

## Improving Anaphylaxis Outcomes: Approaches for Enhancing Access to Epinephrine

Hybrid Meeting | Duke in DC Office

December 16, 2025 | 9:00 AM – 4:30 PM ET

### Discussion Guide

#### Background and Event Objectives

Anaphylaxis is a severe, progressive allergic reaction that can be fatal if not promptly treated with epinephrine. Failure to treat anaphylaxis within minutes can lead to airway obstruction, shock and multi-organ failure. Despite being the only effective first-line treatment approved by the Food and Drug Administration (FDA), barriers may limit access to and use of epinephrine. For example, patients and caregivers may experience challenges in determining whether and how to administer epinephrine to treat an anaphylactic reaction. Institutional barriers may also inhibit access to and use of epinephrine in community settings, such as schools, workplaces, restaurants and other public venues. Additionally, there are potential procedural barriers to obtain authorization from a health care professional before carrying epinephrine. These barriers may be magnified in communities with limited health care infrastructure, and by the cost of epinephrine products. While Federal and state legislation has sought to expand access to epinephrine by directly addressing barriers to use, additional policy and regulatory solutions may be needed to help ensure life-saving treatment for anaphylaxis is readily available when needed in an emergency to improve anaphylaxis outcomes.

This hybrid public workshop will initiate a discussion on expanding epinephrine accessibility and use, including in community settings, to reduce anaphylaxis-related morbidity and mortality. Prospective approaches intended to improve anaphylaxis outcomes include but are not limited to expanding training on use, enhancing civil liability protections for administrators of epinephrine, incentivizing availability in public spaces, and considering development of epinephrine for nonprescription use.

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

This session will feature presentations on the latest clinical guidelines and current practices for diagnosing allergic diseases and anaphylaxis. Panel discussion will explore how these practices are referenced to advise individuals on when to carry and administer epinephrine. Challenges to recognizing anaphylaxis and challenges experienced by individuals carrying epinephrine or administering undesigned epinephrine will also be explored.

#### Discussion Questions

1. How do you decide when to prescribe epinephrine to patients for emergency use in the community setting?
2. How do you counsel patients or caregivers to recognize anaphylaxis, and when they should administer epinephrine in community settings?
3. How do you advise patients when to seek emergency medical care after treatment with epinephrine?

4. What do you advise patients to do if they have persistent symptoms or recurring anaphylactic reactions after an initial dose of epinephrine administration?
5. What other conditions present similarly to anaphylaxis and what are the clinical implications for use of epinephrine in those settings?
6. How does the treatment of anaphylaxis vary between adults and children?
7. Discuss the benefit-risk assessment for using epinephrine to treat anaphylaxis in populations at greater risk from adverse reactions, e.g., cardiovascular diseases. Is there a higher threshold for use?

### **Session II: Regulatory Pathways for Epinephrine Products, Including Considerations for Prescription and Nonprescription Development**

This session will cover the regulatory pathway for approval of epinephrine products for treatment of anaphylaxis in the community setting and the risk-benefit considerations for epinephrine use as a prescription or nonprescription drug. Discussion will include the available dosage forms, delivery devices, use in adults versus pediatrics, data requirements to demonstrate that a drug is appropriate for nonprescription use, including assessments of consumer behavior as well as the capacity for consumers to self-diagnose allergies associated with anaphylaxis and self-diagnose anaphylaxis.

#### *Discussion Questions*

1. What is a layperson's ability to self-diagnose allergic diseases associated with anaphylaxis without the oversight of a healthcare professional?
2. What is a layperson's ability to successfully achieve the following steps without the oversight of a healthcare professional: 1) recognize the key indicators of anaphylaxis, 2) know when epinephrine should be administered, and 3) know when to seek emergency care?
3. What would be the advantages and disadvantages of nonprescription epinephrine for different epinephrine delivery devices and routes of administration, and for different populations (e.g. children versus adults, considering the presence of risk factors for severe disease such as cardiovascular disease or use of drugs that interfere with epinephrine efficacy, e.g., beta blockers)?
4. What are the elements of epinephrine's prescribing information that would be the most challenging to translate to a Drug Facts label? Are there other educational resources that would be needed to support nonprescription use?
5. What would be potential unintended consequences of nonprescription epinephrine availability?

### **Session III: Current Accessibility to Epinephrine for Treating Anaphylaxis**

This session will include discussions on the available data to assess barriers with obtaining, carrying, and using epinephrine. Panelists will consider the institutional barriers presented in community settings and by differing state immunity laws. Panelists will explore why patients may decide not to use epinephrine during anaphylaxis despite carrying it. There will also be consideration for challenges in accessing care and the need for a prescription to acquire epinephrine.

#### *Discussion Questions*

1. What is the current state of patient access to epinephrine, and differences for children versus adults?

2. What are the barriers to epinephrine access and use? Discuss available data regarding barriers to epinephrine access.
3. How have previously implemented efforts impacted access to epinephrine?
4. What role have state and Federal legislation played in enhancing patient access to epinephrine in community settings like schools, recreational facilities, and airplanes?

#### **Session IV: Opportunities to Enhance Access to and Use of Epinephrine**

This session will examine promising approaches to increase access to and use of epinephrine, along with the authorities governing those measures. Reflecting on prior discussions, panelists will consider how various interventions may improve epinephrine access. Potential interventions include, but are not limited to, increased availability of methods for administration and educational resources informed by the latest clinical guidelines. Panelists will also discuss the feasibility of potential policy actions and the potential impact on anaphylaxis outcomes.

#### *Discussion Questions*

1. What other policy and regulatory approaches may enhance patient access to epinephrine, and which stakeholders could contribute to these policy and regulatory approaches?
2. How could new technologies help improve patient understanding and outcomes in anaphylaxis emergencies?
3. What initial steps can stakeholders prioritize to address barriers to epinephrine access and use?
4. What further research needs to be done to fill knowledge gaps related to patient access to and use of epinephrine?

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