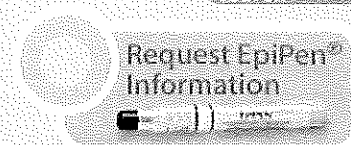


EPIPEN ADMINISTRATION CLASS

OBJECTIVES

- Teach general principles of medication administration of Epi-pen (injectable epinephrine) to staff members.
- Discuss the rise of anaphylactic reactions within the United States, statistics provided by Anaphylaxis.com.
- Teach staff members the definition of allergy. Discuss differences between intolerance vs. allergy.
- Teach staff members the common causes of anaphylaxis: common foods, latex, medications and insect bites.
- Have the staff members verbalize the common symptoms of anaphylactic reactions and emphasize the importance of administering the Epi-pen as quickly as possible to the anaphylactic child.
- The Epi-pen is to be given only to the child whom it is ordered for, checking the “5 rights” before administering the medication:
 - **RIGHT CHILD**
 - **RIGHT MEDICATION**
 - **RIGHT TIME**
 - **RIGHT DOSE**
 - **RIGHT ROUTE.**
- Teach staff members to call E.M.S. whenever an anaphylactic reaction is suspected, even if the Epi-pen was ordered and given to the child.
- Have the staff demonstrate correct technique of the Epi-pen (with a trainer).
- Describe proper storage (locked cabinet, protected from heat and light).
- Proper documentation of the Epi-pen use.

Welcome to Anaphylaxis.com



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Welcome Health Care Professionals!

Anaphylaxis is a life-threatening allergic reaction that affects millions of Americans every year. Anaphylaxis can be caused by a variety of allergens, with the most common being food, medications, insect venom, and latex. The definitive treatment for anaphylaxis is epinephrine, and all patients at risk for experiencing anaphylaxis are urged to carry self-injectable epinephrine such as EpiPen® epinephrine auto-injectors. Side effects of epinephrine may include palpitations, tachycardia (an abnormally fast heartbeat), sweating, nausea and vomiting, and respiratory difficulty. Cardiac arrhythmias may follow administration of epinephrine. Patients should ask their physician about the circumstances under which this life-saving medication should be used.

As a professional courtesy to the busy clinician, we are pleased to provide you with the opportunity to utilize practice tools such as case studies and questionnaires to determine if your patients are at risk of experiencing anaphylaxis. We also have information on current treatment guidelines, as well as resources related to anaphylaxis, such as a slide presentation and a bibliography.

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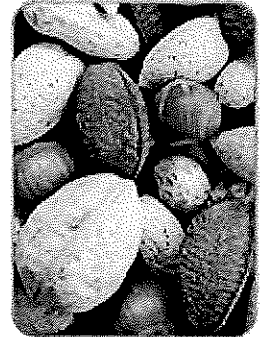
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Food

Food allergy is the most common cause of anaphylaxis outside of the hospital.^{1,2} Experts estimate that from 2% to 2.5% of the general population, or 5.4 to 7 million Americans have food allergies.³ About 3 million of these are believed to be allergic to peanuts or tree nuts alone.³ Food allergy is an increasingly common cause of anaphylaxis that results in about 125 deaths each year in the United States.⁴ Some allergists believe that this perceived rise in incidence may be attributed to children's increased exposure to certain foods, such as peanuts, before their immune systems are mature enough to handle them.^{5,6}



Most food allergies are caused by eight common foods. Some of the symptoms of an allergic reaction to foods may resemble a food intolerance, and it often takes a skilled physician to diagnose a food allergy. Once diagnosed, a physician should guide the patient to the best treatment and prevention practices.

Definition

Having a food allergy, as with any other severe allergy, means that a person's immune system reacts to a protein, in this case in food, as a threatening foreign substance and primes the body's defenses against it by producing IgE antibodies.

IgE antibodies, once formed, attach to tissue mast cells on body surfaces so that they stand ready to react when the allergen is reintroduced. On re-exposure to the allergen, mast cells release mediators (histamine, chemotactic factors) or cause the formation of other mediators (prostaglandins, leukotrienes) in the surrounding tissue. The mediators are responsible for producing the immediate symptoms of an allergic reaction.⁹

Late-phase allergic reactions occur when eosinophils and other cells are attracted to the affected region.⁹

Eosinophils are leukocytes that can drive IgE production in allergic responses and also can release cytokines.

Common Culprits

There are eight types of foods that are accountable for 90% of all food-allergic reactions.^{7,9} The foods that most commonly cause anaphylaxis (called *allergenic foods*) are:

- Peanuts
- Tree nuts (walnuts, pecans, pistachios, filberts, cashews, almonds, etc.)
- Shellfish (crab, crayfish, prawns, shrimp, lobster, etc.)
- Fish
- Milk
- Soy
- Wheat
- Eggs

Sulfites added to foods can also set off anaphylactic reactions, as well as exercising, within a few hours after eating for a small number of people who do not otherwise experience food-related anaphylaxis.

Children, who have immature immune systems, are most susceptible to a broad array of food allergies. People have been known to outgrow allergies to milk, soy, and eggs after childhood. However, peanuts, tree nuts, and shellfish allergies tend to be lifelong.^{5,8,9} In fact, the reactions to these foods may become more serious over time.

In any case, when sensitivity exists, the intensity of a given anaphylactic attack is unpredictable because it depends on:

- The amount of allergen contained in the food eaten
- The person's degree of hypersensitivity to the allergen⁸

Also, if someone already has another immune problem, he or she may be at increased risk for a strong reaction to the food to which he or she is allergic. For example, patients who have asthma or atopic dermatitis, as well as food allergies, are at increased risk for severe anaphylaxis.^{1,2,10,11}

Symptoms

The symptoms of food allergies can range from mildly irritating to life threatening. The most common are:

- Hives
- Vomiting
- Diarrhea
- Abdominal cramping

Other symptoms typical of anaphylaxis generally include:

- Swelling of the throat, lips, or tongue
- Difficulty breathing or swallowing
- Metallic taste or itching in the mouth
- Generalized flushing, itching, or redness of the skin (hives)
- Nausea
- Increased heart rate
- Plunging blood pressure (and accompanying paleness)
- Sudden feeling of weakness
- Anxiety or an overwhelming sense of doom

- Collapse
- Loss of consciousness

For some people with food allergies, just a taste or even a touch of the foods to which they are allergic can result in any of these symptoms and can set off a chain reaction that takes only minutes to culminate in full-blown anaphylaxis: swelling of the airways, loss of blood pressure, loss of consciousness, shock, and even death.¹² This can happen with their first exposure to a food. There have even been cases in which inhalation exposure to a food has triggered an anaphylactic reaction.¹³ The more rapidly symptoms present themselves; the more likely the reaction is to be severe.¹³

Intolerance Versus Allergy

Food allergy and intolerance are often mistaken for each other. While they may share similar symptoms, including diarrhea and vomiting, food allergy is an immune system response and food intolerance occurs when the digestive tract reacts adversely to a food.

For example, one of the most common food intolerances arises in response to lactose, the sugar in milk. Lactose intolerance occurs when a person lacks an enzyme, lactase, that is needed to digest this sugar, and the body reacts with gas, bloating, diarrhea, and abdominal pain when milk products that contain lactose are consumed. When these symptoms occur as a result of intolerance rather than allergy, they do not indicate an anaphylactic reaction. However, anyone who has such symptoms should seek medical care to get a diagnosis and counseling in order to determine what dietary and medical measures are needed.

Diagnosis

A person who has experienced even mild allergic reactions to food should seek a diagnosis by a board-certified allergist (direct your patients to [Find an Allergist](#) to locate an allergist near you).

To make a proper diagnosis, the allergist will record a complete history of the symptoms, which foods were eaten, how much of the food was eaten, and how soon afterward the symptoms began. The doctor may also perform a skin prick test, RAST (radioallergosorbent test), or oral food challenge to confirm the diagnosis. In vitro testing with RAST or ELISA for IgE to food proteins is the safest diagnostic procedure. Food challenges are generally reserved for patients with unclear in vitro diagnostic results or when identification of the food allergen is deemed to be life saving.¹³

Prevention and Treatment

In most cases, there is no cure for food allergies. Therefore, it is essential that people with food allergies protect themselves by

carefully avoiding the foods that trigger their reactions, and by being prepared to immediately treat anaphylactic reactions that do occur with epinephrine, followed by emergency medical care.

Avoidance

Avoiding foods that trigger allergic reactions is critical and more challenging than one might expect. While steering clear of a food in its isolated form may not be so difficult, people with allergies, or the parents of children with food allergies, must know to check product labels for alternative names of food ingredients that may contain their allergens. People who have food allergies must also try to avoid foods that may contain hidden ingredients or that may have been prepared using equipment contaminated by an allergenic food.

Since it is often difficult to avoid hidden foods—and because it is often difficult for children to resist sharing foods—it is important that an allergic person's family, friends, and teachers know about and understand the ramifications of food allergy so that they can aid in preventing anaphylaxis and be ready to assist should an emergency arise.

Epinephrine

Exposure to allergenic foods is sometimes unavoidable, so people with food allergies need to be prepared to treat allergic reactions. The treatment of choice for severe allergic reactions to food, which can swiftly lead to anaphylaxis, is an immediate injection of epinephrine followed by emergency medical attention.¹⁴ Many physicians also recommend taking antihistamines such as diphenhydramine to relieve the symptoms of allergic reactions, but antihistamines are not a substitute for epinephrine. Only epinephrine can stop the potentially deadly effects of anaphylaxis.

A 1992 study in children and adolescents with food allergy, which was published in the *New England Journal of Medicine*, shows how important it is for people with food allergies to carry epinephrine at all times.¹⁰ According to the study, 10 of 13 fatal and near-fatal anaphylactic reactions to food occurred in public places, and none of the adolescents and children who died had epinephrine with them. All of the adolescents and children who survived received epinephrine before or within 5 minutes after the development of severe symptoms.¹⁰ Other studies corroborate these findings.¹¹ Thus, all food-allergic individuals should carry self-injectable epinephrine, such as EpiPen® or EpiPen® Jr epinephrine auto-injectors, with them at all times.

Since immediate administration of epinephrine can mean the difference between life and death, the parents of children with life-threatening food allergies should alert their child's school of the particular allergen, and make sure that their child's teachers and caregivers have an epinephrine auto-injector on hand and know how to use it.

The side effects of epinephrine may include palpitations, tachycardia, sweating, nausea and vomiting, and respiratory difficulty. Cardiac arrhythmias may follow the administration of epinephrine. Therefore, the physician should instruct the patient

about the circumstances of which this life-saving medication should be used.

Physicians should also instruct their patients about whether antihistamines should be carried in addition to epinephrine. Wearing a medical identification bracelet describing the patient's allergies and susceptibility to anaphylaxis can help ensure prompt, proper treatment during an emergency.

Emergency medical care

Even after epinephrine has been administered, emergency medical treatment should be sought at once because severely allergic people who have experienced anaphylaxis may need emergency respiratory or cardiac care, or even need to be resuscitated if they stop breathing altogether. More commonly, these patients will need professional care to determine whether additional epinephrine, steroids, antihistamines, or other treatments are required. In either case, follow-up diagnosis and care by medical professionals after the administration of epinephrine is critical to recovery. Delayed or secondary reactions do occur, and patients should remain under medical supervision for at least four hours after an episode of anaphylaxis.⁸

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PATIENT INSERT

PHARMACIST, PLEASE DISPENSE WITH PRODUCT



For allergic emergencies (anaphylaxis)
 Amount of epinephrine delivered:
 EpiPen® • one dose of 0.3 mg epinephrine (USP) (1.00%, 0.3 mL)
 EpiPen Jr • one dose of 0.15 mg epinephrine (USP) (1.20%, 0.3 mL)



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IMPORTANT INFORMATION

Please be prepared! Read both sides of this insert before an emergency occurs! EpiPen® and EpiPen® Jr are disposable, pre-filled automatic injection devices for use during allergic emergencies. They contain a single dose of epinephrine which you inject into your outer thigh. EpiPen® and EpiPen® Jr contain no latex.

It's important that you have this emergency medicine with you at all times. If you need additional units to keep at work, school, etc., please talk to your doctor.

WHEN TO USE

EpiPen® and EpiPen® Jr auto-injectors are used to treat severe allergic reactions (anaphylaxis). You should use this medication only if your doctor has prescribed it for allergic emergencies. Such emergencies may occur from insect stings or bites, foods, drugs, latex, other allergens, exercise-induced anaphylaxis, or unknown causes.

CARE AND STORAGE

- Keep the EpiPen® or EpiPen® Jr auto-injector handy and ready for use at all times.
 - Store at 25°C (77°F); excursions permitted to 15°C-30°C (59°F-86°F) (See USP Controlled Room Temperature). Contains no latex. Protect from light.
 - Do NOT store in refrigerator.
 - Do NOT expose to extreme cold or heat. For example, do NOT store in your vehicle's glove box.
- Your auto-injector has an expiration date
- Example: "DEC 05" = December 31, 2005.
 - Replace it before the expiration date.

To dispose of expired units

Expired auto-injectors must be disposed of properly. To dispose of an expired auto-injector and carrier, take it to your doctor's office or to a receptacle for proper disposal.

Examine contents in clear window of auto-injector periodically

- If the solution is discolored or contains solid particles (precipitate), replace the unit. Solution should be clear.



Take advantage of the EpiPen® Center for Anaphylactic Support™—your FREE information resource for severe allergic reactions.

You'll receive expiration reminders, information about managing your severe allergic reactions, resource listings and valuable offers. To enroll please complete and mail the form below.

Mail to:
 EpiPen® Center for Anaphylactic Support™
 DEY®
 P.O. BOX 4954
 Trenton, NJ 08650

EpiPen® Center for Anaphylactic Support™ Enrollment Form

Please fill in the information below. To ensure accuracy, please PRINT neatly in uppercase letters in black or dark-blue ink.

Name _____

Unit name (if on a sleep unit) _____

Address _____

City _____ State _____ Zip _____

EpiPen® Size: _____

Option: I would prefer to receive communications via email: Yes No

EpiPen®/EpiPen® Jr Lot # (in unit, example 2105) (0000000000)

Exp. Date (in unit, example DEC05) (11 00 00 00)

Is this your first EpiPen® prescription or a refill? First Prescription Refill

For what type of allergy was the EpiPen® prescribed?

Check all that apply:

Food Insect bite or sting

Latex Medication

Other _____



DIRECTIONS FOR USE

- NEVER PUT THUMB, FINGERS, OR HAND OVER BLACK TIP.
- DO NOT REMOVE GRAY SAFETY RELEASE UNTIL READY TO USE.
- DO NOT USE IF SOLUTION IS DISCOLORED OR RED FLAG APPEARS IN CLEAR WINDOW.
- DO NOT PLACE PATIENT INSERT OR ANY OTHER FOREIGN OBJECTS IN CARRIER WITH AUTO-INJECTOR, AS THIS MAY PREVENT YOU FROM REMOVING THE AUTO-INJECTOR FOR USE.



- Unscrew the yellow or green cap off of the EpiPen® or EpiPen® Jr carrying case and remove the EpiPen® or EpiPen® Jr auto-injector from its storage tube.



- Grasp unit with the black tip pointing downward.



- Form fist around the unit (black tip down).

- With your other hand, pull off the gray safety release.



- Hold black tip near outer thigh.

- Swing and jab firmly into outer thigh until it clicks so that unit is perpendicular (at a 90° angle) to the thigh. (Auto-injector is designed to work through clothing.)

- Hold firmly against thigh for approximately 10 seconds. (The injection is now complete. Window on auto-injector will show red.)

- Remove unit from thigh and massage injection area for 10 seconds.

- Call 911 and seek immediate medical attention.

- Carefully place the used auto-injector (without bending the needle), needle-end first, into the storage tube of the carrying case that provides built-in needle protection after use. Then screw the cap of the storage tube back on completely, and take it with you to the hospital emergency room.

Note: Most of the liquid (about 90%) stays in the auto-injector and cannot be reused. However, you have received the correct dose of the medication if the red flag appears in window.

WARNING

- NEVER put thumb, fingers, or hand over black tip. The needle comes out of black tip. Accidental injection into hands or feet may result in loss of blood flow to these areas. If this happens, go immediately to the nearest emergency room.
- EpiPen® and EpiPen® Jr should be injected only into the outer thigh. (See "Directions for Use".)
- Do NOT remove gray safety release until ready to use.

IMMEDIATELY AFTER USE

- Go immediately to the nearest hospital emergency room or call 911. You may need further medical attention. Take your used auto-injector with you.
- Tell the doctor that you have received an injection of epinephrine in your thigh.
- Give your used EpiPen®/EpiPen® Jr to the doctor for inspection and proper disposal.



Join the Free EpiPen® Center for Anaphylactic Support™ Today!

Because it's important that you always have an up-to-date EpiPen® or EpiPen® Jr with you at all times, we started an expiration reminder program as part of the EpiPen® Center for Anaphylactic Support™. Every time you purchase a new EpiPen®, be sure to register it with us, and we'll send you reminders so you can have an up-to-date EpiPen®.

This important program is a FREE service!

See other side for more details.

Name _____

Epipen Test

1. A person can develop an allergy any time in his life.
2. When a person is having an anaphylactic reaction after being stung by an insect, don't bother removing the stinger, just give the epipen injection.
3. Children, who have immature immune systems, are most susceptible to a broad array of food allergies.
4. You will likely outgrow a tree nut or peanut allergy.
5. The severity of an anaphylactic reaction depends on the amount of allergen the person is exposed to and the degree of the person's hypersensitivity to it.
6. Symptoms of anaphylaxis include hives, difficulty breathing, swelling of lips and tongue and a fever.
7. It takes 1-2 minutes for a mild allergic reaction to escalate to anaphylaxis and the faster the onset of an anaphylactic reaction, the greater the likelihood that it will be severe.
8. The mainstays of treating anaphylaxis include avoidance and emergency administration of epinephrine.
9. You must notify EMS that you have used an epipen because most people experience a recurrence in the hours following the beginning of the reaction and will require further medical treatment, including additional epinephrine injections.
10. Epipen should not be used through clothing.