Improving Anaphylaxis Outcomes: Approaches for Enhancing Access to Epinephrine

December 16, 2025 | 9:00 am – 4:30 pm ET

Duke | MARGOLIS INSTITUTE *for* Health Policy

healthpolicy.duke.edu

Welcome and Overview

Valerie J. Parker, Duke-Margolis Institute for Health Policy

Statement of Independence

The Robert J. Margolis, MD, Institute for Health Policy is part of Duke University, and as such it honors the tradition of academic independence on the part of its faculty and scholars. Neither Duke nor the Margolis Institute take partisan positions, but the individual members are free to speak their minds and express their opinions regarding important issues.

For more details on relevant institutional policies, please refer to the Duke Faculty Handbook, including the Code of Conduct and other policies and procedures. In addition, regarding positions on legislation and advocacy, Duke University policies are available at http://publicaffairs.duke.edu/government.

This event is supported by the Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award U01FD008451 totaling $1,399,999 with 100 percent funded by FDA/HHS. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by FDA/HHS, or the U.S. Government.

Logistics

Questions

- All attendees are encouraged to submit questions via Slido.

Zoom Issues?

- Please type your issue in the Q&A or email us at margolisevents@duke.edu.

Meeting Materials

- All meeting materials will be available on the Duke-Margolis website.

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Join at

slido.com

#Epi

Event Agenda

9:00 am	Welcome and Overview
9:10 am	FDA Opening Remarks
9:20 am	Session 1: Allergic Diseases, Anaphylaxis, and Treatment of Anaphylaxis in the Community Setting
10:30 am	Break
10:45 am	Session 2: Regulatory Pathways for Epinephrine Products, Including Considerations for Prescription and Nonprescription Development
11:50 am	Lunch Break

All times listed in ET

Event Agenda

1:05 pm	Public Comment Session
2:05 pm	Session 3: Current Accessibility to Epinephrine for Treating Anaphylaxis
3:05 pm	Break
3:20 pm	Session 4: Opportunities to Enhance Access to and Use of Epinephrine
4:30 pm	Closing Remarks and Adjournment

All times listed in ET

FDA Opening Remarks

Mary Thanh Hai, U.S. Food and Drug Administration

Session 1: Allergic Diseases, Anaphylaxis, and Treatment of Anaphylaxis in the Community Setting

Moderator: Paul Greenberger, Northwestern University

Food Allergy Diagnosis & Management

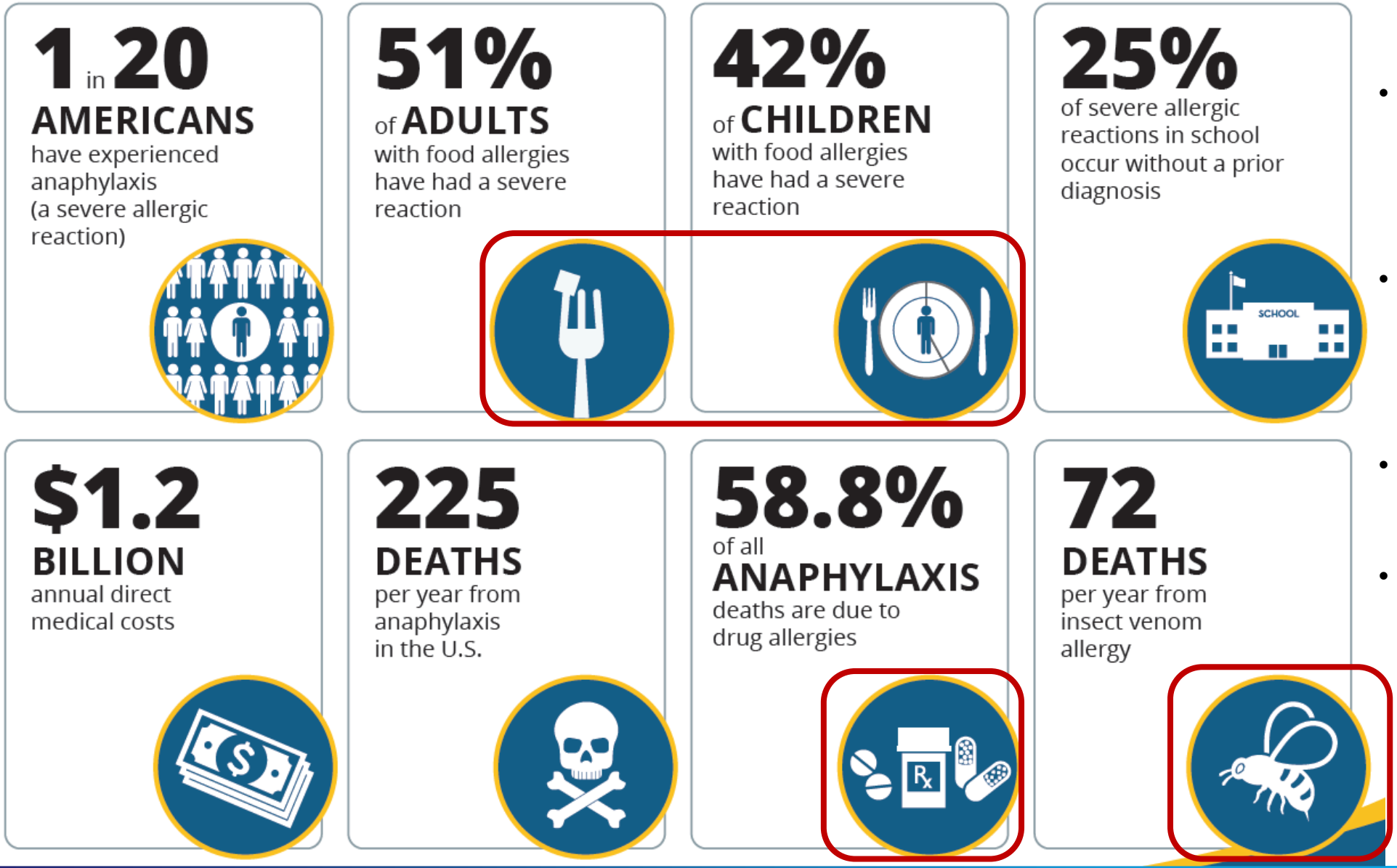
Hugh A Sampson, MD

Kurt Hirschhorn Professor of Pediatrics
Jaffe Food Allergy Institute
Icahn School of Medicine at Mount Sinai

Duke Margolis Institute for Health Policy – December 16,2025

Icahn School of Medicine at Mount Sinai

Severe or Life-threatening Allergies



- Estimated that ~30 million Americans have **food** allergies
  - ~10% of adults
  - ~ 6% of children
- Estimated that ~2 million Americans have **bee sting** allergies
  - 0.5 – 3% of adults
  - 0.15 – 0.8% of children
- Estimated ~1 – 6% of Americans have **latex** allergy
- Estimated that ~33 million Americans have a **drug** allergy
  - 10% of the population

Adapted from –
AllergyAsthmaNetwork.org
April 2025

Objectives

- **Understand how allergist diagnose food allergies & other preventable allergies leading to anaphylaxis**

- **Understand how allergists manage food allergies & other preventable allergies leading to anaphylaxis**

Spectrum of Possible Food Allergic Reactions

- 10 m/o vomits repetitively 2 hrs. after ingesting rice cereal
- 43 y/o gets bloating & diarrhea after eating pizza & ice cream
- 12 y/o develops anaphylaxis after ingesting a “trail bar”
- 4 family members develop pruritus, facial erythema & vomiting after eating tuna at a local restaurant
- 3 y/o with atopic dermatitis has eczematous flare after eating eggs
- 24 y/o seen in ER after steak “gets stuck going down”
- 32 y/o hunter develops anaphylaxis 4 hrs. after eating steak

Getting to the Right Diagnosis & Treatment

Requires –

- Careful history
- Choosing & interpreting the right tests
- Educating patient & caregivers about allergen avoidance & recognition of anaphylaxis
- Educating patients & caregivers about the use of rescue medications, e.g. epinephrine
- Discuss potential therapies, e.g. omalizumab & immunotherapy

Step 1: Careful History

History is key:

- **Timing** (minutes to a few hours)
- **Symptoms** (skin, gut, respiratory, cardiovascular)
- **Quantity & preparation of food** (e.g. raw vs. cooked vs. baked)
- **Reproducibility** (previously or subsequently tolerated?)
- **Treatment** (resolution/outcome)
- **Co-factors** (exercise, fever, alcohol, medications [e.g. NSAIDs])

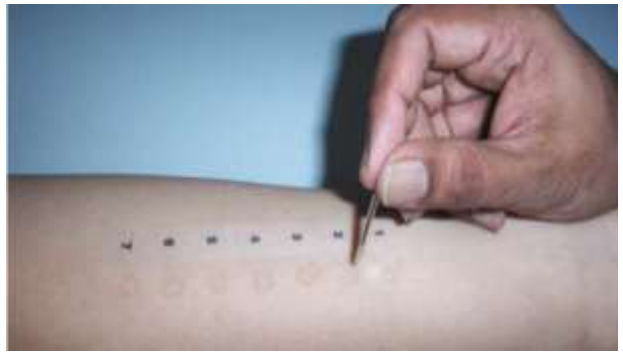
History informs testing – provides "pre-test probability"

Diagnostic testing serves to support/refute diagnosis of suspected allergy based on history

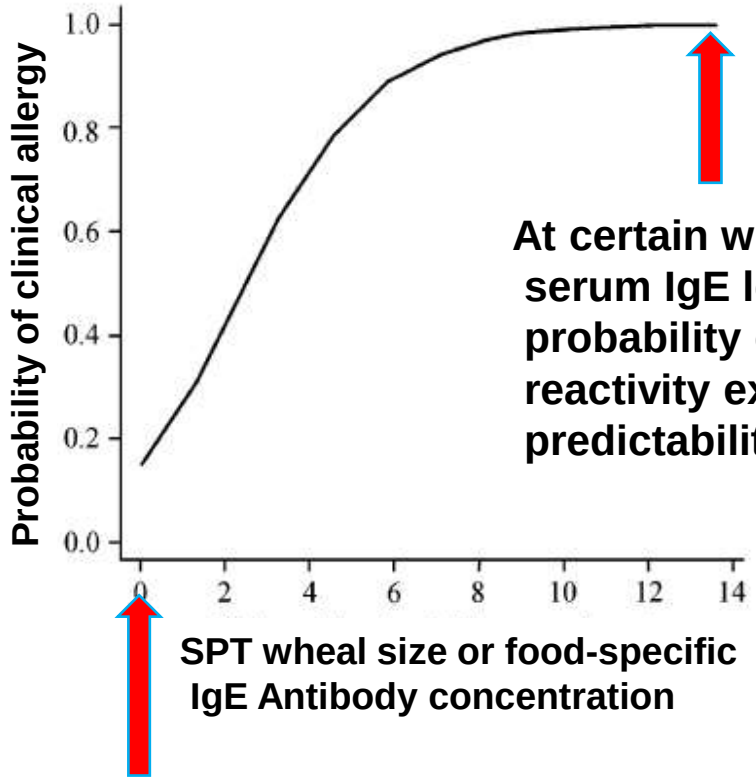
Step 2: Food Allergy Testing

Skin prick testing & food-specific IgE testing

- Avoid panel testing (poor positive predictive value → overdiagnosis, unnecessary avoidance)
- Sensitization (+ test) alone is <u>not</u> diagnostic without convincing history of clinical reaction
- Larger wheals on SPT, higher values of food-specific IgE correlate with higher likelihood of reactivity (not severity of reaction)
- Negative results → allergy unlikely



Curve varies by –
- **Food**
- **Patient age**
- **Assay (brand)**



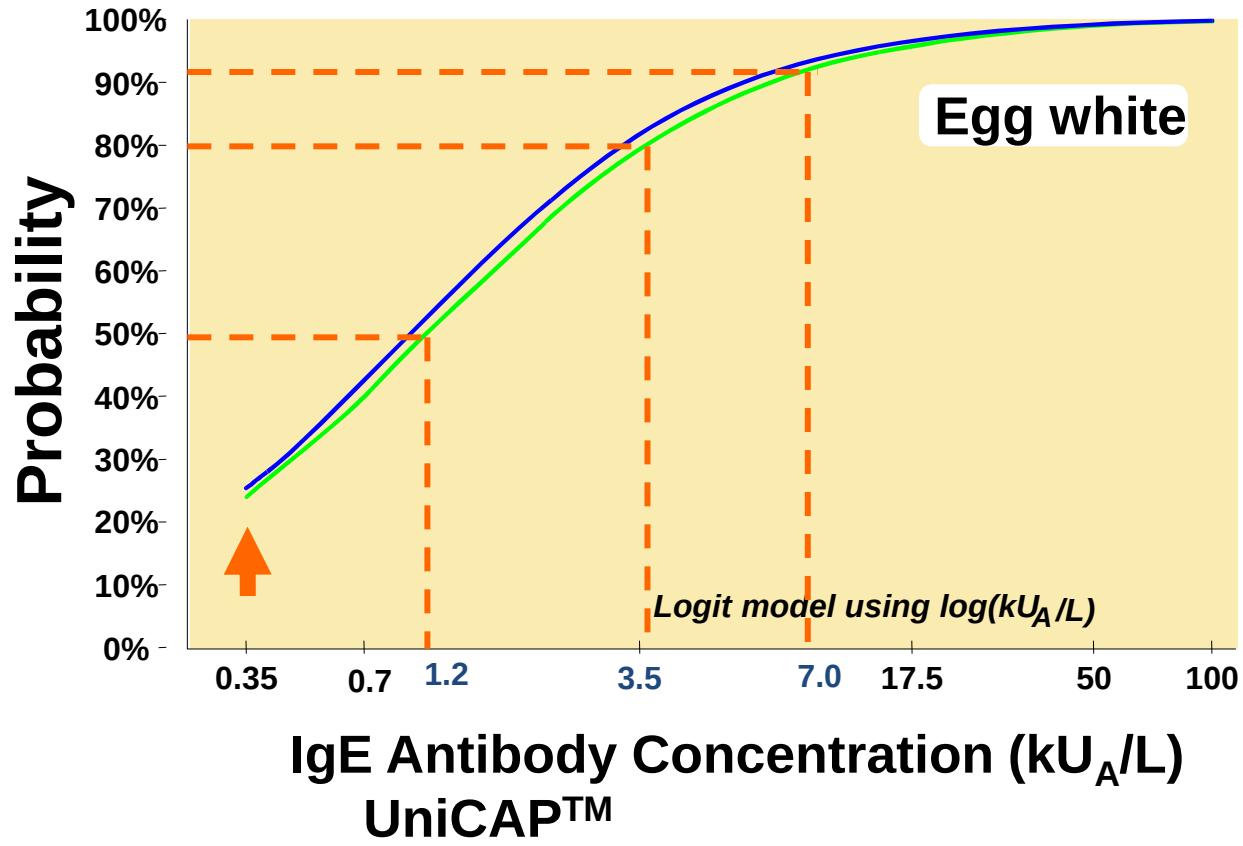
At certain wheal size or serum IgE level, probability of clinical reactivity exceeds 95% predictability

SPT wheal size or food-specific IgE Antibody concentration

Negative test is not zero risk of reactivity

Sporik R et al. *Clin Exp Allergy* 2000; 30:1541-46; Sampson HA. *JACI* 2001; 107:891-96.

Step 3: Predictive Value of Food-specific IgE



Allergen	Decision Pt (kU$_A$/L)
Egg	7
(< 2 yrs of age)+	2
Milk	15
(< 1yr of age)++	5
Peanut	14
(< 3yrs of age)	5
Soy	30
Wheat	26
Tree nuts+++	15

Quantity of food-specific IgE correlates with probability of allergic reactivity
- **does not correlate with severity of reaction or sensitivity, i.e. eliciting dose**

Sampson HA. *JACI* 2001; 107:891-896

+ Boyano MT, et al. *Clin Exp Allergy* 2001; 31:1464-9.
++ Garcia-Ara C, et al. *JACI* 2001; 107:185-90.
+++ Clark AT, Ewan P. *Clin Exp Allergy* 2003; 33:1041-45.
Maloney J et al. *JACI* 2008; 122:145-5.

Step 4: Oral Food Challenge [OFC]

- **OFC – double-blind or open**
- **Age-appropriate serving size** divided in 4 – 5 increasing doses spaced 15 – 30 mins apart
- **When to stop the OFC**
  - **Objective signs** of allergic reaction (see table)
  - **Subjective signs** only - use clinical judgement
    - Consider risk/benefit of continuing vs. stopping
    - Persistent symptoms or those associated with change in behavior in a child may be more indicative of reaction
    - May extend observation period before next dose if concern that a reaction may be evolving

Stopping Criteria[*E15]
The OFC should be stopped if any **1** of the following symptoms is present during the OFC:
Skin
• ≥3 urticarial lesions
• Angioedema
• Confluent erythematous, pruritic rash
Respiratory
• Wheezing
• Repetitive cough
• Difficulty breathing/increased work of breathing
• Stridor
• Dysphonia
• Aphonia
Gastrointestinal
• Vomiting alone not associated with gag reflex
• Severe abdominal pain (such as abnormal stillness, inconsolable crying, or drawing legs up to abdomen) that persists for ≥3 min
Cardiovascular
• Hypotension for age not associated with vasovagal episode
If 2 or more of the following are present, the OFC should be stopped:
Skin
• Persistent scratching for ≥3 min
Respiratory
• Persistent rubbing of the nose or eyes for ≥3 min
• Persistent rhinorrhea for ≥3 min
Gastrointestinal
• Diarrhea

Bird JA et al, *JACI* 2020; 8(1):75-90.e17

Step 5: Following-up Diagnosis

- Educate patient/caregivers about allergen avoidance
- Educate patient/caregivers to recognize symptoms of pending anaphylaxis
- Provide and review a comprehensive emergency treatment plan and use of an epinephrine delivery device
- In infants with milk or egg allergy, consider a baked milk/egg OFC
- In infants diagnosed with a food allergy at < 3 yrs of age, discuss initiating immunotherapy [currently peanut-OIT; EPIT & SLIT in clinical trials]
- In older children, adolescents & adults, especially with multiple food allergies, discuss initiating omalizumab [Xolair®] therapy
- Greater than 25 novel therapeutic approaches in development for treating food allergies

Step 5: Education regarding Food Allergen Cross-reactivity

- Cross-reactivity within food groups
- Cross-reactivity with pollens

If Allergic to:	Risk of Reaction to at Least One:	Risk:
A legume* (peanut)	Other legumes (peas, lentils, beans)	5%
A tree nut (walnut)	Other tree nuts (brazil, cashew, hazelnut)	37%
A fish* (salmon)	Other fish (swordfish, sole)	50%
A shellfish (shrimp)	Other shellfish (crab, lobster)	75%
A grain* (wheat)	Other grains (barley, rye)	20%
Cow's milk*	Beef (hamburger)	10%
Cow's milk*	Goat's milk (goat)	92%
Cow's milk*	Mare's milk (horse)	4%
Pollen (birch, ragweed)	Fruits/vegetables (apple, peach, honeydew)	55%
Peach*	Other Rosaceae (plum, pear, apple, cherry)	55%
Melon* (cantaloupe)	Other fruits (watermelon, banana, avocado)	92%
Latex* (latex glove)	Fruits (kiwi, banana, avocado)	35%
Fruits (kiwi, avocado, banana)	Latex (latex glove)	11%

Sicherer SH, *J Allergy Clin Immunol* 2003; 108(6):881-90

Epinephrine should be provided to patients at risk for anaphylaxis

	Recommendation	Strength of Recommendation	Certainty of Evidence
CBS 23	We recommend clinicians routinely **prescribe epinephrine to patients at higher risk of anaphylaxis**. When deciding whether to prescribe epinephrine to lower-risk patients, we suggest that clinicians engage in a shared-decision making process that considers the patients' risk factors, values, and preferences.	Conditional	Very low (there are no validated risk-stratification algorithms)

Golden D, et al. *Ann Allergy Asthma Immunol* 2024; 132:124-126

When to Prescribe Epinephrine

	Lower likelihood	Higher likelihood of anaphylaxis
IgE-mediated food allergy		• Hx of prior systemic allergic reaction following exposure
Pollen food allergy syndrome	• No hx of anaphylaxis to causative food	• Hx of anaphylaxis to causative food
Venom or insect bite/sting allergy	• Hx of only large local or cutaneous systemic reaction(s) • Hx of anaphylaxis, but on maintenance VIT or discontinued VIT after more than 5 years of tx with no high-risk factors	• Hx of anaphylaxis, not treated with a complete course of venom immunotherapy (VIT) • Current VIT, with hx of prior systemic reaction(s) to VIT • Honeybee allergy • Elevated basal tryptase level • Frequent exposure
Latex allergy	• Low likelihood of exposure	• Occupational exposure
Drug allergy	• Low likelihood of exposure	• Occupational exposure
Exercise-induced anaphylaxis		• All cases
Physical urticarias		• Cold induced
Aeroallergen immunotherapy	• No hx of prior systemic reaction(s) to AIT and no relevant comorbidities (e.g., asthma)	• Hx of prior systemic reaction(s) to AIT and/or relevant comorbidities (e.g., asthma)

Golden D, et al. *Ann Allergy Asthma Immunol* 2024; 132:124-126

Summary

- A detailed clinical history is critical for informing the diagnostic work-up and for arriving at the correct diagnosis
- Evaluation of skin tests & serum IgE laboratory tests alone are **NOT** sufficient to diagnose food allergy
- While the oral food challenge remains the “gold standard” for diagnosing food allergy, the majority cases can be diagnosed with a thorough medical history & appropriate lab studies
- Once the diagnosis is established, patients must be educated on allergen avoidance, recognition & management of anaphylaxis, and informed about potential treatments available

Thank you

Anaphylaxis

Julie Wang, MD
Professor of Pediatrics
Division of Allergy & Immunology
December 16, 2025

Icahn School of Medicine at Mount Sinai

Objectives

1. Define anaphylaxis
2. Review signs and symptoms of anaphylaxis
3. Discuss management of anaphylaxis with self-administration of epinephrine

Recognizing anaphylaxis

Anaphylaxis definition, overview, and clinical support tool: 2024 consensus report—a GA²LEN project

Timothy E. Dribin, MD, Antonella Muraro, MD, PhD, Carlos A. Camargo Jr, MD, DrPH, Paul J. Turner, FRCPCH, PhD, Julie Wang, MD, Graham Roberts, DM, et al

J Allergy Clin Immunol
August 2025

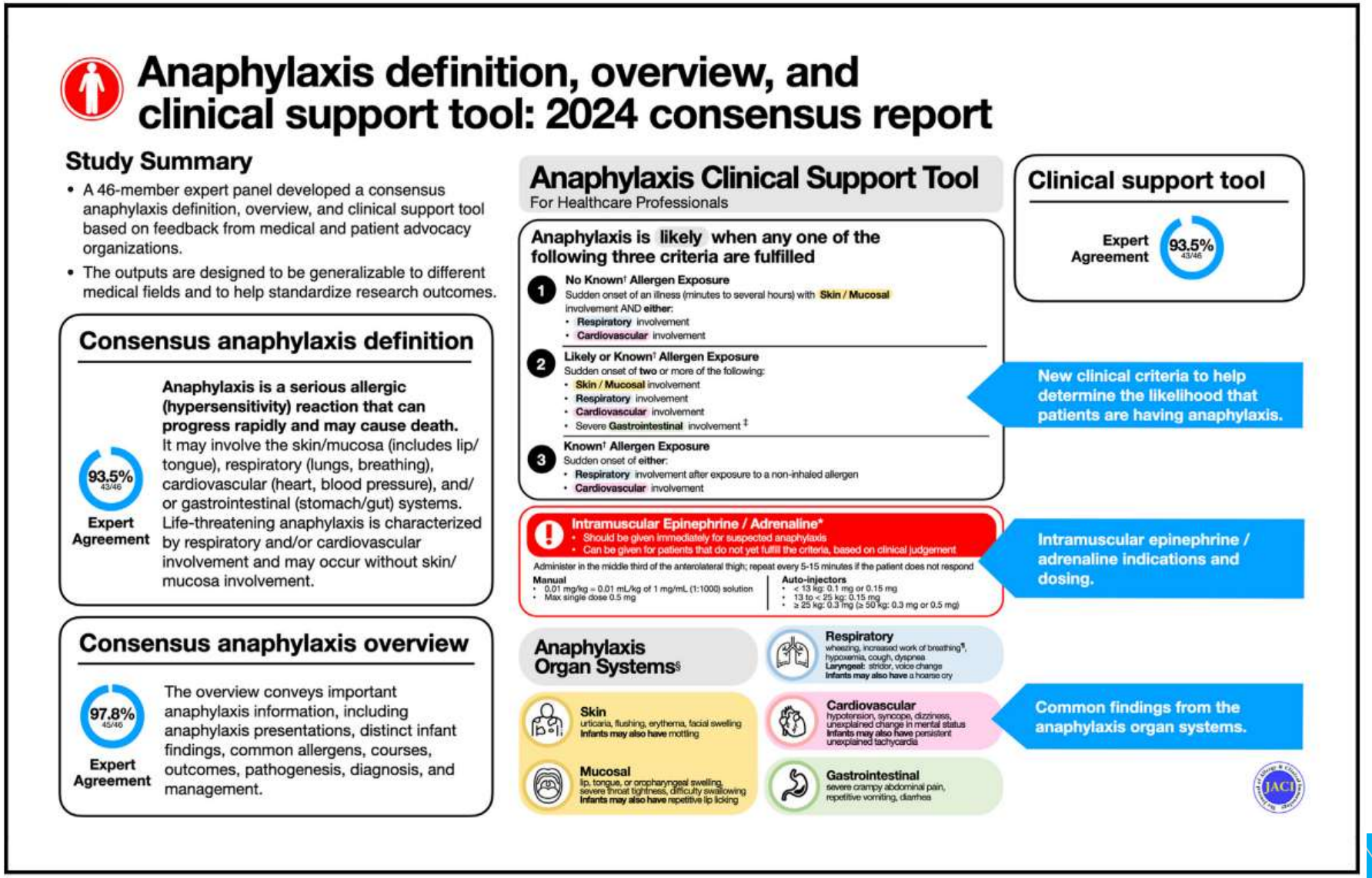


TABLE E2. Expert panel characteristics

Characteristic	No. (%)
Medical specialty*	
Allergy/immunology	40 (87.0)
Anesthesia	2 (4.3)
Emergency medicine	5 (10.9)
Epidemiology, public health	1 (2.2)
Intensive care	2 (4.3)
Primary care	1 (2.2)
Pulmonary	1 (2.2)
Patient population	
Pediatric	27 (58.7)
Adult	4 (8.7)
Pediatric and adult	15 (32.6)
Country of practice/work	
Argentina	1 (2.2)
Australia	3 (6.5)
Canada	2 (4.3)
China	1 (2.2)
Denmark	2 (4.3)
France	3 (6.5)
Germany	3 (6.5)
Italy	3 (6.5)
Japan	2 (4.3)
The Netherlands	1 (2.2)
Spain	4 (8.7)
Sweden	1 (2.2)
United Kingdom	5 (10.9)
United States	15 (32.6)

*Experts may be trained in more than one specialty.

Box 3. Organizations that endorsed study outputs

Medical

American Academy of Allergy, Asthma & Immunology (AAAAI)
American Academy of Pediatrics (AAP)
American Association of Nurse Anesthesiology (AANA)
American Association of Nurse Practitioners (AANP)
American College of Asthma, Allergy & Immunology (ACAAI)
Asia Pacific Association for Adult Allergy and Clinical Immunology (APAACI)
Asia Pacific Academy of Pediatric Allergy, Respirology and Immunology (APAPARI)
Australasian Society for Allergy and Clinical Immunology (ASCIA)
British Society for Allergy & Clinical Immunology (BSCAI)
Canadian Society for Allergy and Clinical Immunology (CSACI)
Chinese Society of Allergy
Emergency Nurses Association (ENA)
European Society for Emergency Medicine (EuSEM)
European Society of Anaesthesiology and Intensive Care (ESAIC)
German Society for Allergology and Clinical Immunology (DGAKI) Deutsche Gesellschaft für Allergologie und klinische Immunologie
National Association of Emergency Medical Technicians (NAEMT)
National Association of EMS Physicians (NAEMSP)
National Association of State EMS Officials (NASEMSO)
Polish Society of Allergology
Society of Critical Care Medicine (SCCM)
Society of Emergency Medicine PAs

Anaphylaxis Definition

Anaphylaxis is a serious allergic reaction that can progress rapidly and may cause death.

It may involve the skin/mucosa (includes lip/tongue), respiratory (lungs, breathing), cardiovascular (heart, blood pressure), and/or gastrointestinal (stomach/gut) systems.

Life-threatening anaphylaxis is characterized by respiratory and/or cardiovascular involvement and may occur without skin/mucosa involvement.

Anaphylaxis Clinical Support Tool

For Healthcare Professionals

Anaphylaxis is **likely** when any one of the following three criteria are fulfilled

1 **No Known† Allergen Exposure**

Sudden onset of an illness (minutes to several hours) with **Skin / Mucosal** involvement AND **either**:

- **Respiratory** involvement
- **Cardiovascular** involvement

---

2 **Likely or Known† Allergen Exposure**

Sudden onset of **two** or more of the following:

- **Skin / Mucosal** involvement
- **Respiratory** involvement
- **Cardiovascular** involvement
- Severe **Gastrointestinal** involvement ‡

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3 **Known† Allergen Exposure**

Sudden onset of **either**:

- **Respiratory** involvement after exposure to a non-inhaled allergen
- **Cardiovascular** involvement

Dribin, TE, et al. J Allergy Clin Immunol 2025

Anaphylaxis Organ Systems§

Skin
urticaria, flushing, erythema, facial swelling
Infants may also have mottling

Mucosal
lip, tongue, or oropharyngeal swelling, severe throat tightness, difficulty swallowing
Infants may also have repetitive lip licking

Respiratory
wheezing, increased work of breathing¶, hypoxemia, cough, dyspnea
Laryngeal: stridor, voice change
Infants may also have a hoarse cry

Cardiovascular
hypotension, syncope, dizziness, unexplained change in mental status
Infants may also have persistent unexplained tachycardia

Gastrointestinal
severe crampy abdominal pain, repetitive vomiting, diarrhea

Epinephrine for anaphylaxis

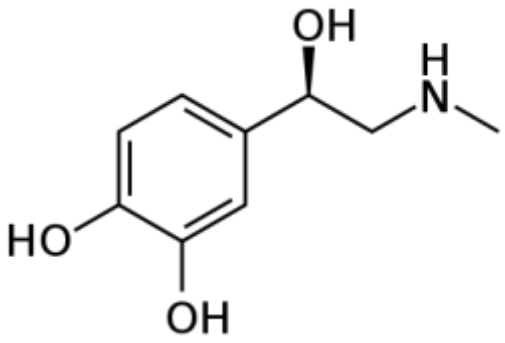
Practice Parameters

Anaphylaxis: A 2023 practice parameter update

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[****];

Ann Allergy Asthma Immunol 132 (2024) 124–176

Epinephrine is first line treatment for anaphylaxis



Mechanism of action
Alpha-adrenergic stimulation:
• increased vascular smooth muscle contraction (vasoconstriction)
• pupillary dilator muscle contraction (mydriasis)
• intestinal sphincter muscle contraction
• decreased edema
Beta-adrenergic stimulation:
Beta-1 receptors
• increased heart rate
• increased myocardial contractility
• renin release
Beta-2 receptors
• bronchodilation
• dose-dependent inhibition of mast cell degranulation
• vasodilation
• tocolysis
• increased aqueous humor production

Lieberman P, et al. Ann Allergy Asthma Immunol 2015

Early use of epinephrine during severe allergic reactions can improve outcomes

Decreased risk of:
✓ Needing additional doses of epinephrine
✓ Biphasic anaphylaxis
✓ Hospitalization
✓ Fatality

	Recommendation	Strength of Recommendation	Certainty of Evidence
CBS 27	Serious adverse reactions to intramuscular epinephrine are **very rare** and should not pose a barrier to the prescription or early administration of epi when indicated.	**Strong**	Low
CBS 6	We suggest that meeting diagnostic criteria for anaphylaxis is **not required** prior to the use of epinephrine.	Conditional	Low

Antihistamines and steroids should not be used in place of epinephrine for anaphylaxis

2015 Anaphylaxis Practice Parameter

- Antihistamines are considered **2nd line**
- Corticosteroids have **no role** in the acute management of anaphylaxis

2020 Anaphylaxis Practice Parameter

- Suggest **against** administering antihistamines and corticosteroids as interventions to prevent biphasic anaphylaxis

Lieberman P, et al. Ann Allergy Asthma Immunol 2015
Shaker MS, et al. J Allergy Clin Immunol 2020

Preparing patients and families to manage anaphylaxis

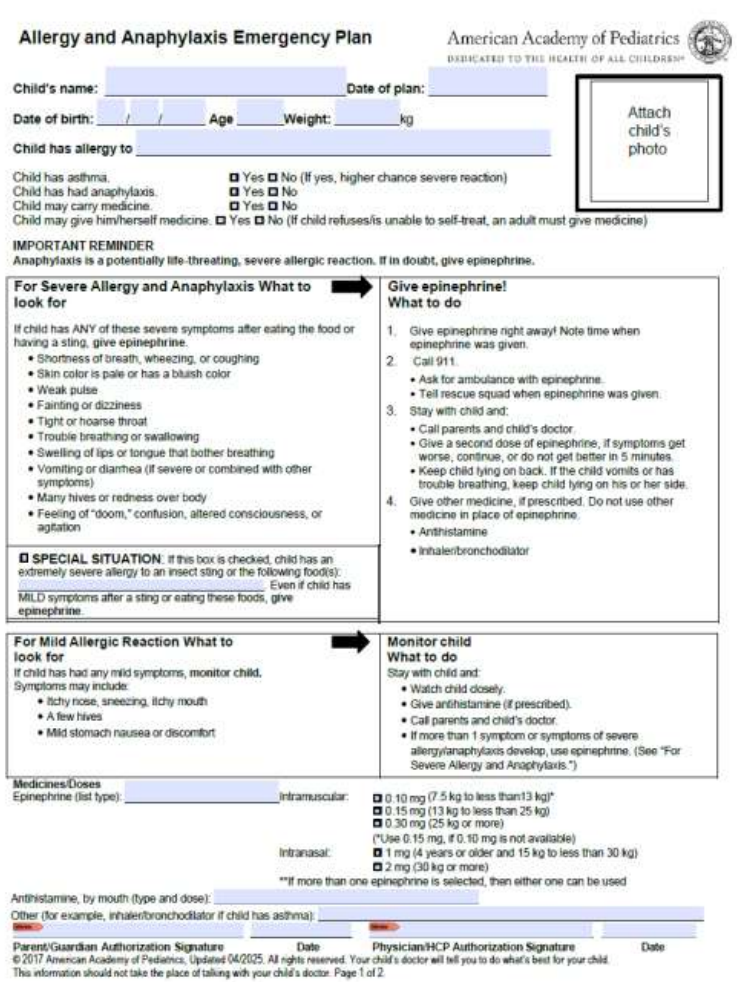
CLINICAL REPORT Guidance for the Clinician in Rendering Pediatric Care

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN™

This Clinical Report was reaffirmed September 12, 2023.

Guidance on Completing a Written Allergy and Anaphylaxis Emergency Plan

Julie Wang, MD, FAAP,[a] Scott H. Sicherer, MD, FAAP,[a,b] SECTION ON ALLERGY AND IMMUNOLOGY



Allergy and Anaphylaxis Emergency Plan

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN™

Child's name: _____ Date of plan: _____

Date of birth: ___/___/___ Age _____ Weight: _____kg

Attach child's photo

Child has allergy to _____

Child has asthma. ☐ Yes ☐ No (If yes, higher chance severe reaction)
Child has had anaphylaxis. ☐ Yes ☐ No
Child may carry medicine. ☐ Yes ☐ No
Child may give him/herself medicine. ☐ Yes ☐ No (If child refuses/is unable to self-treat, an adult must give medicine)

IMPORTANT REMINDER
Anaphylaxis is a potentially life-threating, severe allergic reaction. If in doubt, give epinephrine.

For Severe Allergy and Anaphylaxis What to look for

If child has ANY of these severe symptoms after eating the food or having a sting, **give epinephrine**.
- Shortness of breath, wheezing, or coughing
- Skin color is pale or has a bluish color
- Weak pulse
- Fainting or dizziness
- Tight or hoarse throat
- Trouble breathing or swallowing
- Swelling of lips or tongue that bother breathing
- Vomiting or diarrhea (if severe or combined with other symptoms)
- Many hives or redness over body
- Feeling of "doom," confusion, altered consciousness, or agitation

☐ **SPECIAL SITUATION**: If this box is checked, child has an extremely severe allergy to an insect sting or the following food(s): _____ Even if child has MILD symptoms after a sting or eating these foods, **give epinephrine**.

Give epinephrine!
What to do

1. Give epinephrine right away! Note time when epinephrine was given.
2. Call 911.
   - Ask for ambulance with epinephrine.
   - Tell rescue squad when epinephrine was given.
3. Stay with child and:
   - Call parents and child's doctor.
   - Give a second dose of epinephrine, if symptoms get worse, continue, or do not get better in 5 minutes.
   - Keep child lying on back. If the child vomits or has trouble breathing, keep child lying on his or her side.
4. Give other medicine, if prescribed. Do not use other medicine in place of epinephrine.
   - Antihistamine
   - Inhaler/bronchodilator

For Mild Allergic Reaction What to look for

If child has had any mild symptoms, **monitor child.**
Symptoms may include:
- Itchy nose, sneezing, itchy mouth
- A few hives
- Mild stomach nausea or discomfort

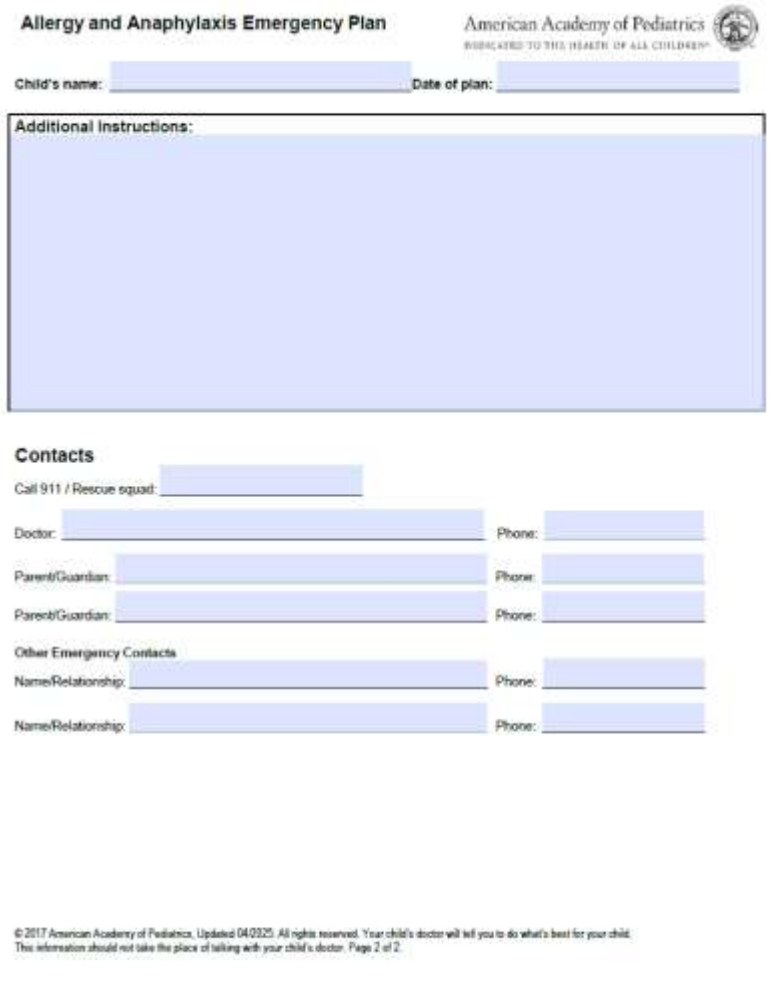
Monitor child
What to do

Stay with child and:
- Watch child closely.
- Give antihistamine (if prescribed).
- Call parents and child's doctor.
- If more than 1 symptom or symptoms of severe allergy/anaphylaxis develop, use epinephrine. (See "For Severe Allergy and Anaphylaxis.")

Medicines/Doses
Epinephrine (list type): _____ Intramuscular: ☐ 0.10 mg (7.5 kg to less than13 kg)* ☐ 0.15 mg (13 kg to less than 25 kg) ☐ 0.30 mg (25 kg or more)
(*Use 0.15 mg, if 0.10 mg is not available)
Intranasal: ☐ 1 mg (4 years or older and 15 kg to less than 30 kg) ☐ 2 mg (30 kg or more)
**If more than one epinephrine is selected, then either one can be used

Antihistamine, by mouth (type and dose): _____
Other (for example, inhaler/bronchodilator if child has asthma): _____

Parent/Guardian Authorization Signature _____ Date _____ Physician/HCP Authorization Signature _____ Date _____



Allergy and Anaphylaxis Emergency Plan

American Academy of Pediatrics
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Child's name: _____ Date of plan: _____

Additional Instructions:

Contacts

Call 911 / Rescue squad: _____

Doctor: _____ Phone: _____

Parent/Guardian: _____ Phone: _____

Parent/Guardian: _____ Phone: _____

Other Emergency Contacts

Name/Relationship: _____ Phone: _____

Name/Relationship: _____ Phone: _____

English – aap.org/aaep
Spanish – aap.org/aaep.spanish

American Academy of Pediatrics

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- Tight or hoarse throat
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- Many hives or redness over body
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   - Antihistamine
   - Inhaler/bronchodilator

For Mild Allergic Reaction
What to look for

If child has had any mild symptoms, **monitor child.**

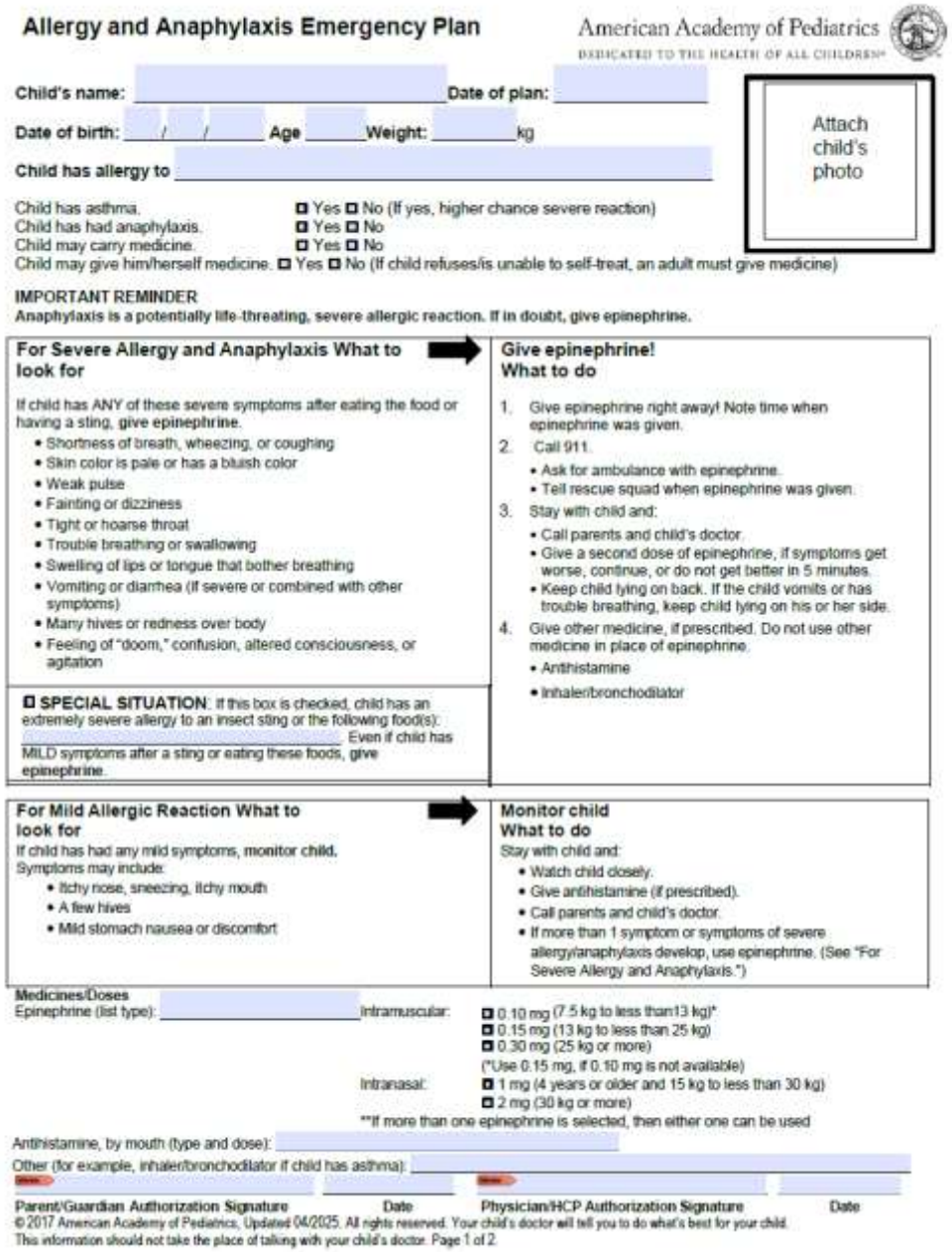
Symptoms may include:

- Itchy nose, sneezing, itchy mouth
- A few hives
- Mild stomach nausea or discomfort

Monitor child
What to do

Stay with child and:

- Watch child closely.
- Give antihistamine (if prescribed).
- Call parents and child's doctor.
- If more than 1 symptom or symptoms of severe allergy/anaphylaxis develop, use epinephrine. (See "For Severe Allergy and Anaphylaxis.")



Allergy and Anaphylaxis Emergency Plan

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN™

Child's name: _____ Date of plan: _____

Date of birth: ___/___/___ Age _____ Weight: _____kg

Child has allergy to _____

Attach child's photo

Child has asthma. ☐ Yes ☐ No (If yes, higher chance severe reaction)
Child has had anaphylaxis. ☐ Yes ☐ No
Child may carry medicine. ☐ Yes ☐ No
Child may give him/herself medicine. ☐ Yes ☐ No (If child refuses/is unable to self-treat, an adult must give medicine)

IMPORTANT REMINDER
Anaphylaxis is a potentially life-threating, severe allergic reaction. If in doubt, give epinephrine.

For Severe Allergy and Anaphylaxis What to look for

If child has ANY of these severe symptoms after eating the food or having a sting, **give epinephrine**.

- Shortness of breath, wheezing, or coughing
- Skin color is pale or has a bluish color
- Weak pulse
- Fainting or dizziness
- Tight or hoarse throat
- Trouble breathing or swallowing
- Swelling of lips or tongue that bother breathing
- Vomiting or diarrhea (if severe or combined with other symptoms)
- Many hives or redness over body
- Feeling of "doom," confusion, altered consciousness, or agitation

☐ **SPECIAL SITUATION**: If this box is checked, child has an extremely severe allergy to an insect sting or the following food(s): _____ Even if child has MILD symptoms after a sting or eating these foods, **give epinephrine**.

Give epinephrine!
What to do

1. Give epinephrine right away! Note time when epinephrine was given.
2. Call 911.
   - Ask for ambulance with epinephrine.
   - Tell rescue squad when epinephrine was given.
3. Stay with child and:
   - Call parents and child's doctor.
   - Give a second dose of epinephrine, if symptoms get worse, continue, or do not get better in 5 minutes.
   - Keep child lying on back. If the child vomits or has trouble breathing, keep child lying on his or her side.
4. Give other medicine, if prescribed. Do not use other medicine in place of epinephrine.
   - Antihistamine
   - Inhaler/bronchodilator

For Mild Allergic Reaction What to look for

If child has had any mild symptoms, **monitor child.**
Symptoms may include:

- Itchy nose, sneezing, itchy mouth
- A few hives
- Mild stomach nausea or discomfort

Monitor child
What to do

Stay with child and:

- Watch child closely.
- Give antihistamine (if prescribed).
- Call parents and child's doctor.
- If more than 1 symptom or symptoms of severe allergy/anaphylaxis develop, use epinephrine. (See "For Severe Allergy and Anaphylaxis.")

Medicines/Doses
Epinephrine (list type): _____

Intramuscular:
☐ 0.10 mg (7.5 kg to less than13 kg)*
☐ 0.15 mg (13 kg to less than 25 kg)
☐ 0.30 mg (25 kg or more)
(*Use 0.15 mg, if 0.10 mg is not available)

Intranasal:
☐ 1 mg (4 years or older and 15 kg to less than 30 kg)
☐ 2 mg (30 kg or more)

**If more than one epinephrine is selected, then either one can be used

Antihistamine, by mouth (type and dose): _____
Other (for example, inhaler/bronchodilator if child has asthma): _____

Parent/Guardian Authorization Signature **Date** **Physician/HCP Authorization Signature** **Date**

Epinephrine is first line treatment for anaphylaxis

Intramuscular:
☐ 0.10 mg (7.5 kg to less than13 kg)*
☐ 0.15 mg (13 kg to less than 25 kg)
☐ 0.30 mg (25 kg or more)
(*Use 0.15 mg, if 0.10 mg is not available)

Intranasal:
☐ 1 mg (4 years or older and 15 kg to less than 30 kg)
☐ 2 mg (30 kg or more)

**If more than one epinephrine is selected, then either one can be used

When to call EMS after epinephrine use

When should EMS be activated after epinephrine use?

	Recommendation	Strength of Recommendation	Certainty of Evidence
CBS 26	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.	Conditional	Very low

Use of multiple epinephrine doses in anaphylaxis: A systematic review and meta-analysis

Check for updates

Nandinee Patel, MD,[a] Kok Wee Chong, MD,[b] Alexander Y. G. Yip, BSc,[c] Despo Ierodiakonou, MD, PhD,[d] Joan Bartra, MD, PhD,[e] Robert J. Boyle, MD, PhD,[a] and Paul J. Turner, FRCPCH, PhD[a] *London, United Kingdom; Singapore; Nicosia, Cyprus; and Barcelona, Spain*

86 studies (36,557 anaphylaxis events) met the inclusion criteria

Epinephrine	Anaphylaxis events
>1 dose	7.7% (95% CI=6.4-9.1)
>2 doses (3 or more)	2.2% (95% CI=1.1-4.1)

>90% treated with 1 dose

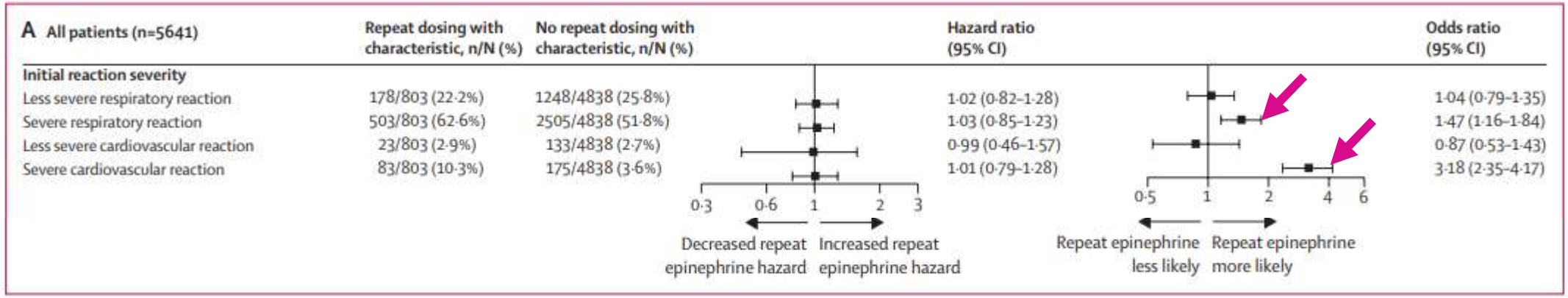
>97% treated with 2 doses

Patients with severe respiratory or cardiovascular symptoms more likely receive repeat epi

- Retrospective cohort study, 2016-2019
- 30 ED in the USA and 1 ED in Canada
- 5641 patients, median age = 7.9 years, 43.9% female

>97% cases treated with 1-2 doses of epinephrine

Figure 3: Predictors of repeat epinephrine



A All patients (n=5641)	Repeat dosing with characteristic, n/N (%)	No repeat dosing with characteristic, n/N (%)	Hazard ratio (95% CI)	Odds ratio (95% CI)
Initial reaction severity				
Less severe respiratory reaction	178/803 (22·2%)	1248/4838 (25·8%)	1·02 (0·82–1·28)	1·04 (0·79–1·35)
Severe respiratory reaction	503/803 (62·6%)	2505/4838 (51·8%)	1·03 (0·85–1·23)	1·47 (1·16–1·84)
Less severe cardiovascular reaction	23/803 (2·9%)	133/4838 (2·7%)	0·99 (0·46–1·57)	0·87 (0·53–1·43)
Severe cardiovascular reaction	83/803 (10·3%)	175/4838 (3·6%)	1·01 (0·79–1·28)	3·18 (2·35–4·17)

Dribin TE, et al. Lancet Child Adolesc Health 2025

Summary points

- Important to teach recognition of signs/symptoms of anaphylaxis and how/when to use epinephrine
- Provide families with allergy and anaphylaxis emergency plans to guide management of allergic reactions
- Home management of anaphylaxis may be an option and requires shared decision-making

Thank you!

Session 1: Allergic Diseases, Anaphylaxis, and Treatment of Anaphylaxis in the Community Setting

Moderator:

- **Paul Greenberger,** Northwestern University

Panelists:

- **Hugh Sampson,** Icahn School of Medicine at Mount Sinai
- **Hemant Sharma,** Children's National Hospital
- **Brian Vickery,** Emory University
- **Julie Wang,** Icahn School of Medicine at Mount Sinai

Moderated Discussion and Q&A

Moderator: Paul Greenberger, Northwestern University

Break

Our program will resume at 10:45 am ET

Session 2: Regulatory Pathways for Epinephrine Products, Including Considerations for Prescription and Nonprescription Development

Moderator: Thomas Roades, Duke-Margolis Institute for Health Policy

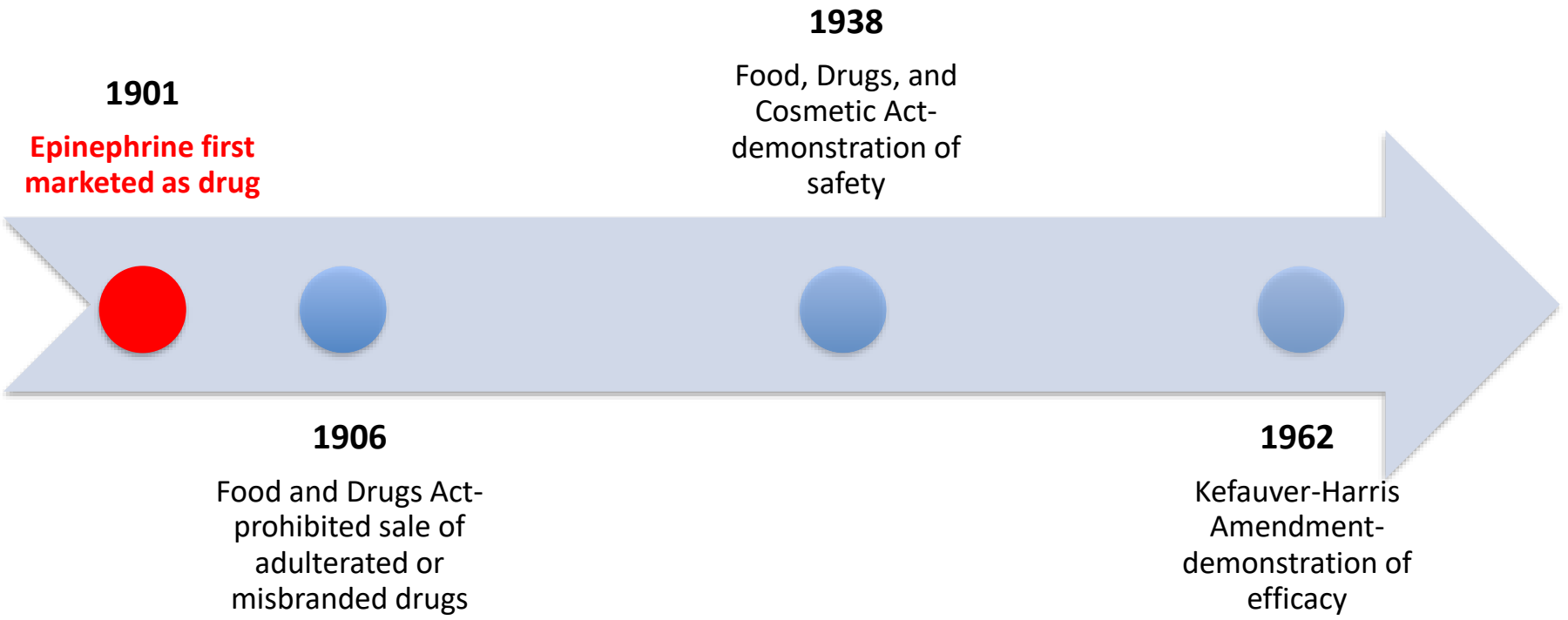
FDA Regulation of Prescription Epinephrine Products for the Treatment of Anaphylaxis

Miya Paterniti, MD
Clinical Team Leader
Division of Pulmonology, Allergy, and Critical Care
Office of Immunology and Inflammation
Office of New Drugs
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Overview

- History of epinephrine
- Approval of epinephrine autoinjectors
- Labeled risks of epinephrine
- Human factors considerations
- Chemistry, manufacturing, and controls
- Alternative routes of epinephrine administration
- Conclusions

FDA History



- **1901**: Parke Davis & Co. first marketed Adrenalin® (epinephrine), predating all major federal drug regulations
  - Epinephrine available as marketed, unapproved product

FDA History | FDA

History of Epinephrine Autoinjectors

- **1970s:** Sheldon Kaplan, et al./Survival Technology invented auto-injector devices for medical and military uses
  - Application to epinephrine administration led to first epinephrine approval (EpiPen)

United States Patent [19]

Kaplan et al.

[11] **4,031,893**

[45] **June 28, 1977**

[54] **HYPODERMIC INJECTION DEVICE HAVING MEANS FOR VARYING THE MEDICAMENT CAPACITY THEREOF**

[75] Inventors: **Sheldon Kaplan**, Potomac; **George B. Calkins**; **Stanley J. Sarnoff**, both of Bethesda; **N. Lawrence Dalling**, Wheaton, all of Md.

[73] Assignee: **Survival Technology, Inc.**, Bethesda, Md.

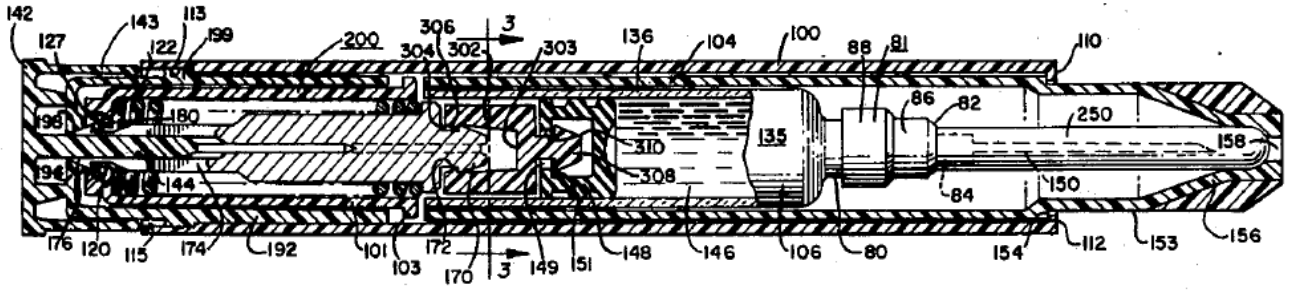
[22] Filed: **May 14, 1976**

[21] Appl. No.: **686,636**

Primary Examiner—John D. Yasko
Attorney, Agent, or Firm—Witherspoon, Lane & Hargest

[57] **ABSTRACT**

A hypodermic injection device comprising a cartridge holder having a cylindrical body open at one end and closed at the other end, the closed end being provided with an aperture, a cartridge with the holder, the cartridge including an ampoule having a cylindrical sleeve open at one end and having a necked portion at the other end to receive a hub mounting a cannula, the cannula facing the apertured end of the cylindrical



Approved Epinephrine Injection Products for Treatment of Anaphylaxis

Product	Year of Approval	Dosage Strength	Indicated Weight
Autoinjectors			
EpiPen/EpiPen Jr	1987	0.15 mg/injection 0.3 mg/injection	15 to < 30 kg ≥ 30 kg
Adrenaclick	2009	0.15 mg/injection 0.3 mg/injection	15 to < 30 kg ≥ 30 kg
Auvi-Q	2012	0.1 mg/injection 0.15 mg/injection 0.3 mg/injection	7.5 to < 15 kg 15 to < 30 kg ≥ 30 kg
Generic epinephrine injection	2018	0.15 mg/injection 0.3 mg/injection	15 to < 30 kg ≥ 30 kg
Pre-Filled Syringe			
Symjepi	2017	0.3 mg/injection	≥ 30 kg
Vial-Syringe (Medical Setting)			
Adrenalin and other epinephrine injections	2012	1 mg/mL	all

Approval of Epinephrine Autoinjectors

- Dose and route of administration supported by >100 years of use and published literature
- Accepted as standard of care for the treatment of anaphylaxis- efficacy and safety
- Autoinjectors are combination drug-device products; review based on:
  - Device review- 99.999% reliable (5- 9s)
  - Product quality and manufacturing review
  - Human factors review
    - Pharmacokinetic data is not required for approval
    - Clinical efficacy studies are not required, and have not been conducted to support approval for any approved epinephrine product

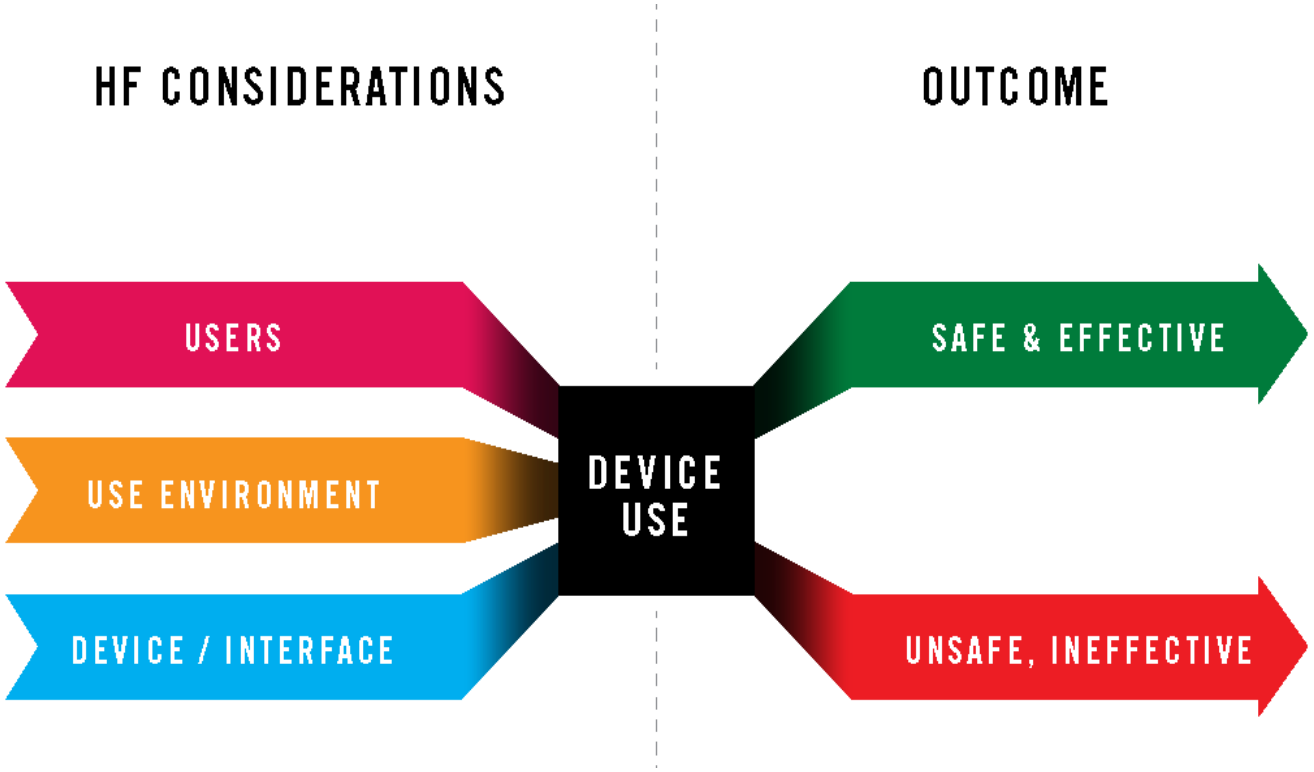
Labeled Risks of Epinephrine

- Cardiovascular
  - Angina, arrhythmias (including fatal ventricular fibrillation), cerebral hemorrhage, hypertension, pallor, palpitations, tachyarrhythmia, tachycardia, vasoconstriction, ventricular ectopy, and stress cardiomyopathy
- Metabolism and Nutrition Disorders
  - Transient hyperglycemia, sweating
- Neurological
  - Disorientation, impaired memory, panic, psychomotor agitation, sleepiness, tingling, weakness
- Psychiatric
  - Anxiety, apprehensiveness, restlessness
- Respiratory
  - Respiratory difficulties

HUMAN FACTORS CONSIDERATIONS

What is ‘Human Factors’?

“Ergonomics (or human factors (HF)) is the scientific discipline concerned with the **understanding of interactions among humans and other elements of a system**, and the profession that applies theory, principles, data and methods to design in order to optimize human well-being and overall system performance.”



Human Factors Validation Studies

- Systematic collection of actual use data from representative participants in realistic situations
- Help determine whether users can safely and correctly perform tasks involved in using the product
- Characterize risks and develop mitigation strategies
- Should be conducted before product is submitted for approval, before any product modifications, or additions to a product line
  - Studies are generally small in size and short in duration (as compared to clinical studies)

CHEMISTRY, MANUFACTURING, AND CONTROLS

Chemistry, Manufacturing, and Controls (CMC)

- Epinephrine readily oxidizes when exposed to air, light, and temperature changes creating multiple degradants, which must be monitored for safety
- Acidic conditions promote the conversion of the active L-form epinephrine to inactive D-form, reducing effectiveness
- Medication may contain too much inactive form or harmful impurities to be reliably effective

Chemistry, Manufacturing, and Controls (CMC) Contd.

- Manufacturers must provide stability testing data demonstrating the product maintains strength, quality, and purity throughout its shelf-life
- FDA examines epinephrine concentration, impurity levels, degradation products, and antioxidant content
- Testing must account for various storage conditions that affect medication stability
- FDA sets conservative expiration dates based on rigorous testing standards to ensure efficacy and safety

Potential Development Strategies to Address *R*-Epinephrine Solution Instability

- Explore new routes of administration (e.g., nasal, sublingual) that may not require solution formulations
- Develop dosage forms with dry formulations
- Employ prodrug strategies
- Use of complexing agents (e.g., crown ethers, β-cyclodextrin) to reduce *R*-epinephrine's susceptibility to degradation in solution
- Explore use of non-sulfite antioxidants
- Use excipients with low levels of oxidants and metal ions

ALTERNATIVE ROUTES OF EPINEPHRINE ADMINISTRATION

Alternative Routes of Epinephrine Administration

- Alternative routes explored include:
  - Intranasal
  - Sublingual
  - Inhaled
- Potential Advantages
  - Improved compliance; earlier administration; higher carriage rate
- Limitations
  - Local adverse effects; diminished depot effect; impact of mucosal abnormalities on absorption; challenges administering in anaphylaxis (effort-dependent in some cases)

Alternative Routes for Epinephrine Administration Contd.

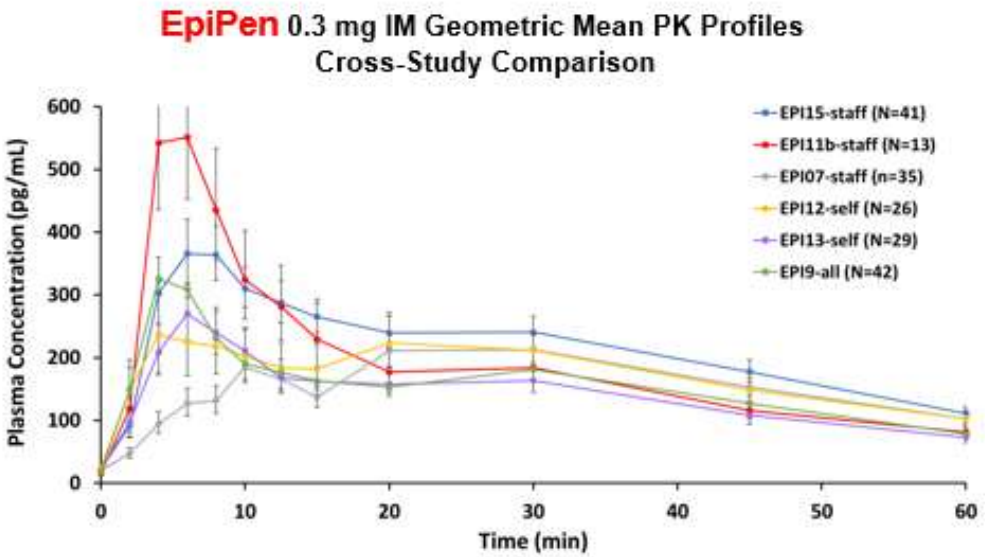
- Regulatory review:
  - Efficacy based on PK ≥ PK for approved epinephrine injection products, with supportive hemodynamic PD (HR, SBP, DBP)
  - Systemic safety based on PK bracketing between PK for approved injection products
  - Local safety based on adverse events reported during development programs
  - PK/PD studies performed in healthy volunteers and in allergic patients with local allergic reactions
  - No clinical efficacy studies required
  - Approach discussed at Pulmonary-Allergy AC meeting on May 11, 2023

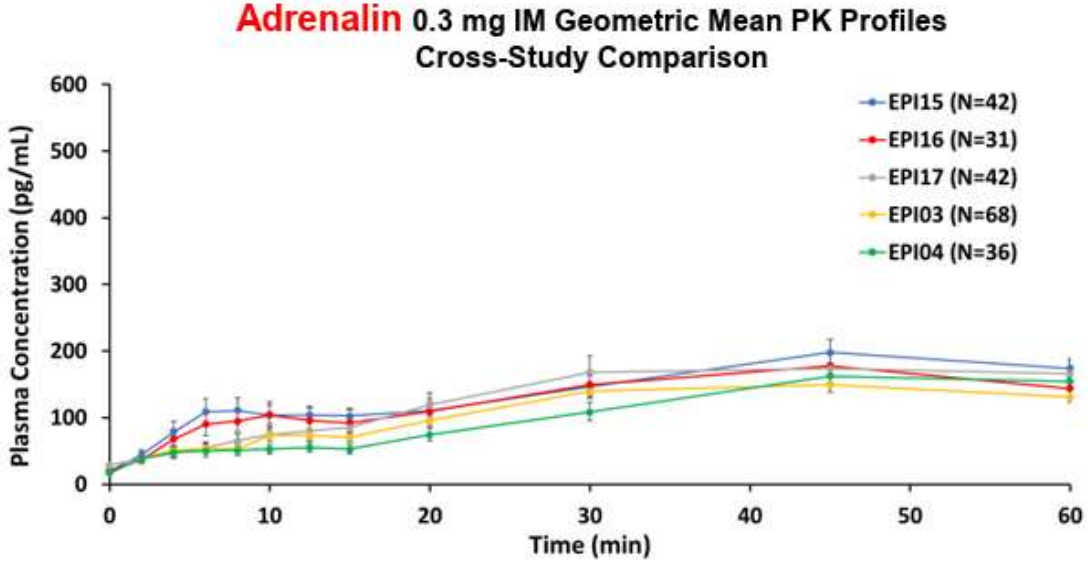
Abbreviations: AC, advisory committee; DBP, diastolic blood pressure; HR, heart rate; PD, pharmacodynamic; PK, pharmacokinetic; SBP, systolic blood pressure

Challenges with Regulatory Review of Alternative Routes of Epinephrine

- Limited PK and PD data, and most in healthy volunteers
- No dose ranging studies for epinephrine injection- optimal dose in the setting of anaphylaxis is not established
- PK of epinephrine injection products is highly variable
  - Impact of needle length on delivery
  - Impact of device (autoinjector versus vial-syringe) on delivery- force of injection, angle, etc.
  - Others?

Pharmacokinetics for Epinephrine Injection Products





- Autoinjectors (EpiPen) with early Tmax and higher Cmax, possibly related to force and speed of administration
- Manual syringe (Adrenalin) administration with late Tmax and lower Cmax compared to autoinjectors
- Biphasic absorption has been reported
- High intra- and inter-subject variability

Source: Meeting of the Pulmonary-Allergy Drugs Advisory Committee – FDA presentation, May 11, 2023.

Approved Epinephrine Products

Product	Year of Approval	Dosage Strength	Indicated Weight
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Symjepi	2017	0.3 mg/injection	≥ 30 kg
Vial-Syringe (Medical Setting)			
Adrenalin and other epinephrine injections	2012	1 mg/mL	all
Epinephrine nasal spray			
Neffy	2024	1 mg/spray 2 mg/spray	15 to < 30 kg ≥ 30 kg

Conclusions

- Epinephrine predates modern drug regulations
- Efficacy and safety relies on ≥ 100 years of clinical use and literature
- Epinephrine injection products require human factors, device reliability, and chemistry, manufacturing, and controls to support approval
- Alternative routes of epinephrine approval based on PK bridging with supportive PD to approved epinephrine injection products resulting in approval of epinephrine nasal spray


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U.S. FOOD & DRUG
ADMINISTRATION

Switching a Drug from Prescription-Only Status to Nonprescription Status, with Some Considerations for Epinephrine

Karen Minerve Murry, MD, FACE
Acting Director, Office of Nonprescription Drugs
Office of New Drugs
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

When is a Drug Considered Nonprescription?

Durham-Humphrey Amendment (1951)

Establishment of Two Drug Classes

- Prescription (Rx) Legend
  - Requires practitioner supervision, because of toxicity or potentiality for harmful effect, or method of use
  - Labeling indicates that it is by prescription only

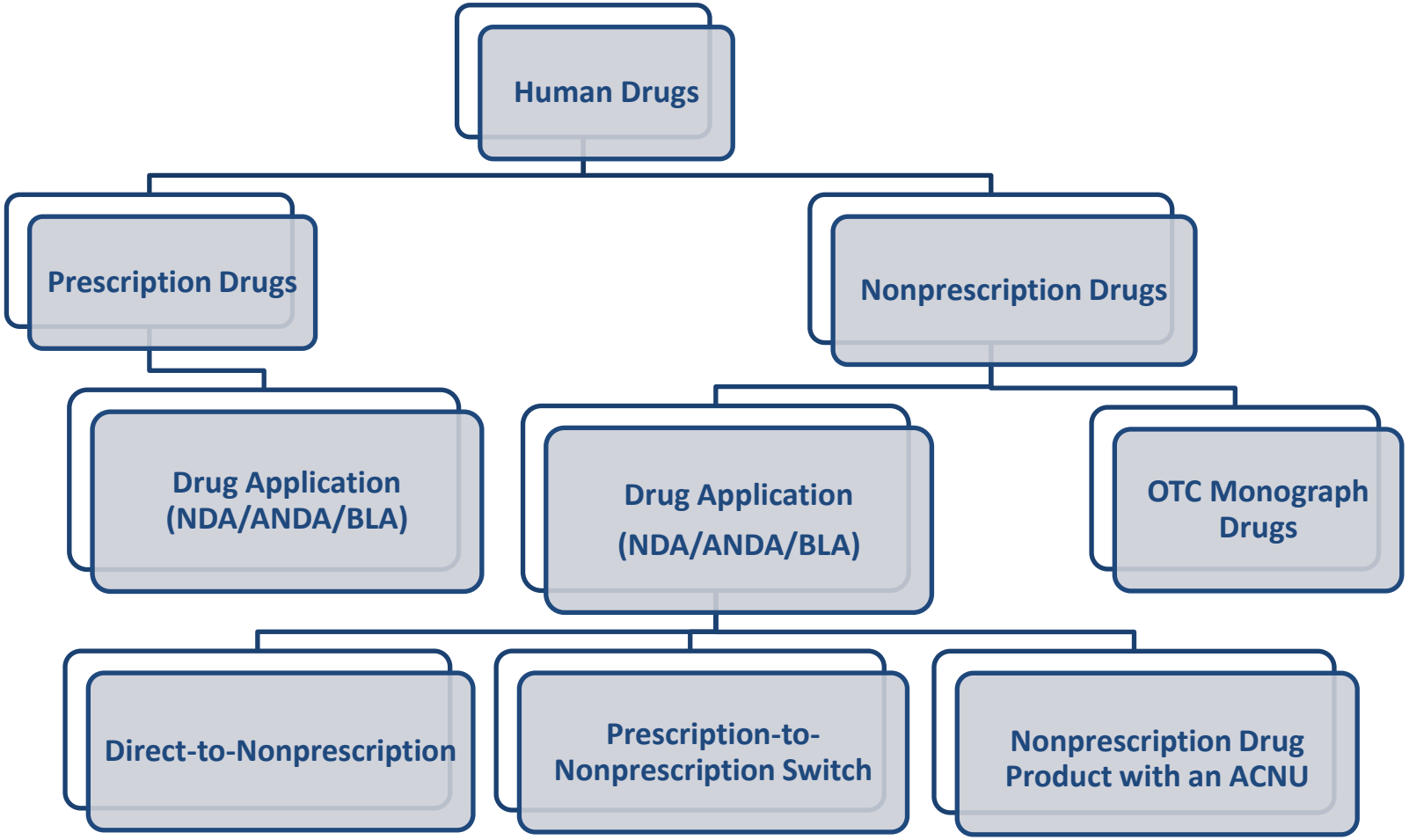
- Nonprescription (Over-the-Counter (OTC))
  - Drugs that do not meet the definition for Rx

Characteristics of Nonprescription Drug Products

- Safety margin is such that the benefits of nonprescription availability outweigh the risks
- Consumer can self-diagnose, self-treat, and self-manage the condition being treated
- Low potential for misuse and abuse
- Does not require a healthcare practitioner for safe and appropriate use
- Labeling is adequate to enable consumers to:
  - Self-diagnose and self-select
  - Use properly as directed by the label
  - Know when to stop use or contact a healthcare practitioner

Often requires consumer studies to support this

Drug Development Pathways



Abbreviations: ACNU, Additional condition for nonprescription use; ANDA, Abbreviated New Drug Application; BLA, Biological License Application; NDA, New Drug Application; OTC, Over-the-Counter

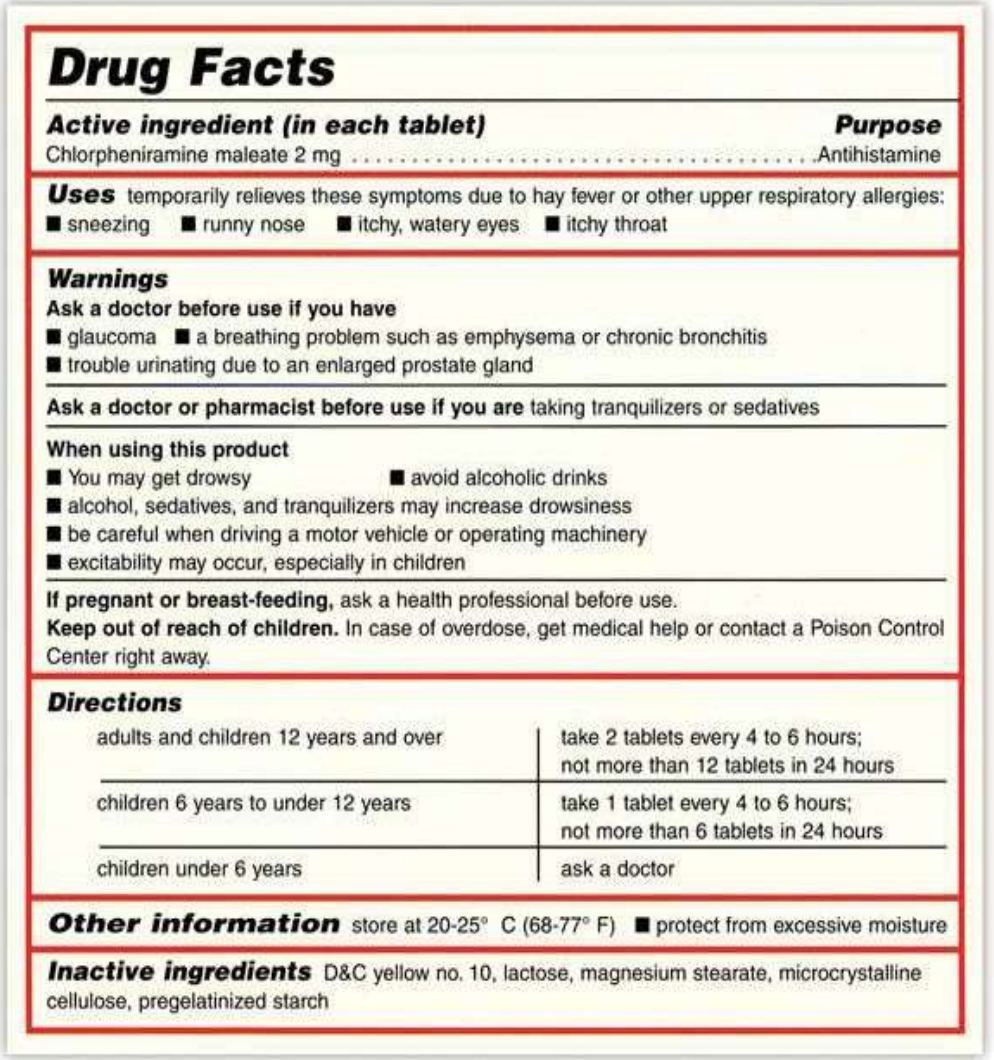
Development Programs for Prescription-to-Nonprescription Switch

- Often rely on safety and efficacy established for the prescription product
- New clinical studies may be required, such as when proposing a new indication or a new patient population
- Need to “translate” key elements of the prescription label into consumer-friendly terms
- Consumer studies are needed to evaluate the suitability of the product for use in the nonprescription setting
- Issues to be addressed are identified from prescription label and clinical use of product

Drug Facts Labeling

- Nonprescription drug products must comply with Code of Federal Regulations labeling requirements, including meeting Drug Facts labeling (DFL) requirements

- The DFL is intended to help enable consumers to self-select appropriately and use the nonprescription drug product safely and effectively, without assistance from a healthcare practitioner



Drug Facts

Active ingredient (in each tablet) — **Purpose**
Chlorpheniramine maleate 2 mg ..... Antihistamine

Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
- sneezing
- runny nose
- itchy, watery eyes
- itchy throat

Warnings

Ask a doctor before use if you have
- glaucoma
- a breathing problem such as emphysema or chronic bronchitis
- trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives

When using this product
- You may get drowsy
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

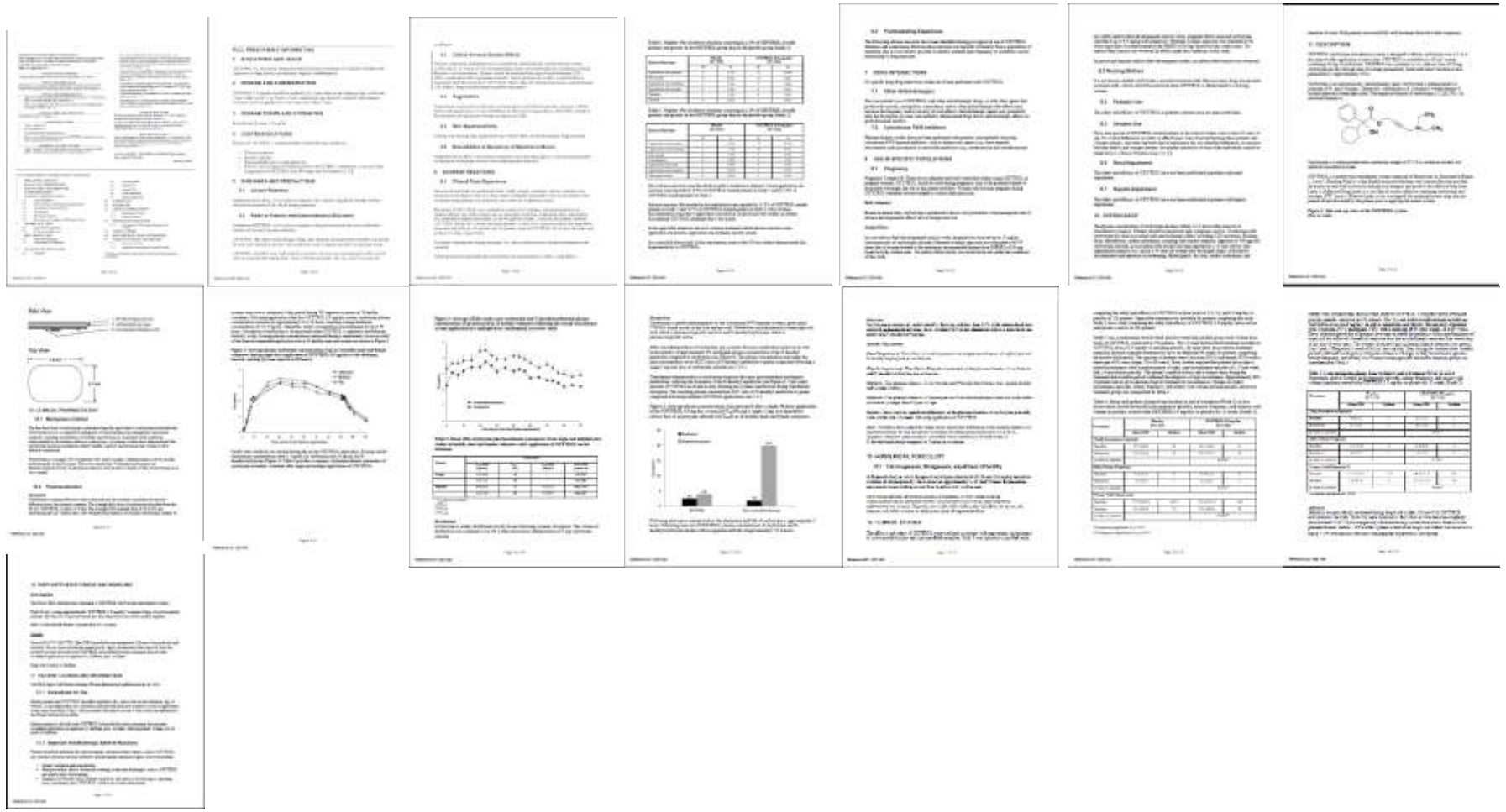
adults and children 12 years and over	take 2 tablets every 4 to 6 hours; not more than 12 tablets in 24 hours
children 6 years to under 12 years	take 1 tablet every 4 to 6 hours; not more than 6 tablets in 24 hours
children under 6 years	ask a doctor

Other information store at 20-25° C (68-77° F) ■ protect from excessive moisture

Inactive ingredients D&C yellow no. 10, lactose, magnesium stearate, microcrystalline cellulose, pregelatinized starch

Image found at:
http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143551.htm

Rx Labeling is Typically Lengthy and Challenging to Condense into a Consumer-Friendly DFL



Nonprescription Consumer Studies

Label Comprehension Study

- Understanding the key label message

Self- Selection Study

- Choosing the right product

Actual Use Study

- Using according to labeled directions

Human Factors Study

- Interacting with the product

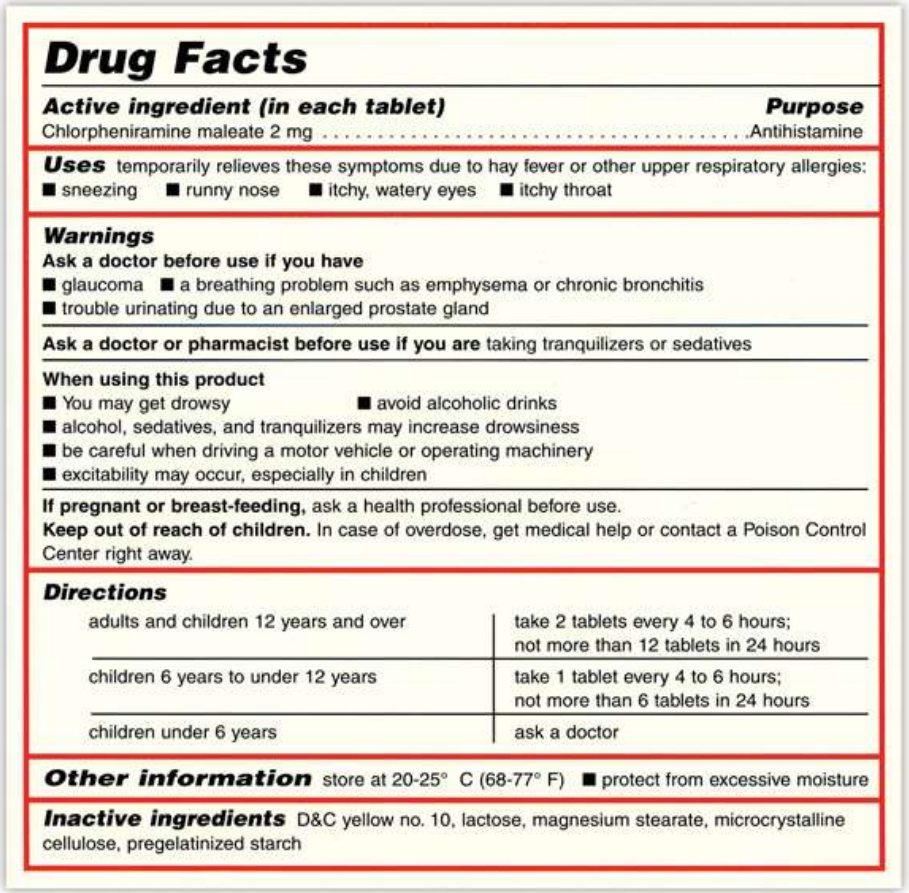
What Dosage Forms are Suitable for Prescription-to-Nonprescription Switch?

- Any approved dosage form is a possible switch candidate
- Sponsor must provide adequate data to support that consumers can correctly administer the drug by following the directions
- If there are unique attributes for administration of the drug, the sponsor needs to develop and test a user-friendly format for the labeling/packaging

Challenges for "Traditional" Prescription-to-Nonprescription Switch

Until recently:

- Traditionally had to rely on nonprescription labeling alone for purchase decision, and for safe/effective use
- The existing regulations made it difficult for FDA to consider other means of improving safe and effective use



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Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

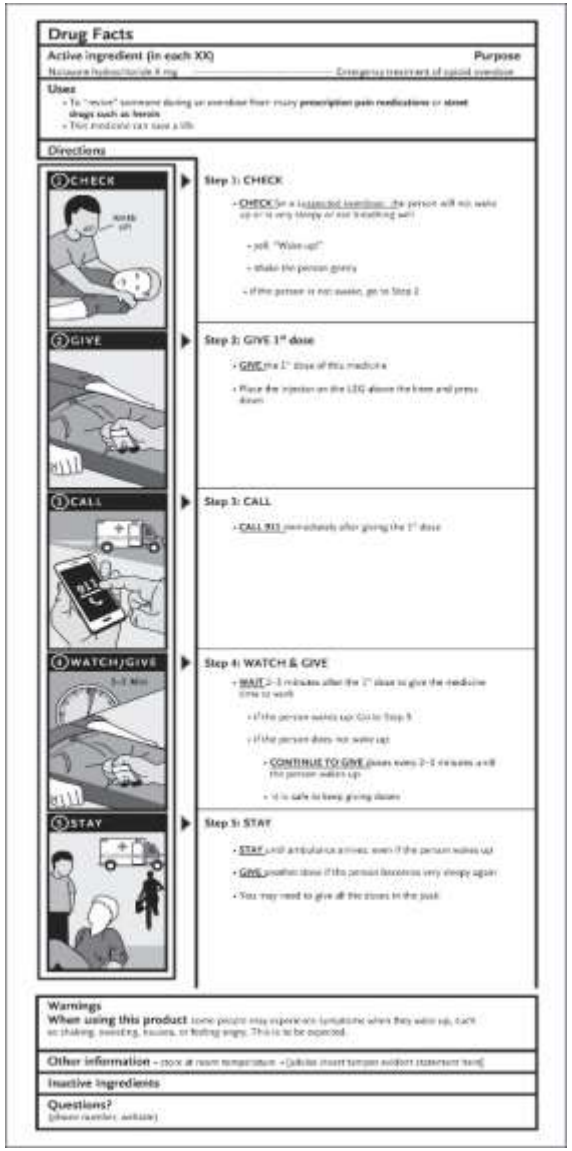
Directions

adults and children 12 years and over	take 2 tablets every 4 to 6 hours; not more than 12 tablets in 24 hours
children 6 years to under 12 years	take 1 tablet every 4 to 6 hours; not more than 6 tablets in 24 hours
children under 6 years	ask a doctor

Other information store at 20-25° C (68-77° F) ■ protect from excessive moisture

Inactive ingredients D&C yellow no. 10, lactose, magnesium stearate, microcrystalline cellulose, pregelatinized starch

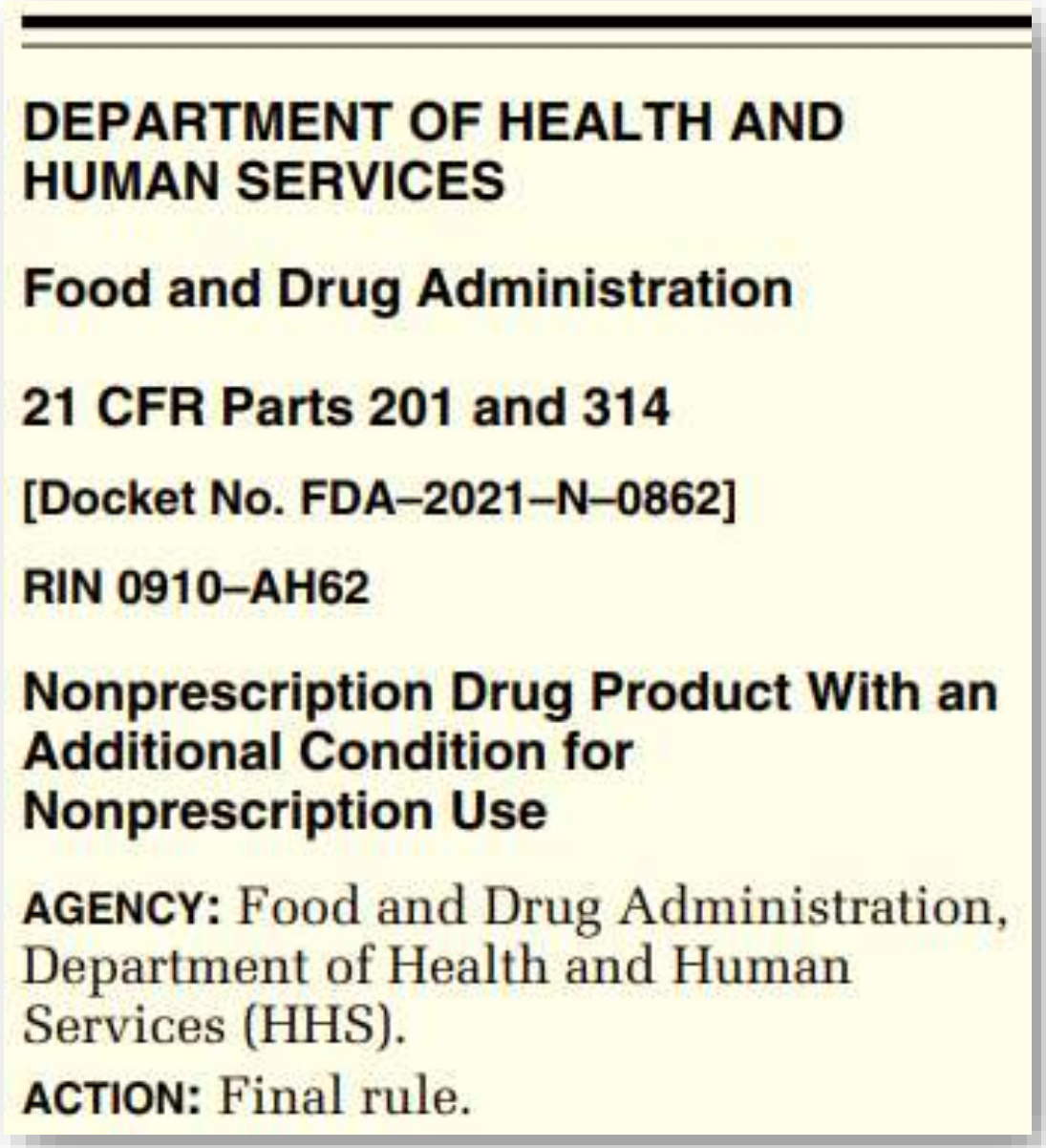
Potentially Useful Prior FDA Initiative- Nonprescription Naloxone



Possible Use of Technology to Address Nonprescription Labeling Challenges

- In what other ways can information be delivered to consumers to ensure appropriate self-selection and appropriate use of nonprescription drug products?
- How can technology be leveraged to develop innovative approaches to nonprescription drug products?

Additional Condition for Nonprescription Use (ACNU) Rule



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 201 and 314

[Docket No. FDA–2021–N–0862]

RIN 0910–AH62

Nonprescription Drug Product With an Additional Condition for Nonprescription Use

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Final rule.

- Final rule to increase options for the development and marketing of safe and effective nonprescription drug products
- Published December 26, 2024; effective date May 27, 2025
- Establishes requirements for a nonprescription drug product with an additional condition for nonprescription use (ACNU) that an applicant must implement to ensure appropriate self-selection or appropriate actual use, or both, by consumers without the supervision of a healthcare practitioner

Possible Challenges for Development of a Nonprescription Epinephrine Drug Product

We would like input on possible challenges, but here are a few to begin with:

- Serious adverse effects, particularly cardiovascular
- Given in a stressful emergency situation
- Possible challenges in condensing lengthy Rx label into small but adequate DFL
- User might not read the labeling ahead of time- must be able to figure it out quickly
- Often given by the person experiencing the allergic reaction, but might be given by a bystander with no prior experience with epinephrine
- Unforeseen challenges?

We want to hear a wide array of ideas for expanding epinephrine access, with a possible future nonprescription drug product being only one of the areas of discussion.


FDA
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ADMINISTRATION

Session 2: Regulatory Pathways for Epinephrine Products, Including Considerations for Prescription and Nonprescription Development

Moderator:

- **Thomas Roades,** Duke-Margolis Institute for Health Policy

Panelists:

- **Carla Davis**, Howard University
- **Paul Greenberger**, Northwestern University
- **Alice Hoyt**, Code Ana
- **Karen Murry,** U.S. Food and Drug Administration
- **Miya Paterniti,** U.S. Food and Drug Administration
- **Kelly Stone**, U.S. Food and Drug Administration

Moderated Discussion and Q&A

Moderator: Thomas Roades, Duke-Margolis Institute for Health Policy

Lunch Break

Our program will resume at 1:20 pm ET

Public Comment Session

Moderator: Brian Canter, Duke-Margolis Institute for Health Policy

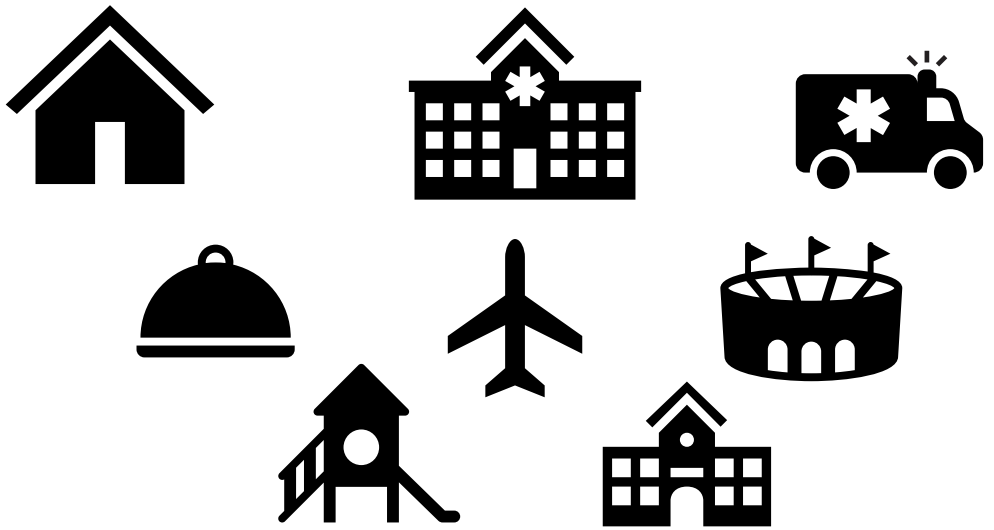
Session 3: Current Accessibility to Epinephrine for Treating Anaphylaxis

Moderator: Michael Pistiner, Massachusetts General Hospital for Children

Accessibility to Epinephrine for Treating Anaphylaxis

Patient Factors

Setting



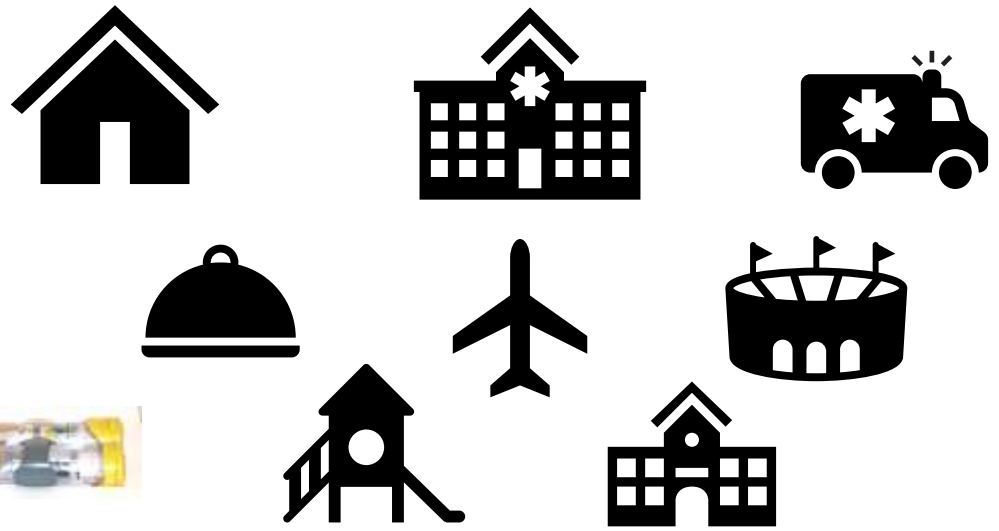
Cost/Insurance/Availability

Training/Preparation

Accessibility to Epinephrine for Treating Anaphylaxis

Patient Factors

Setting



Cost/Insurance/Availability

Training/Preparation

Session 3: Current Accessibility to Epinephrine for Treating Anaphylaxis

Moderator:

- **Michael Pistiner,** Massachusetts General Hospital for Children

Panelists:

- **Kelly Cleary,** Food Allergy Research and Education
- **Ruchi Gupta,** Northwestern University
- **Linda Herbert,** Children's National Hospital
- **Charity Luiskutty,** Food Allergy & Anaphylaxis Connection Team
- **Christopher Warren,** Northwestern University

Moderated Discussion and Q&A

Moderator: Michael Pistiner, Massachusetts General Hospital for Children

Break

Our program will resume at 3:20 pm ET

Session 4: Opportunities to Enhance Access to and Use of Epinephrine

Moderator: Julie Wang, Icahn School of Medicine at Mount Sinai

Session 4: Opportunities to Enhance Access to and Use of Epinephrine

Moderator:

- **Julie Wang,** Icahn School of Medicine at Mount Sinai

Panelists:

- **Timothy Dribin,** Cincinnati Children's Hospital Medical Center
- **Matthew Greenhawt,** Asthma and Allergy Foundation of America
- **Nissa Shaffi,** Allergy & Asthma Network
- **Marcus Shaker,** Dartmouth College

Moderated Discussion and Q&A

Moderator: Julie Wang, Icahn School of Medicine at Mount Sinai

Closing Remarks

Karen Murry, U.S. Food and Drug Administration

Thank You!

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healthpolicy.duke.edu

Subscribe to our monthly newsletter at dukemargolis@duke.edu

1201 Pennsylvania Avenue, NW,
Suite 500 • Washington, DC 20004

DC office: 202-621-2800
Durham office: 919-419-2504

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