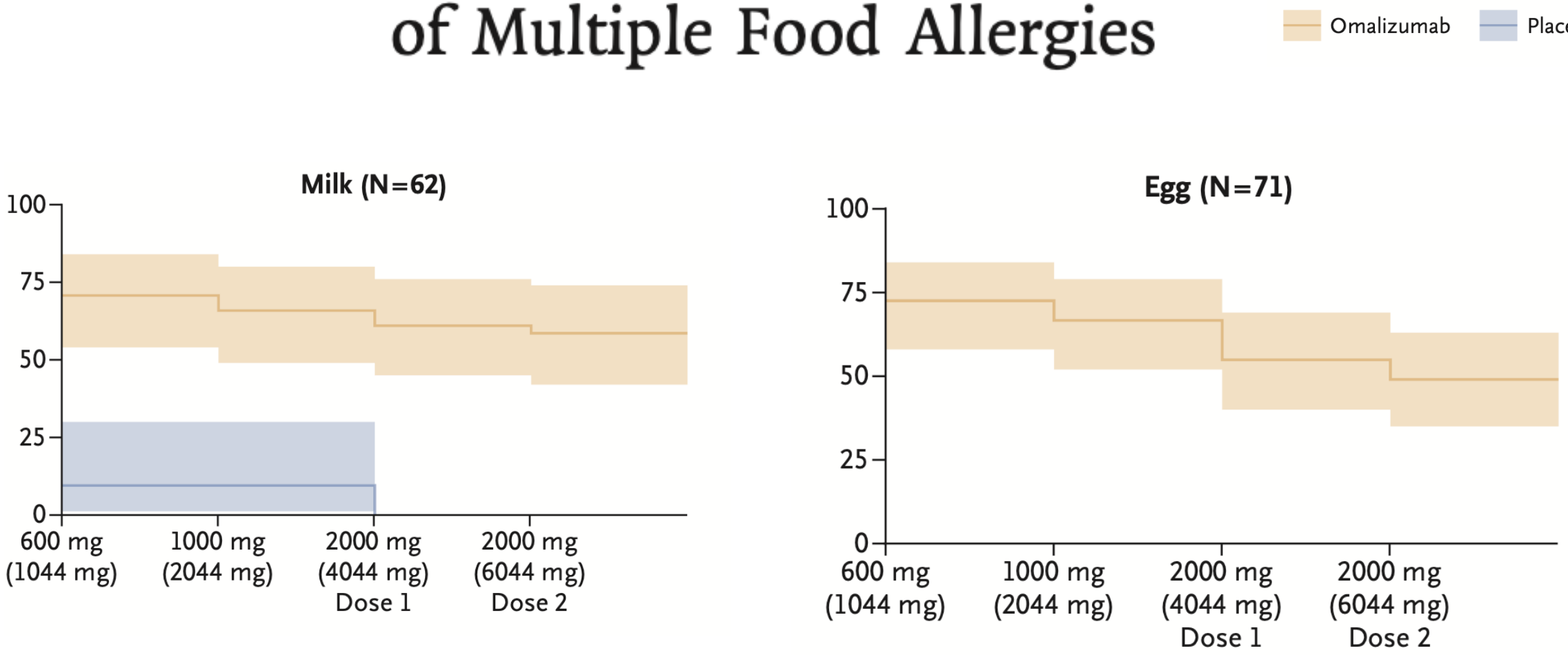


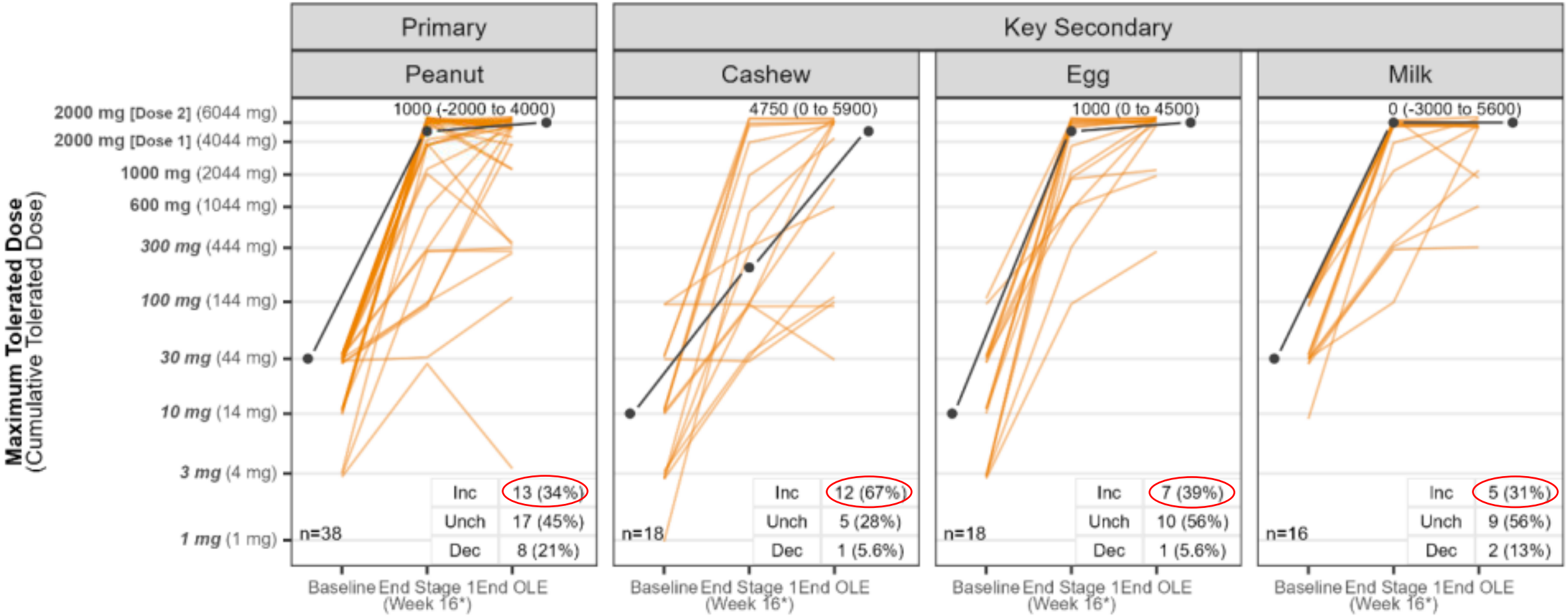
2024

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 ≤100 mg**
- **Dose limiting sx to other foods (x2) at ≤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/x[redacted]_prescribing.pdf

Omalizumab: Approved for FA in February

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 2 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	Insufficient data to Recommend a Dose				
>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							

***Dosing frequency:**

- Subcutaneous doses to be administered every 4 weeks
- Subcutaneous doses to be administered every 2 weeks

"To be used in conjunction with food avoidance"

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

Certainty in Patient Selection

SDM

- How should the patient values and preferences be incorporated into selection for an expensive biologic?
- How do payor requirements impact this conversation?

A phase II, randomized, double-blind, parallel-group, placebo-controlled oral food challenge trial of [redacted] (omalizumab) in peanut allergy

To the Editor:

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Stacie M. Jones, MD[f]
Dennis A. Wong, MD[g]

JACI 2011

WILEY Allergy

A perspective on the pediatric death from oral food challenge reported from the Allergy Vigilance Network

Allergy. 2019;74:1035–1036.

Upton J, Alvaro M, Nadeau K

Certainty in Patient Outcome

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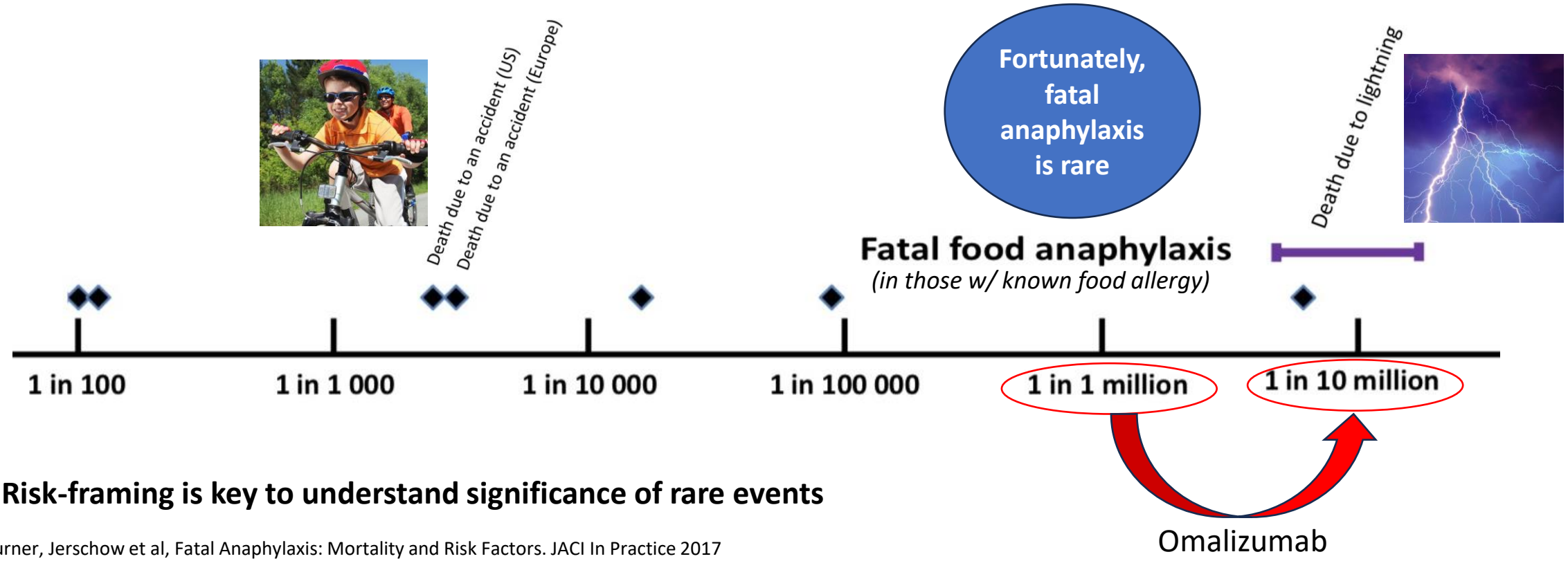
- Need to identify responders?
- Role of SDM?
- Patient goals and preferences are key
- Some patients may choose 'off-label' threshold challenges
- Others may choose to follow labeled indication
- Durability of response assumed?

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

Clinical Commentary Review

Fatal Anaphylaxis: Mortality Rate and Risk Factors

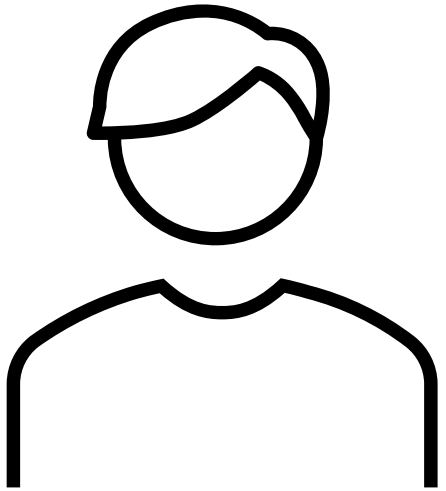
Paul J. Turner, MD, PhD[a,b], Elina Jerschow, MD[c], Thisanayagam Umasunthar, MD[a], Robert Lin, MD[d], Dianne E. Campbell, MD, PhD[b,e], and Robert J. Boyle, MB, ChB, PhD[a] *London, United Kingdom; Bronx, New York, NY; and Sydney, Australia*



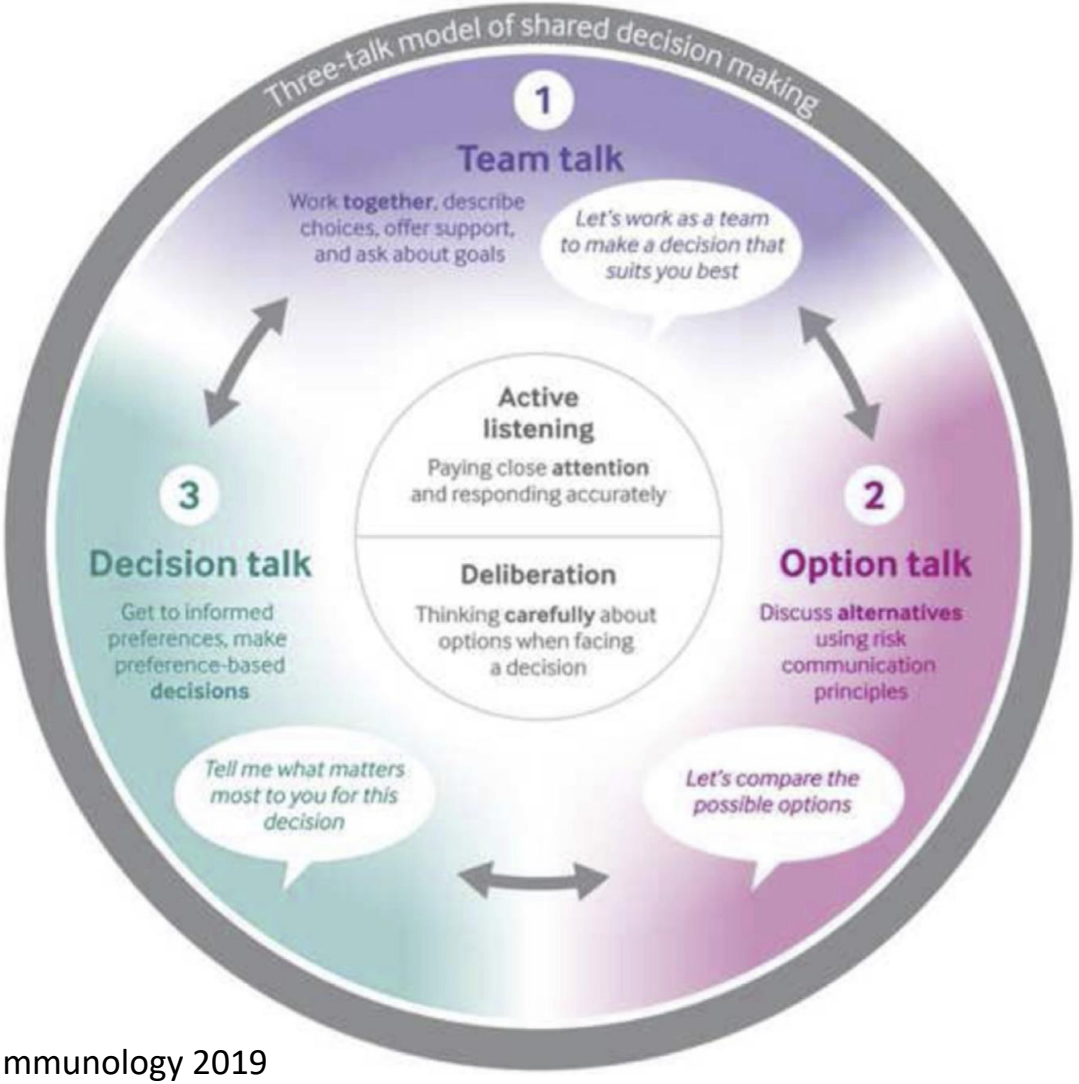
Risk-framing is key to understand significance of rare events

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

Shared Decision Making and Risk



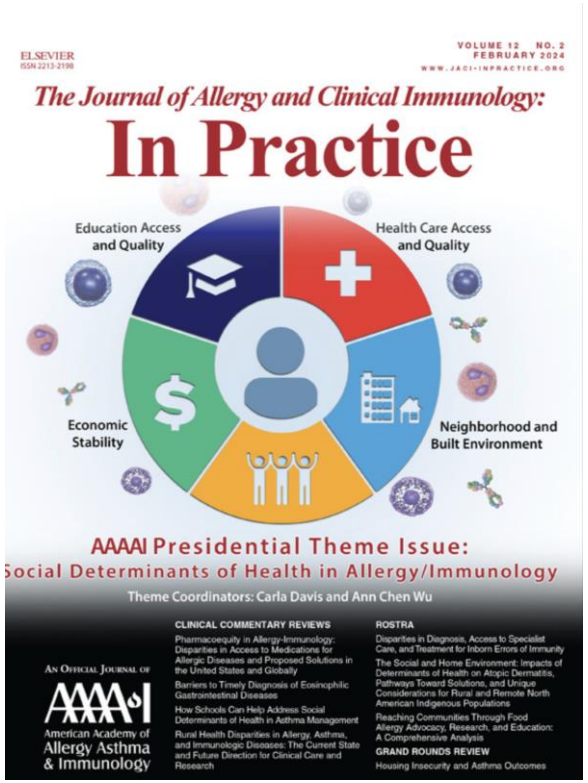
Patient Expertise in their Values and Preferences



Clinician Expertise and Experience in Clinical Science

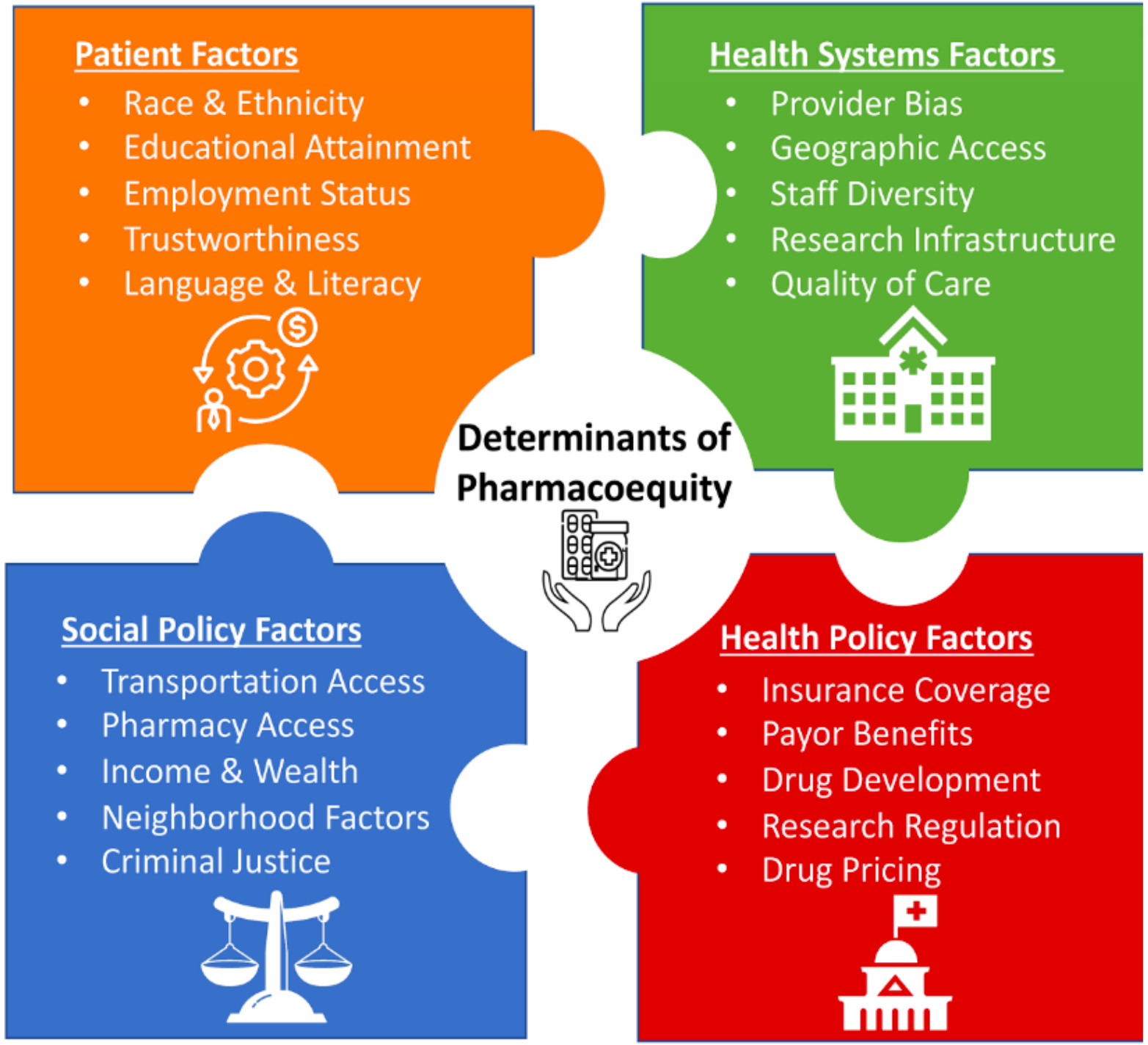
Blaiss et al. Annals of Allergy, Asthma, and Immunology 2019

Social Determinants of Health



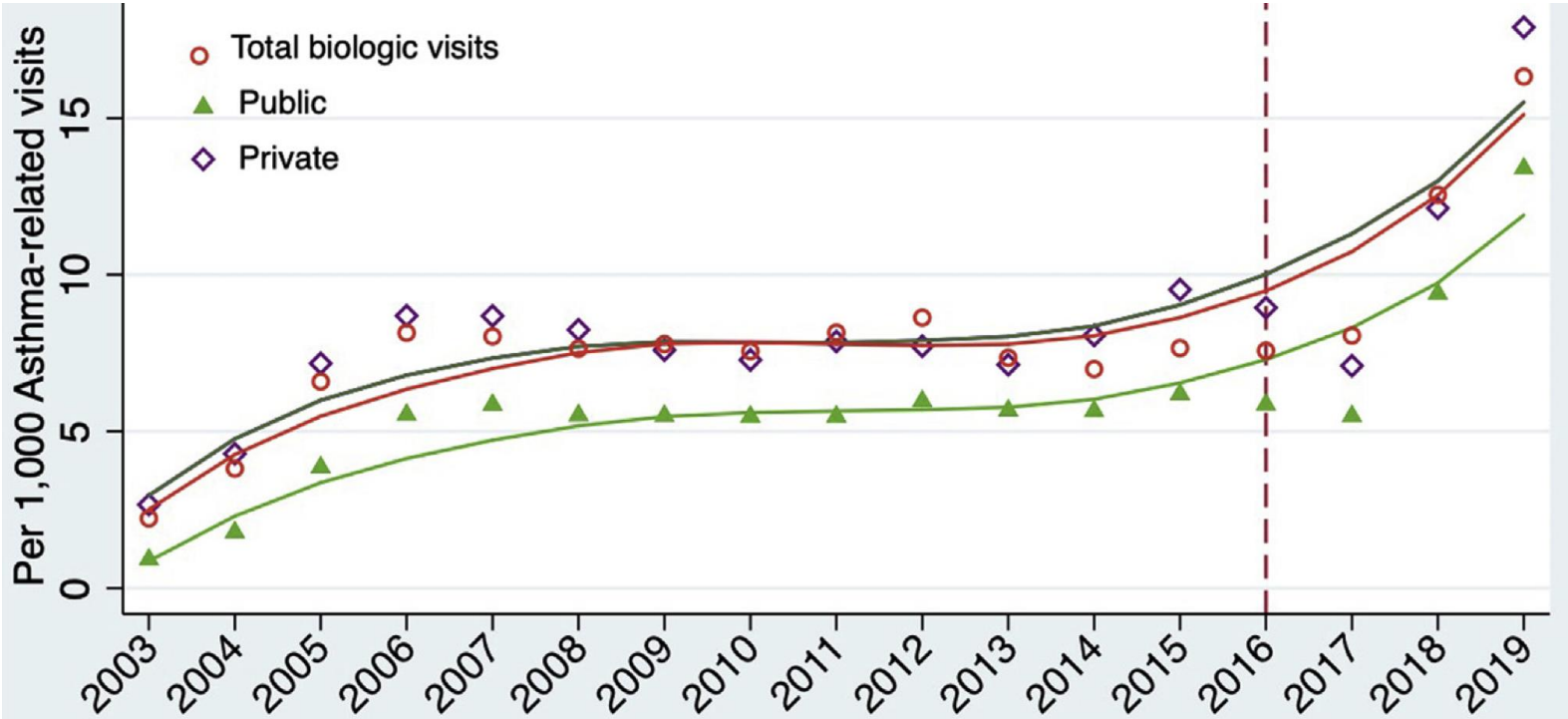
www.healthy.gov

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

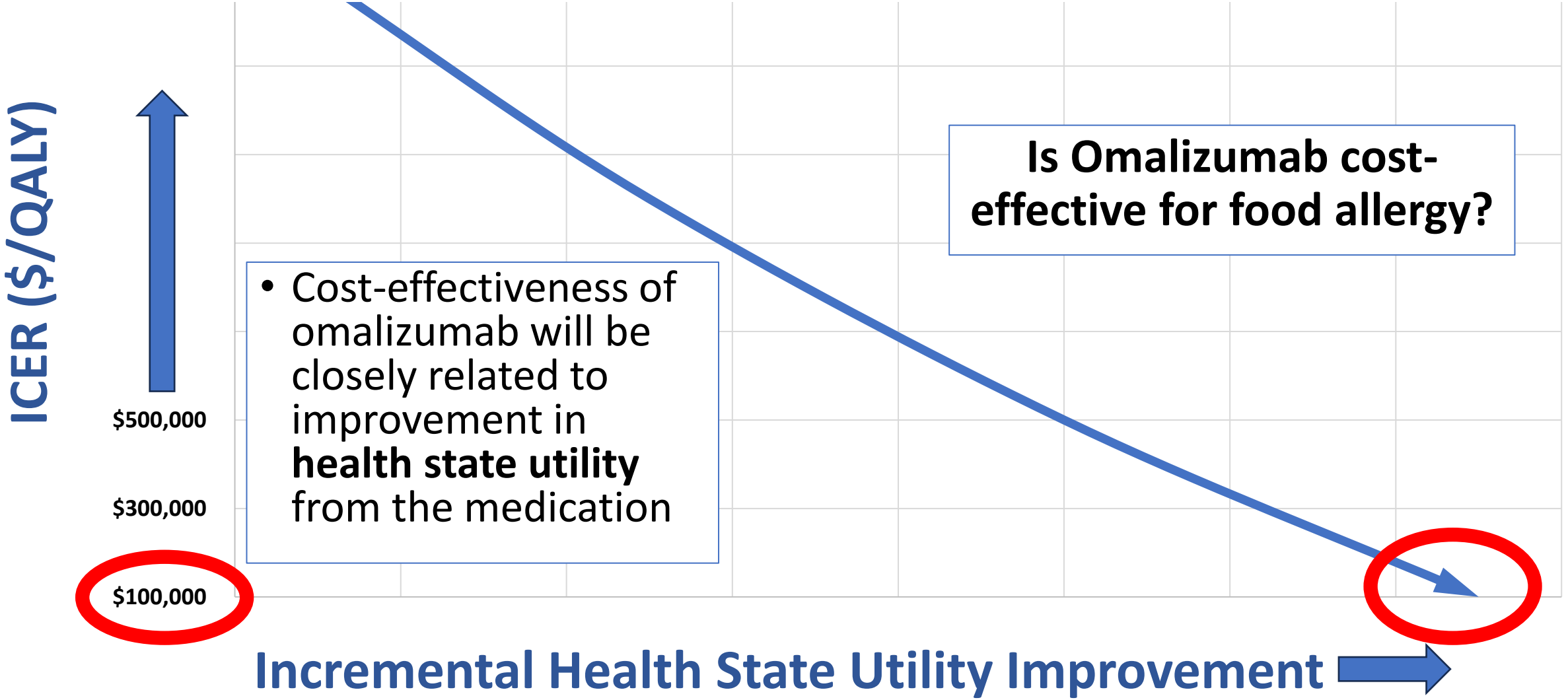
*Annual estimates by the Institute for Clinical & Economic Review 2018. ICERs $100k-$150k/QALY

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."*

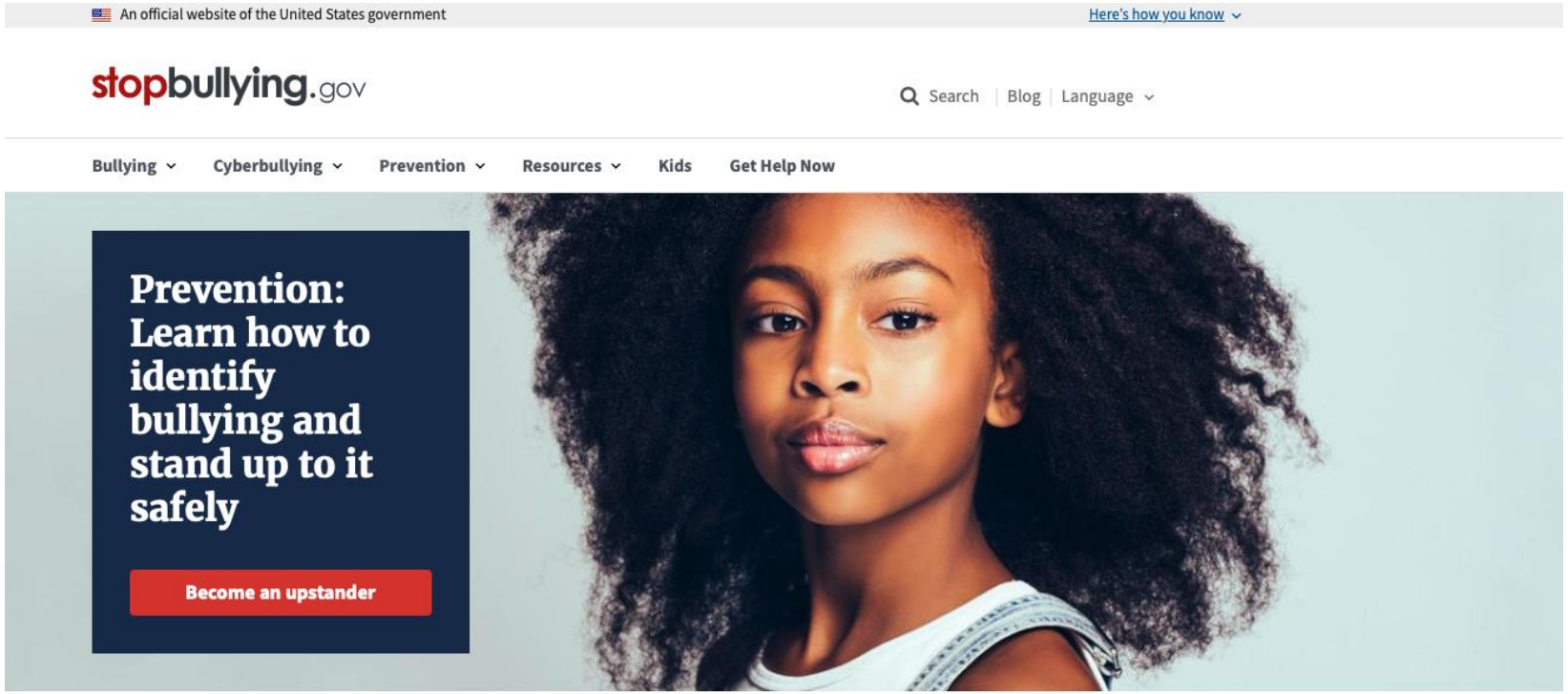
JACI In Practice 2021

Cost-Effectiveness of Biologics for Allergic Diseases



What is the Burden of Illness?

Patient Selection is critical



Stop Bullying on the Spot

When adults respond quickly and consistently to bullying behavior they send the message that it is not acceptable. Research shows this can stop bullying behavior over time.

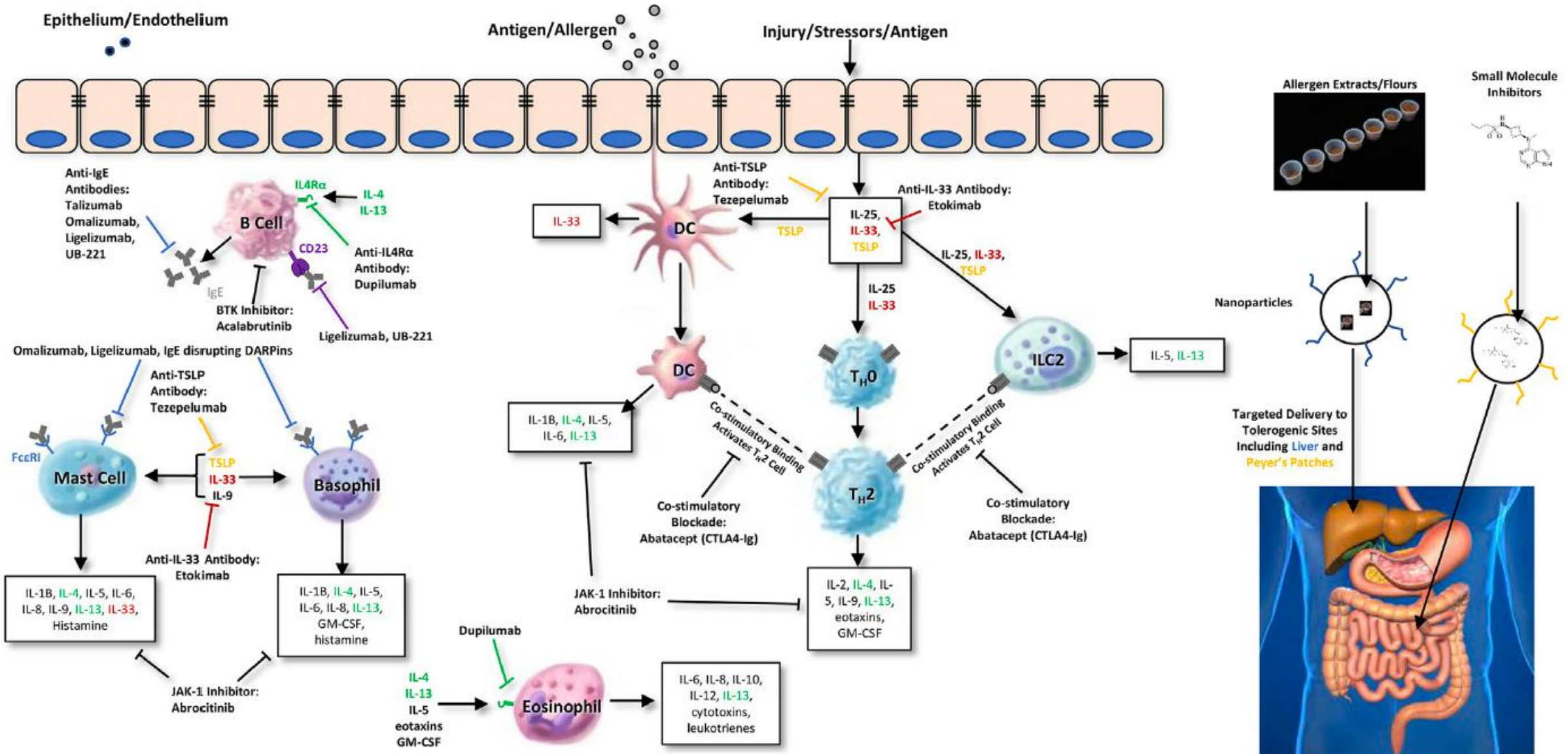
Parents, school staff, and other adults in the community can help kids prevent bullying by talking about it, building a safe school environment, and creating a community-wide bullying prevention strategy.

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

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

Burden of Illness for Patient, Family, Community, Society

What will the future hold?



Sindher et al. Annals of Allergy, Asthma, and Immunology. 2023

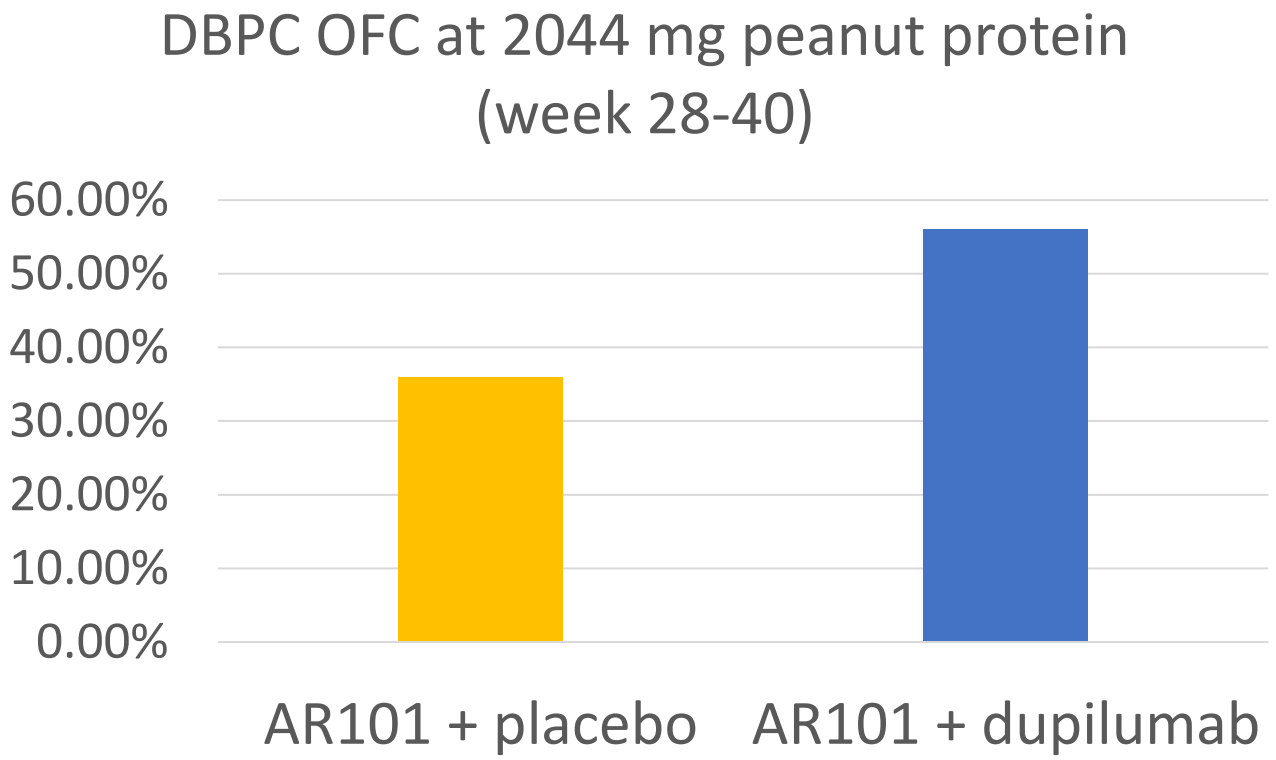
National Library of Medicine
National Center for Biotechnology Information

ClinicalTrials.gov ID NCT03682770

ClinicalTrials.gov

Study in Pediatric Subjects With Peanut Allergy to Evaluate Efficacy and Safety of Dupilumab as Adjunct to AR101 (Peanut Oral Immunotherapy)

- Phase 2 randomized DBPC study to assess indefinite use of dupilumab with OIT (children 6-17 years of age)
- Slight benefit from dupilumab in challenge outcome



35.90% (95% CI, 21.2% - 52.8%)
vs.
55.95% (95% CI, 44.7%-66.8%)

Take Home Points

Food allergy impacts patients, family, community and larger society

The benefits of effective and safe food allergy therapy must be considered from a societal perspective

Omalizumab may be safe and effective for some patients – but patient identification is complex

Thank You