Pharmacoequity & Cost-Effective Care in the Allergy Immunology Clinic

Understanding the challenges we face to providing the right care, at the right time, every time, to everyone

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Geisel School of Medicine at Dartmouth

Disclosures

- I serve on the Allergy Immunology Joint Task Force on Practice Parameters and the AAAAI Board of Directors, am an Associate Editor for Annals of Allergy, Asthma, and Immunology, and an Editorial Board Member for the Journal of Allergy and Clinical Immunology In Practice and the Journal of Food Allergy. Views expressed are my own

Learning Objectives

- **Discuss pharmacoequity as an essential component to ensure treatment options and modalities are available to all patients regardless of race, ethnicity, and class.**
- **Describe a role of cost-effective care in addressing racial and socioeconomic disparities and beyond.**
- **Consider innovation in clinical practice**

"What is the right care for Jeremy?"

- You are counseling the family of a 16 year old adolescent with severe persistent asthma
- The medical history is notable for
  - Three asthma admissions, 2 ICU stays, 1 intubation
  - Multiple environmental and food allergies
  - Ongoing issues of adherence
  - Uses OTC epinephrine inhaler for symptoms due to cost and access issues
- His insurer has refused to allow reimbursement for an asthma biologic until his insurance claims demonstrate regular use of an inhaled corticosteroid

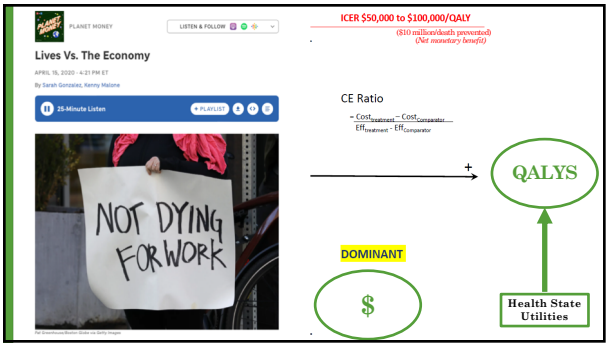
What is Pharmacoequity?

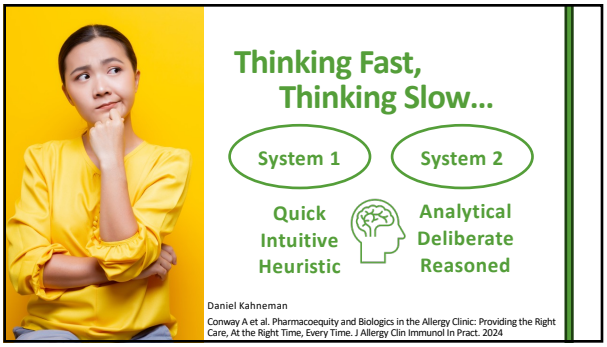
- **The US pays more for medical care than anywhere else in the world**
- **The costs are not equitably distributed**
- **Unequal access = unequal care**

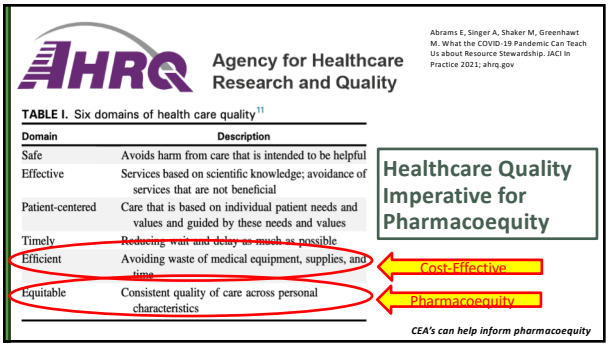
- ***"Pharmacoequity is equity in access to ensure that all patients, regardless of race, ethnicity, socioeconomic status, or availability of resources, have access to the highest quality of pharmacotherapy to mange their health condition"***

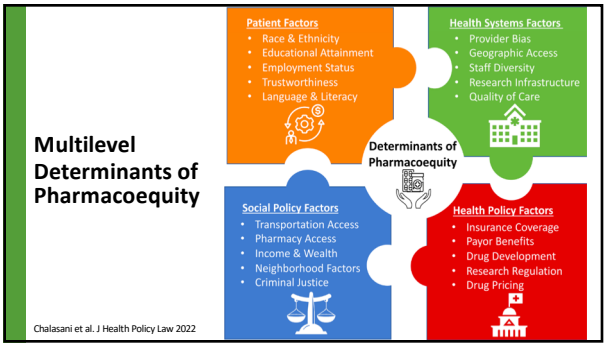
Conway A et al. J Allergy Clin Immunol In Pract 2024
Chalasani et al. J Health Policy Law 2022

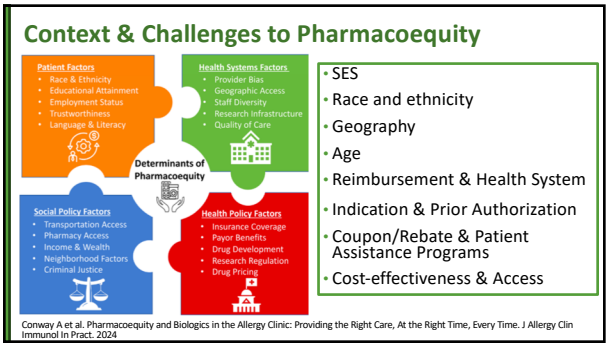
What is Cost-Effective Care Look Like?


PLANET MONEY
LISTEN & FOLLOW
Lives Vs. The Economy
APRIL 15, 2020 · 4:21 PM ET
By Sarah Gonzalez, Kenny Malone
25-Minute Listen
+ PLAYLIST
NOT DYING FOR WORK
ICER $50,000 to $100,000/QALY
($10 million/death prevented)
(Net monetary benefit)
CE Ratio
QALYS
DOMINANT
$
Health State Utilities


Thinking Fast, Thinking Slow...
System 1
System 2
Quick
Intuitive
Heuristic
Analytical
Deliberate
Reasoned
Daniel Kahneman
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


AHRQ
Agency for Healthcare Research and Quality
Abrams E, Singer A, Shaker M, Greenhawt M. What the COVID-19 Pandemic Can Teach Us about Resource Stewardship. JACI In Practice 2021; ahrq.gov
TABLE I. Six domains of health care quality[1]
Domain
Description
Safe
Avoids harm from care that is intended to be helpful
Effective
Services based on scientific knowledge; avoidance of services that are not beneficial
Patient-centered
Care that is based on individual patient needs and values and guided by these needs and values
Timely
Reducing wait and delay as much as possible
Efficient
Avoiding waste of medical equipment, supplies, and time
Equitable
Consistent quality of care across personal characteristics
Healthcare Quality Imperative for Pharmacoequity
Cost-Effective
Pharmacoequity
CEA's can help inform pharmacoequity


Multilevel Determinants of Pharmacoequity
Patient Factors
Race & Ethnicity
Educational Attainment
Employment Status
Trustworthiness
Language & Literacy
Health Systems Factors
Provider Bias
Geographic Access
Staff Diversity
Research Infrastructure
Quality of Care
Determinants of Pharmacoequity
Social Policy Factors
Transportation Access
Pharmacy Access
Income & Wealth
Neighborhood Factors
Criminal Justice
Health Policy Factors
Insurance Coverage
Payor Benefits
Drug Development
Research Regulation
Drug Pricing
Chalasani et al. J Health Policy Law 2022


Context & Challenges to Pharmacoequity
Patient Factors
Race & Ethnicity
Educational Attainment
Employment Status
Trustworthiness
Language & Literacy
Health Systems Factors
Provider Bias
Geographic Access
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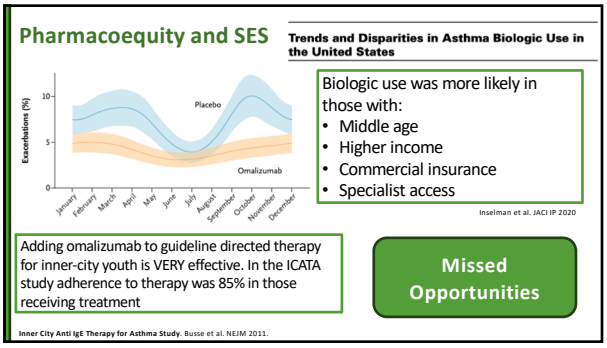
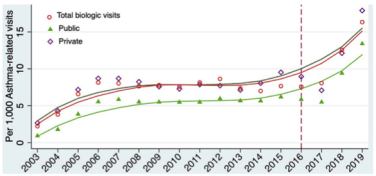
Income & Wealth
Neighborhood Factors
Criminal Justice
Health Policy Factors
Insurance Coverage
Payor Benefits
Drug Development
Research Regulation
Drug Pricing
SES
Race and ethnicity
Geography
Age
Reimbursement & Health System
Indication & Prior Authorization
Coupon/Rebate & Patient Assistance Programs
Cost-effectiveness & Access
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


Pharmacoequity and SES
Trends and Disparities in Asthma Biologic Use in the United States
Exacerbations (%)
10
5
0
Placebo
Omalizumab
January
February
March
April
May
June
July
August
September
October
November
December
Biologic use was more likely in those with:
Middle age
Higher income
Commercial insurance
Specialist access
Inselman et al. JACI IP 2020
Adding omalizumab to guideline directed therapy for inner-city youth is VERY effective. In the ICATA study adherence to therapy was 85% in those receiving treatment
Missed Opportunities
Inner City Anti IgE Therapy for Asthma Study. Busse et al. NEJM 2011.

Pharmacoequity, Insurance, 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

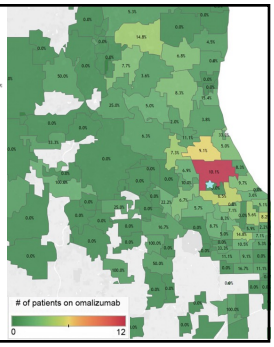
Do regional geography and race influence management of chronic spontaneous urticaria?

Giselle S. Mosnaim, MD, MS,[1,2] Matthew Greenhawt, MD, MSc, MBA,[3] Polina Imas, BS,[4] Loretta Au, PhD,[4] Stephanie Mehlis, MD,[1,2] John Oppenheimer, MD,[5] David Lang, MD,[6] Jonathan Bernstein, MD,[7] and Marcus Shaker, MD, MD[8,9]
Evanston and Chicago, Ill; Aurora, Colo; Newark, NJ; Cleveland, Ohio; and Lebanon and Hanover

JACI IP 2022

Geography and Race

- In a large Chicago-area health care system, small-area geographic practice variation was noted
- Rates of omalizumab use varied by patient zip code with greater rates near the academic medical center
- Higher rates of omalizumab use were associated with White race in patient-level analyses



Estimation of Health and Economic Benefits of Clinic Versus Home Administration of Omalizumab and Mepolizumab

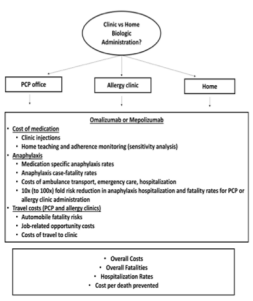
Marcus Shaker, MD, MSc[1,2], Aaron Briggs, MD[3], Ahmad Dbouk, MD[3], Emily Dutille, PharmD[1,2], John Oppenheimer, MD[3], and Matthew Greenhawt, MD, MBA, MSc[4]
Lebanon and Hanover, NH; Newark, NJ; and Aurora, Colo

JACI IP 2020

Geography, Access, & Risk

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

- A universal requirement for indefinite administration of omalizumab in the specialist clinic was associated with greater costs and worse outcomes because the risk of automobile-related fatalities from repeated clinic visits offset the risk of fatal anaphylaxis



American Hospital Association. www.aha.org

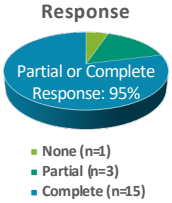
ELSEVIER

Omalizumab for chronic urticaria in children younger than 12 years

Al-Shaikhly et al. Annals of Allergy, Asthma, and Immunology 2019

Pharmacoequity by Age

- In a 2019 systematic review of omalizumab for urticaria 95% of those treated had a partial or complete response
- Still, despite approval for asthma to 6 years of age, and food allergy to 1 year of age, omalizumab is denied to many younger patients who would benefit from the therapy for urticaria



Pharmacoequity by Indication

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use XOLAIR safely and effectively. See full prescribing information for XOLAIR.

----------INDICATIONS AND USAGE----------

XOLAIR is an anti-IgE antibody indicated for:

- Moderate to severe persistent asthma in adults and pediatric patients 6 years of age and older with a positive skin test or in vitro reactivity to a perennial aeroallergen and symptoms that are inadequately controlled with inhaled corticosteroids (1.1)
- Chronic rhinosinusitis with nasal polyps (CRSwNP) in adult patients 18 years of age and older with inadequate response to nasal corticosteroids, as add-on maintenance treatment (1.2)
- Chronic spontaneous urticaria (CSU) in adults and adolescents 12 years of age and older who remain symptomatic despite H1 antihistamine treatment (1.3)

Limitations of Use:

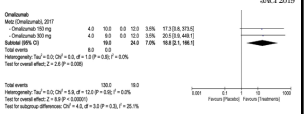
- Not indicated for acute bronchospasm or status asthmaticus. (1.1, 5.3)
- Not indicated for other allergic conditions or other forms of urticaria. (1.1, 1.3)

Omalizumab may be effective in other conditions but access is limited by variable ability to advocate for off-label use

Treatments of cold urticaria: A systematic review

Kanokvalai Kulthanan, MD,[a] Saowalak Hunnangkul, PhD,[b] Papapit Tuchinda, MD,[a] Leona Chularojanamontri, MD,[a] Puncharas Weerasubpong, MD,[a] Chanika Subchookul, MD,[a] and Marcus Maurer, MD[c]
Bangkok, Thailand, and Berlin, Germany

JACI 2019



"Omalizumab at 150 and 300 mg every 4 weeks was shown to be effective for patients with ColdU refractory to antihistamines."

> J Allergy Clin Immunol Pract. 2025 Sep 30:S2213-2198(25)00924-9.
doi: 10.1016/j.jaip.2025.09.030. Online ahead of print.

Penny-wise and Pound-foolish: A Cost-Effectiveness Analysis Of Unrealized Gains And Hidden Costs of 95165 Reimbursement

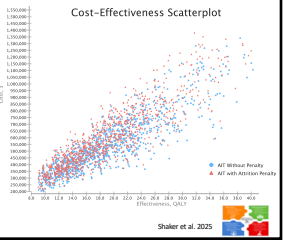
Costs of incomplete allergist reimbursement could exceed $1.3 billion

Marcus Shaker [1], Weily Soong [2], Priya Bansal [3]
Affiliations + expand

PMID: 41038315 DOI: 10.1016/j.jaip.2025.09.030

Pharmacoequity by Reimbursement

- A non-penalized analysis dominated all non-subsidized scenarios
- Withholding allergist reimbursement was not cost-effective if it limited access to less than 10% of patients (societal perspective)



White bagging, brown bagging and site of service policies: best practices in addressing provider markup in the commercial insurance market Journal of Comparative Effectiveness Research

Pearson et al 2023

"Policies should be structured to promote health equity by keeping front and center the risks to patients with less income and social support who may have the greatest challenges navigating these policies"

Pharmacoequity by Health system

- Traditional 'buy and bill' is replaced by another entity supplying the drug to the clinician and reimbursing the clinician only for administration
- Payers favor this to reduce costs
- Health systems express concerns for patient safety, misrouted medications, and access

"Site of service" policies pose similar logistic hurdles

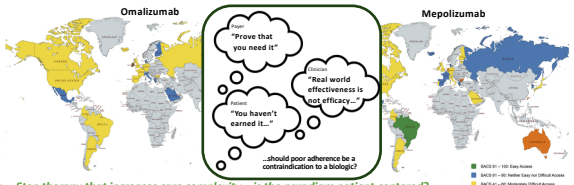
The patient can be stuck in the middle if there are not rapid exceptions made for clinical & social factors

Special Article Poushjeng et al JACI IP 2023

Global Variability in Administrative Approval Prescription Criteria for Biologic Therapy in Severe Asthma

"Biologic prescription criteria differed substantially across 28 countries from five continents"

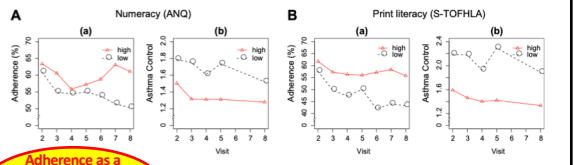
Pharmacoequity by Prior Authorization



- *Step therapy that increases care complexity – is the paradigm patient-centered?*
- *Delay in access of therapy increases risk for disease exacerbation*

Dudiak et al. Prior authorization delays biologic initiation and is associated with a risk of asthma exacerbations Allergy Asthma Proc 2021

Adherence Rates: Correspond to health literacy, asthma control, and inpatient admission



Adherence as a barrier to a biologic threatens equity

Asthma Numeracy and Print Literacy Score = Number correct
Asthma Control Questionnaire. 0 = Total control, 6 = Extremely uncontrolled

Apter et al. JACI 2013; Poowuttikul et al. Global Pediatric Health 2017

Pharmacoequity through PAP's

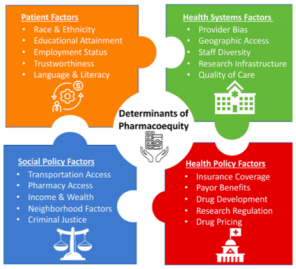
- **Despite best intentions, Patient Assistance Programs may represent a "Band-Aid solution for an imperfect system"**

Zafar SY, Peppercorn JM. Patient Assistance Programs: A Path to Affordability or Barrier. J Clin Onc. 2017

- **PAPs can be a solution for some who are underinsured but there can be a lack of transparency in these programs**
- **PAPs increased care complexity**
- **However, PAPs are not accessible to everyone and generally require**
  - **Permanent legal residency in the U.S. or Puerto Rico**
  - **Proof of lack of insurance or lack of coverage**
  - **Additional eligibility requirements**
  - **Manufacture rebates violate Federal Anti-kickback law and are not accessible to patients receiving Medicare or Medicaid**

Patient Assistance Programs: What Are They and How Do They Work? – GoodRx
Medicare Patients Aren't Allowed To Use Drugmaker Discount Coupons : Shots - Health News : NPR

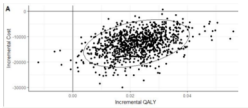
Context & Challenges to Pharmacoequity



- SES ✓
- Race and ethnicity ✓
- Geography ✓
- Age ✓
- Reimbursement & Health System ✓
- Indication & Prior Authorization ✓
- Coupon/Rebate & Patient Assistance Programs ✓
- Cost-effectiveness & Access

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

Access to SMART for the Underinsured – An Example



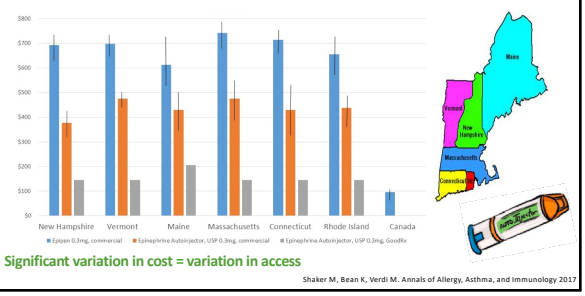
- Compared to OTC epinephrine, OTC budesonide-formoterol:
  - **Was associated with 11,865 fewer deaths**
  - **Saved $70.29 billion**
  - **Prevented 14.64 million severe exacerbations**

Microsimulation of Underinsured U.S. Patients (n=5,250,000 patients with mild asthma per arm)

- When used to manage asthma, inhaled epinephrine has well-founded safety concerns, as beta-agonists use alone without inhaled corticosteroids increases the risk of asthma death, whereas inhaled corticosteroids can prevent asthma fatalities
- In 2021, full year Primatene Mist sales increased by 41% up to $73 million
- No professional society recommends use of this drug

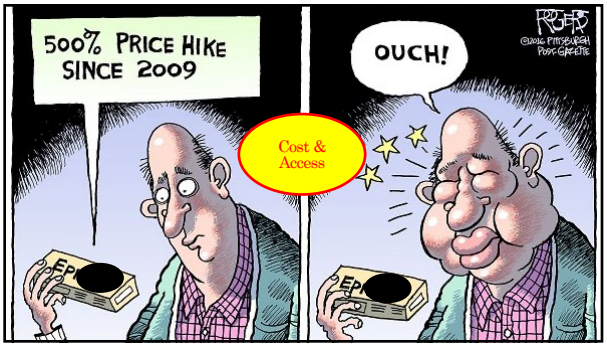
Ho J, Shaker M, et al. Annals of Allergy, Asthma, Immunology 2023
Feldman et al JAMA 2022; Spitzer et al NEJM 1992; Suissa et al NEJM 2000; www.generics.pharmaintelligence.inofrma.com. Accessed December 18, 2022

The Epinephrine Problem: Geographic Variation in SIE costs



Significant variation in cost = variation in access

Shaker M, Bean K, Verdi M. Annals of Allergy, Asthma, and Immunology 2017



Comparative Cost-effectiveness

Table 2. Cost-effectiveness of Personal Self-injectable Epinephrine

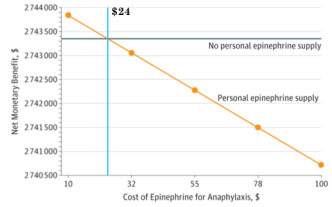
	$715 per Year				$30 per Year	
Anaphylaxis Preparedness Strategy	Cost, $	QALY, No.	Risk-Specific Fatalities, No.	ICER, $	Cost, $	ICER, $
Annual personal epinephrine prescriptions (95% CI)	25 478 (25 399-25 557)	27.4446 (27.4247-27.4645)	0.00056 (0.000414-0.000706)	2 742 697	1685 (1675-1695)	161 810
No annual personal epinephrine prescriptions (95% CI)	654 (645-663)	27.4335 (27.4134-27.4536)	0.00148 (0.001242-0.001718)		NA	

Abbreviations: ICER, incremental cost-effectiveness ratio; NA, not applicable; QALY, quality-adjusted life-year.

Way Too Expensive !

Shaker MS, Greenhawt M. JAMA Netw Open. 2018

Deterministic Sensitivity Analysis → Lower Prices Needed



Sensitivity Analysis of Personal Epinephrine Cost-effectiveness at a willingness-to-pay threshold of $100 000 per quality-adjusted life-year demonstrates a ceiling value-based cost of $24 for an annual personal epinephrine prescription in the base-case analysis.

Meaning: Epinephrine is central to managing anaphylaxis, and $24 personal auto-injectors are cost-effective for community-based anaphylaxis management

Net Monetary Benefit (NMB = "Life Dollars" - expenses)

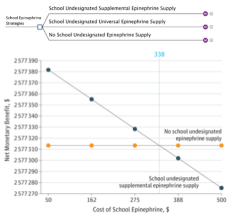
QALY * $100K/QALY = "Life dollars"

Shaker MS, Greenhawt M. JAMA Netw Open. 2018

Value-Based Pricing

What About Devices in Schools?

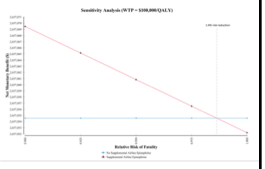
- **Shared epinephrine is cost-effective when the annual school epinephrine expenditures do not exceed $338 per school (10-fold fatality risk reduction)**
- **A Universal Model dominates a Supplemental Model**



Shaker MS, Greenhawt M JAMA Pediatr. 2019
DeSantiago-Cardenas et al. Am J Prev Med 2015
Shaker MS, Greenhawt M. JAMA Netw Open. 2018

And Elsewhere…

- **Also cost-effective on airplanes**
- **771 million passengers each year**
- **7309 aircraft in the US commercial fleet**
- **At the school based cost of $338 per aircraft, cost is $0.08 per at-risk passenger**
- **Cost-effective if autoinjectors provide at least a 1.4% fatality risk reduction.**



Shaker MS, Greenhawt M JACI In Practice 2019

Dartmouth-Hitchcock

Anaphylaxis Practice Parameter 2023

CBS 22 *Strength: Conditional* *Evidence certainty: Very low*	**We suggest keeping stock EAI in community settings be encouraged, if feasible.**

Golden DBK, Wang, et al. Anaphylaxis: A 2023 Practice Parameter Update. Annals of Allergy, Asthma, and Immunology. 2023

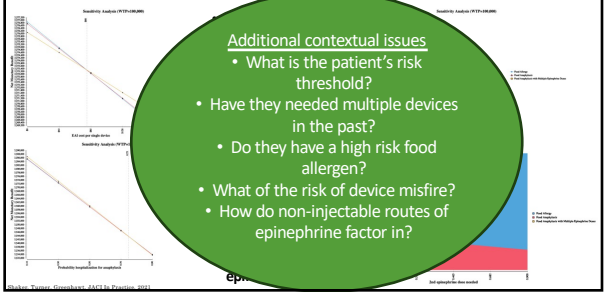
Fewer Devices = Lower Cost

Does EVERYONE need multiple devices?

- **The dogma in food allergy management is to always have 2 epinephrine autoinjector devices on one's person at all times**
  - **Fewer than 12% of children require 2nd epinephrine dosing, schools now stock undesignated epinephrine, and people don't carry 1 device let alone 2 devices….**
- **We compared three scenarios: everyone gets 2 devices (universal approach), 2nd device only given with a prior history of anaphylaxis (PMH anaphylaxis), and 2nd device only given with prior history of anaphylaxis requiring multiple epinephrine doses (multi-epi)**

Shaker, Turner, Greenhawt. Journal of Allergy and Clinical Immunology In Practice. 2021

Sensitivity Analyses: When It makes sense that everyone get two…



Additional contextual issues
- What is the patient's risk threshold?
- Have they needed multiple devices in the past?
- Do they have a high risk food allergen?
- What of the risk of device misfire?
- How do non-injectable routes of epinephrine factor in?

Shaker, Turner, Greenhawt. JACI In Practice. 2021

Anaphylaxis Practice Parameter 2023

CBS 24 *Strength: Conditional* *Evidence certainty: Very low*	**We suggest that in jurisdictions where single-packs of EAIs are available, clinicians consider a patient's risk factors for severe anaphylaxis, their values and preferences, and contextual factors when deciding whether to prescribe only 1 vs multiple EAIs. We suggest routinely prescribing more than one EAI when patients have previously required multiple doses of epinephrine to treat an episode of anaphylaxis and/or have biphasic reactions**

Golden DBK, Wang, et al. Anaphylaxis: A 2023 Practice Parameter Update. Annals of Allergy, Asthma, and Immunology. 2023

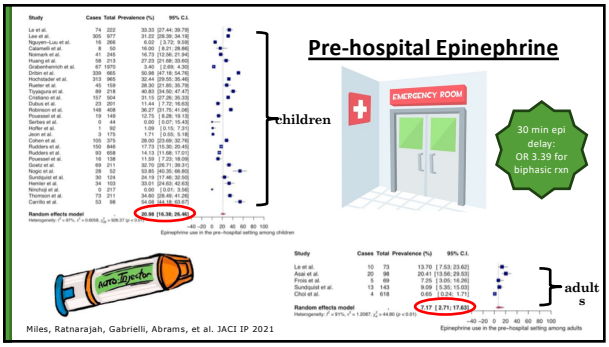
What about non-injectable routes of epinephrine?

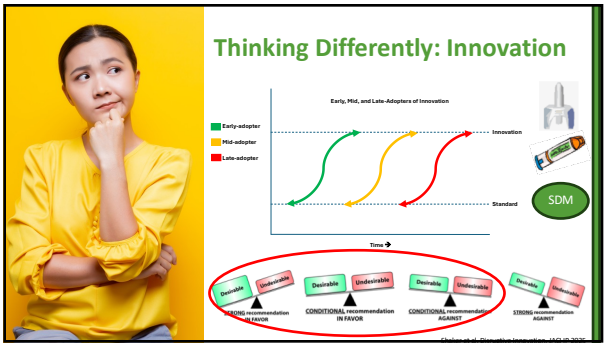
Needle Phobia, Cost, Access, & Equity

Needle fear: **Nearly universal in children; 20-50% of adolescents; 20-30% of young adults; 16% of adults defer flu vaccine due to needle fear**

"This is gonna hurt like hell."

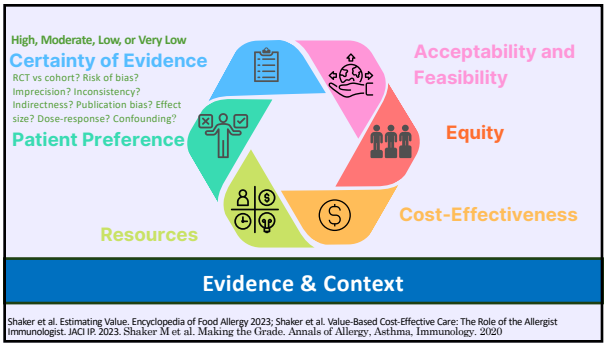
CartoonStock.com





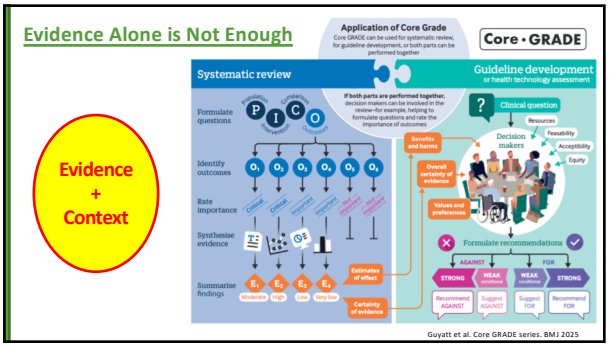
Certainty of Evidence + Context Inform Recommendations

Evidence Certainty	
High	Further research is very unlikely to change the confidence in the estimate of effect.
Moderate	Further research is likely to have an important impact on the confidence in the estimate of effect and may change the estimate.
Low	Further research is very likely to have an important impact on the confidence in the estimate of effect and is likely to change the estimate.
Very Low	Any estimate of effect is very uncertain.



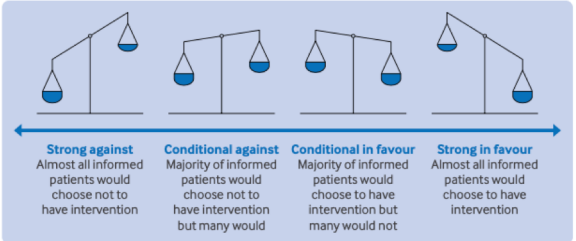
Shaker et al. Estimating Value. Encyclopedia of Food Allergy 2023; Shaker et al. Value-Based Cost-Effective Care: The Role of the Allergist Immunologist. JACI IP. 2023. Shaker M et al. Making the Grade. Annals of Allergy, Asthma, Immunology. 2020

Evidence Alone is Not Enough



Guyatt et al. Core GRADE series. BMJ 2025

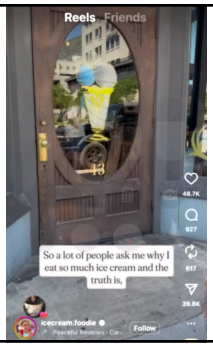
What Do Recommendations Imply?



Guyatt et al. Core GRADE series. BMJ 2025

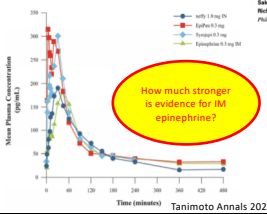
Evidence Still Matters!

- Evidence is foundational
- Certainty of evidence is variable
- Comfort with very low certainty evidence is variable
- Context is variable
- SDM is key when strong recommendations are absent and evidence is very low certainty



Evidence Still Matters!

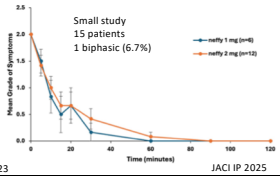
- Nasal epinephrine has comparative pharmacokinetic and pharmacodynamic effects to IM



Tanimoto Annals 2023

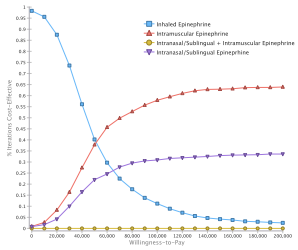
Original Article

Epinephrine Nasal Spray Improves Allergic Symptoms in Patients Undergoing Oral Food Challenge, Phase 3 Trial



JACI IP 2025

Nasal epinephrine: Cost, Access, and Evidence Certainty

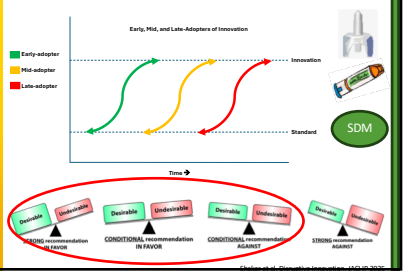


Shaker et al. Ann Allergy Asthma Immunol. 2024

- Intranasal epinephrine can be cost effective provided the annual incremental cost dose not exceed $4 compared to injectable epinephrine
- Carrying both an intranasal device and a back-up autoinjector due to fear of nasal device failure is not cost-effective

What's Your Comfort level?

And What's The Patient's?



Elsaigh et al. Disruption in Innovation. JACI IP 2025

Disruptive Innovation in A/I - Examples

- A **Disruptive Innovation** is a type of advancement in which a new product or service line meets some aspect of a consumer gap
- The DI *may* be accompanied by some limitation

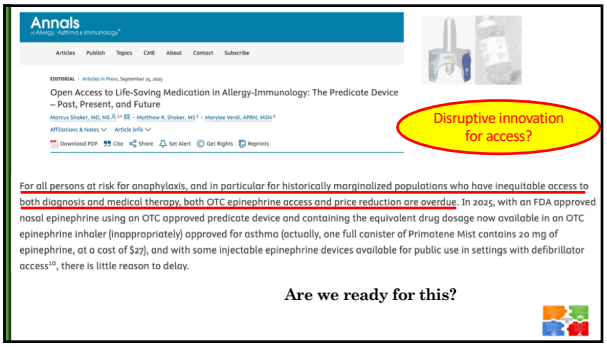
As an innovation, what is the role of nasal epinephrine? Equivalent to IM?

TABLE I. Disruptive innovations in allergy-immunology

Established allergy-immunology procedure	DI	Explanation
Inhaled corticosteroids	Leukotriene receptor antagonists	The DI facilitated a once-daily oral therapy for asthma without drug monitoring but proved less effective than inhaled corticosteroids.[19] Additional concerns emerged for adverse neuropsychiatric effects.[20]
Face-to-face office visit	Telemedicine	The DI facilitated healthcare for individuals unable to travel or preferring not to for an in-person visit; however, telemedicine visits do not provide for all capabilities as in-person visits.[21]
One-size-fits-all approach to treatment of refractory asthma	Treatment with biologic agent for refractory asthma based on biomarkers	A personalized approach in patients with refractory asthma may facilitate endotype-driven care models; however, it may also challenge equitable care delivery for those without subspecialist access.[22,23]
In-office lung function testing	At-home lung function monitoring	A home lung function monitoring is more accessible but also more limited in scope than in-person evaluation.[24]

DI, disruptive innovation.

Shaker et al. JACI IP 2025

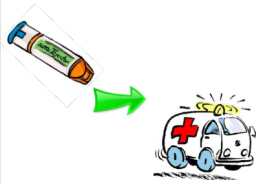


For all persons at risk for anaphylaxis, and in particular for historically marginalized populations who have inequitable access to both diagnosis and medical therapy, both OTC epinephrine access and price reduction are overdue. In 2025, with an FDA approved nasal epinephrine using an OTC approved predicate device and containing the equivalent drug dosage now available in an OTC epinephrine inhaler (inappropriately) approved for asthma (actually, one full canister of Primatene Mist contains 20 mg of epinephrine, at a cost of $27), and with some injectable epinephrine devices available for public use in settings with defibrillator access[10], there is little reason to delay.

Are we ready for this?

Innovation in Health Care Delivery
Reflex EMS for Resolved Symptoms…

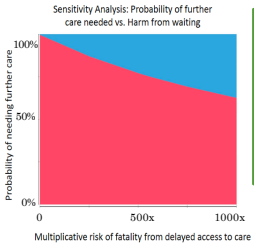
More examples



- The incremental cost per life year saved was nearly $150M/QALY for reflex EMS
- With the cost per death prevented reaching $1.3B

Shaker MS, Kanaoka T, Feenan L, Greenhawt M. Ann Allergy Asthma Immunol. 2018

Reflex EMS



- Early EMS activation could be cost-effective when the **fatality risk increased 500-fold** over a "wait and see" approach, combined with eventual care being required in the "wait and see" cohort 75% of the time

Willingness to pay threshold is $100,000 per life year saved over model horizon

Shaker MS, Kanaoka T, Feenan L, Greenhawt M. Ann Allergy Asthma Immunol. 2018

Anaphylaxis Practice Parameter 2023

CBS 26 *Strength: Conditional* *Evidence certainty: Very low*	**We suggest that clinicians counsel patients that immediate activation of EMS may not be required if the patient experiences prompt, complete, and durable response to treatment with epinephrine, provided that additional epinephrine and medical care are readily available, if needed. We suggest that clinicians counsel patients to always activate EMS following epinephrine use, if anaphylaxis is severe, fails to resolve promptly, fails to resolve completely or nearly completely, or returns or worsens following a first dose of epinephrine.**

Golden DBK, Wang, et al. Anaphylaxis: A 2023 Practice Parameter Update. Annals of Allergy, Asthma, and Immunology. 2023

An important step to assure costs of care are necessary

Considerations for Home Management

- ✓Patients / caregivers engaged in shared decision making
- ✓Immediate access to at least 2 epinephrine autoinjectors
- ✓Immediate access to person(s) who can help
- ✓Clear understanding of thresholds for further care
- ✓Understanding of how to use epinephrine device

- ✗Patient/caregiver not comfortable with home observation
- ✗No extra epinephrine on hand
- ✗No access to additional help
- ✗Unsure (or unwilling) to use epinephrine
- ✗History of near fatal anaphylaxis
- ✗Poor adherence to recommendations

Casale TB, Wang J, Oppenheimer J, Nowak-Wegrzyn. Acute At-Home Management of Anaphylaxis: 911: What is the Emergency? J Allergy Clin Immunol Pract 2022

Contextual Considerations

Home observation following first dose of epinephrine	Signs and symptoms that had emerged prior to epinephrine administration resolve within minutes of epinephrine administration, without recurrence. Patient is asymptomatic. Patients with scattered residual hives or other rash (including erythema), even those with newly emerging but isolated hives or erythema without other symptoms occurring after epinephrine administration may be observed at home provided no additional new symptoms develop.
Consider EMS activation and possibly second dose of epinephrine but can continue to observe at home if comfortable	Signs and symptoms that had emerged prior to epinephrine administration are improving or resolving within minutes of epinephrine administration. For example, persistence of a mild sensation of globus, nausea, coughing, or stomachache may be closely observed at home provided symptoms are improving (not worsening and are perceived to be getting better) and do not persist for longer than 10-20 minutes without any additional signs of improvement.
Activate EMS immediately, consider second dose of epinephrine, do not observe at home	Signs and symptoms that had emerged prior to epinephrine administration are not resolving. Particularly concerning symptoms would include respiratory distress, stridor, altered consciousness, cardiovascular instability, cyanosis, or incontinence not typical for their age. This would also include non-skin symptoms that fail to resolve or worsen, including but not limited to repeated (>2 total episodes of vomiting), persistent hoarseness, cough, dysphagia, wheezing, or lightheadedness.

Disruptive Innovation in Food Allergy Screening and Allergy Diagnosis

More examples

Challenges to Cost-Effectiveness & Pharmacoequity

- Access
- Education
- Transportation
- Diversity
- Cost

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

Shaker MS, Stukus D, Chan ES, et al. Allergy. 2018
Greenhawt M, Shaker MS. JAMA Network Open. 2019
Shaker MS, Verma A K, Greenhawt M. Allergy. 2018
Shaker MS, Iglesia E, Greenhawt M. Allergy. 2019

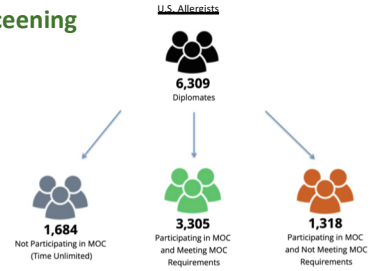
Equity

- Socioeconomic disadvantage may limit access to opportunities for screening and early introduction of potential food allergens
- The cost of food allergy is high
  - Estimated at $4,184 per child in 2013 in the US
  - May disproportionately affect families living in poverty

Gupta et al. The economic impact of childhood food allergy in the United States. JAMA Ped 2013
Jiang et al. Racial, Ethnic, and Socioeconomic Differences in Food Allergies. JAMA Open 2023

Feasibility of Sceening

- Greater than 640,000 infants at risk annually
- Only 40-60% of practicing allergists offer infant food challenges



www.abai.org Accessed October 1, 2023. Shaker et al. 2019; Greiwe et al 2019; Abrams et al 2019

"To Screen or Not to Screen?"

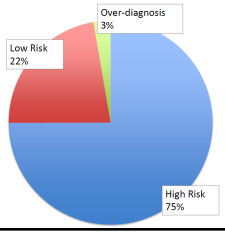
Infants at Risk	Cost Per Patient At Risk	QALY Per Patient At Risk	Allergic Reactions Per Patient At Risk
For Peanut Allergy (Personal History of Early Onset Eczema and/or Egg Allergy)			
No Screening	$6,557	19.63	0.4
Skin Test Screening	$7,576	19.62	0.35
Specific IgE Screening	$7,977	19.6	0.38
Delayed Introduction	$11,708	19.46	0.72
For Peanut Allergy (Sibling History Of Peanut Allergy)			
No Screening	$3,278	19.72	0.2
Skin Test Screening with Challenge	$3,984	19.72	0.2
For Egg Allergy (Early Onset Eczema)			
No Screening Early Cooked Introduction	$2,235	19.78	0.03
Skin Test	$9,100	19.59	0.12
Specific IgE Delayed Cooked Introduction	$18,957 $10,615	19.28 19.53	0.26 0.13

"To Screen or Not to Screen?"

- Compared with alternative international approaches, the US peanut screening strategy costs $654,115,322 from a US societal perspective and results in 3,208 additional peanut allergy diagnoses over a 20 year simulation.

Missed

Almost ¼ of all peanut allergy diagnosed was in the low risk cohort



Shaker MS, Stukus D, Chan ES, et al. Allergy. 2018

Consensus Document

A Consensus Approach to the Primary Prevention of Food Allergy Through Nutrition: Guidance from the American Academy of Allergy, Asthma, and Immunology; American College of Allergy, Asthma, and Immunology; and the Canadian Society for Allergy and Clinical Immunology

A Balanced Approach

"While screening peanut skin or sIgE testing and/or in-office introduction is not required for early introduction, this remains an option to consider for families that prefer to not introduce peanut at home; this decision is preference-sensitive and should be made taking into account current evidence and family preferences"

Journal of Allergy and Clinical Immunology In Practice 2021

Consensus Document

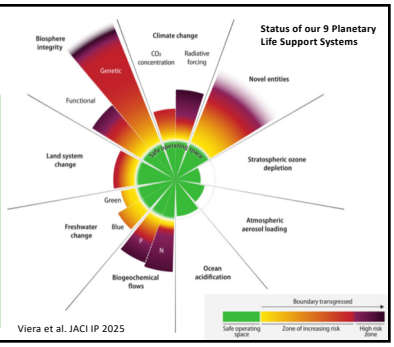
A Consensus App evention
of Food Allergy Th nce from
the American Aca a, and
Immunology; Ame , Asthma,
and Immunology; ty for
Allergy and Clinic

"While screening pear n-office introduction is
not required for early tion to consider for
families that prefer to this decision is
preference-sensitive a account current
evidence and family p

ical Immunology In Practice 2021

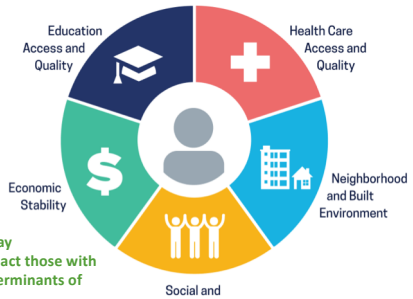
Planetary Health & Low Value Care

- Human health is connected to planetary health
- Reducing low value care is not just an economic imperative
- The healthcare sector contributes to pollution – specifically through green house gas emissions, water use, waste generation, and unnecessary travel



Viera et al. JACI IP 2025

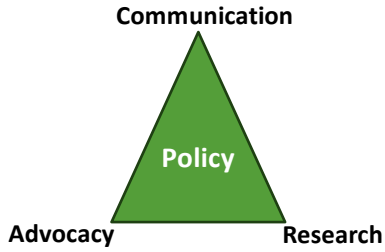
Social Determinants of Health



Low value therapies may disproportionately impact those with inequities in social determinants of health

www.healthy.gov

A Path Forward Toward Pharmacoequity & Value



Take Home Points

- Pharmacoequity involves patient, social, health system, and policy factors
- Many therapies cost too much and patterns of utilization are not equitable
- Current patchwork solutions are not adequate or sustainable
- Value-based models of care and innovation can help

Thank You