BUREAU OF EMERGENCY MEDICAL SERVICES and TRAUMA SYSTEMS

EPINEPHRINE BY AUTO-INJECTOR
TRAINING GUIDELINES FOR UNLICENSED OR UNCERTIFIED PERSONNEL

PURPOSE:

To provide unlicensed or uncertified personnel with the basic knowledge and skills to administer epinephrine by auto-injector in a life-threatening allergic reaction (anaphylaxis) situation in compliance with New York State Public Health Law Article 30, section 3000-c. The law can be found at:

http://www.health.ny.gov/professionals/ems/art30.htm#BM3000c

DEFINITIONS:

For the purpose of this outline, the following terms are defined as:

- "Unlicensed or uncertified personnel" is defined as an individual who does not hold a government issued license or certification that allows them to administer patient-specific prescribed or non-patient specific prescribed medications.

- "Eligible person or entity" means a “… (ii) children's overnight camp, a summer day camp, a traveling summer day camp as defined in subdivision one of section thirteen hundred ninety-two of NYS Public Health Law or a person employed by such a camp; (iii) a school district, board of cooperative educational services, county vocational education and extension board, charter school, and non-public elementary and secondary school in this state or any person employed by any such entity; or (iv) a sports, entertainment, amusement, education, government, day care or retail facility; an educational institution, youth organization or sports league; an establishment that serves food; or a person employed by such entity; and (v) any other person or entity designated or approved, or in a category designated or approved pursuant to regulations of the commissioner in consultation with other appropriate agencies.” – Article 30, section 3000-c (1)(a).

- "Epinephrine auto-injector device" means a single-use device used for the automatic injection of a premeasured dose of epinephrine into the human body, approved by the Food and Drug Administration (FDA) for the purpose of emergency treatment of a person appearing to experience anaphylactic symptoms.
• “Health care practitioner” means a health care practitioner licensed, certified, or authorized to practice under title eight of the education law who is authorized thereby to administer drugs, and who is acting within the scope of his or her practice.

• “Training program instructor” means a physician or his/her designee or an approved instructor of a nationally recognized organization experienced in training laypersons in emergency health treatment.

**COURSE OBJECTIVES:**

An approved training program must include, but may not be limited to the following objectives and competencies approved by the Commissioner of Health. Upon completion of the training, the participants will be able to demonstrate the following knowledge and competencies:

1. identify common causes of allergic reactions;
2. identify the signs and symptoms of a mild and severe allergic reaction (anaphylaxis);
3. identify how signs and symptoms of anaphylaxis differ from other medical conditions;
4. demonstrate knowing when epinephrine should be administered and when it should not be administered;
5. demonstrate determining the correct dose of auto-injector, adult or pediatric, to administer;
6. demonstrate the steps for administering epinephrine by an auto-injector;
7. describe the methods for safely storing and handling epinephrine and appropriately disposing of the auto-injector after use;
8. demonstrate the steps for providing for on-going care of the patient until Emergency Medical Services (EMS) arrives;
9. demonstrate knowledge of appropriate documentation and reporting of an event in which an epinephrine auto-injector was administered; and
10. understand the NYS laws that allow an individual to possess and use an epinephrine auto-injector in a life-threatening situation.
IMPORTANT QUESTIONS AND ANSWERS

1. What are the most common causes of an allergic reaction?

A wide variety of different substances can cause allergic reactions in people. Some of the most common causes include:

- Venom from insect bites and stings, especially those of bees, wasps, hornets, and yellow jackets;
- Foods, including nuts, shellfish/crustaceans, peanuts, milk, eggs, chocolate, etc.;
- Plants, including contact with poison ivy, poison oak, and pollen from ragweed and grasses;
- Medications, including penicillin and other antibiotics, aspirin, seizure medications, muscle relaxants, over-the-counter remedies, etc.;
- Other causes include dust, latex, glue, soaps, make-up, etc.

2. What are the signs and symptoms of an allergic reaction?

Allergic reactions can range from watery eyes and a runny nose as seen with hay fever to severe breathing problems (respiratory distress), low blood pressure (hypoperfusion), and unconsciousness.

Physical findings that may indicate an allergic reaction include any of those listed below.

- **Generalized symptoms**: Itchy, watery eyes, headache, or runny nose.
- **Skin**: Swelling of the face, lips, tongue, neck, or hands. Itching, hives or red skin (flushing).
- **Breathing Problems**: Cough, difficulty swallowing, rapid breathing, difficulty breathing, noisy breathing, change in voice or loss of voice (hoarseness), high pitched noise during inhalation (stridor), or wheezing. **Serious breathing problems (severe respiratory distress) is a sign that the individual is having a severe allergic reaction (anaphylaxis).**
- **Heart/Circulation Problems**: Increased heart rate, decreased blood pressure, or signs of cool, clammy skin (hypoperfusion).
- **Mental Status/Level of Consciousness**: Confusion, agitation, fainting or loss of consciousness.
3. *How can I tell it is a "severe allergic reaction" that needs the epinephrine auto-injector?*

You may need to administer epinephrine with the auto-injector if a patient, who has a history of allergies/allergic reactions, has come in contact with a substance(s) that causes the allergic reaction. If the patient is having a very hard time breathing (*severe respiratory distress*) with any other signs of an allergic reaction, such as a feeling that their throat closing, swelling of tongue and/or lips and/or loss of consciousness, you should to administer the epinephrine auto-injector.

4. *Does the epinephrine come in more than one size or dose?*

Yes, epinephrine auto-injectors comes in both an adult dose (0.3 mg) and a pediatric dose (0.15 mg). Generally, the adult dose is for individuals who weigh 66 lbs. or more and the pediatric dose is for individuals who weigh from 33 to 66 lbs. For children weighing *less than 33 pounds*, do not administer the auto-injector and CALL 911; usage and dosage *must* be determined by an authorized health care professional. **You must consult with your Health Care Practitioner to determine which auto-injector dose is most appropriate to carry and use in your situation.**

5. *If someone has a severe allergic reaction what should I do first?*

**Administer the epinephrine first.** If available, at the same time, have someone else **call 911 or your local emergency number and request an ambulance!** Otherwise, call 911 immediately after administering the epinephrine auto-injector. It is very important to activate your local Emergency Medical Services (EMS) system right away. The patient with a severe allergic reaction may require additional Advance Life Support (ALS) medications or other emergency life-saving procedures. All patients who receive the epinephrine must have immediate follow-up evaluation by a physician.

6. *How do I administer the epinephrine with the auto-injector?*

Sit the patient down and try to calm and reassure him/her. If the patient is confused, disoriented, or unconscious (altered mental state) and exhibits signs of a weak, rapid pulse, cool clammy skin (hypoperfusion), lay him/her down and slightly elevate his/her feet. If oxygen is available, and someone is trained in its use, administer a high concentration of oxygen. **If the patient is having a hard time breathing administer the epinephrine as follows:**
Step – by – Step Administration Instructions

→ **Step One:**
Remove the safety cap from the auto-injector. Check to see if the fluid is clear and colorless. **Never put your fingers over the needle end (red or orange colored cap) of the device when removing the safety cap or after the safety cap has been removed!**

→ **Step Two:**
Place the tip of the injector against the patient’s bare outer thigh. (halfway between their waist and the knee).

→ **Step Three:**
With a quick motion, push the auto-injector firmly against the thigh until the spring-loaded needle is activated. Hold the auto-injector in place for 3 to 10 seconds.

→ **Step Four:**
Remove the auto-injector from the thigh, massage the injection site for 10 seconds and record the time of the injection.

→ **Step Five:**
Carefully re-insert the unit (without replacing the safety cap) -NEEDLE FIRST- into the carrying tube and re-cap the carrying tube. **Never put your fingers over the needle end of the device after the safety cap has been removed!** Give the tube to the ambulance crew so they know exactly what you have given and can appropriately dispose of it at the hospital. Also provide them with the exact time that you administered the epinephrine.

→ **Step Six:**
Watch the patient carefully, and keep them calm. Note if the patient gets any better or worse. Be prepared to give CPR if needed.

7. **What will the patient feel when I use the epinephrine auto-injector?**

The injection itself is relatively painless and the patient may not feel the medication being injected. Soon after the injection, the patient should begin to feel the beneficial effects of the drug. The most common changes the patient may feel are a more rapid heartbeat and a slight nervousness. The patient may experience palpitations, sweating, dizziness and a headache.
8. **What information do I need to give EMS?**

If the epinephrine auto-injector is used, make sure the following information is accurately and concisely shared to the EMS Provider and physician:

- The substance (allergen) the patient was exposed to;
- How long ago the exposure occurred;
- The signs and symptoms the patient experienced (difficulty breathing, tightness in the throat or chest, any swelling, etc.) before the epinephrine was administered;
- The time and dose of the epinephrine administered;
- Note any change(s) in the patient after the epinephrine was administered;
- Other specific information about the patient such as name, age, guardian, physician, medical history, etc.

9. **How should the epinephrine auto-injector be stored?**

The epinephrine auto-injector should be kept where it can be easily accessed in an emergency. Keep it away from children. Keep it in the protective plastic carrying tube in which it is supplied.

It is important to remember that epinephrine needs to be kept at room temperature (between 68 and 77 degrees Fahrenheit). It should not be refrigerated, nor should you allow it to be exposed to extreme heat, such as the glove compartment or trunk of a car during the summer. Do not expose the epinephrine auto-injector to direct sunlight since it is light sensitive; light and heat can cause epinephrine to degrade and/or turn brown.

10. **Does the epinephrine auto-injector have an expiration date or need to be replaced?**

**Yes.** As with any medication, the epinephrine auto-injector will have an expiration date, which is printed directly on the unit. It is important to periodically check the expiration date and replace the unit before it expires. When checking the expiration date, usually 18 months, also check to make sure the fluid is clear and colorless. Replace the unit if the fluid is discolored. If the device is expired, it must be safely disposed of in compliance with regulations (Title 10 NYCRR Part 80.137) at licensed pharmacies, health care facilities or health care practitioners who can prescribe the device.
11.  **Can the auto-injector unit cause injury?**

An auto-injector unit is generally very safe and easy to use. It is important to remember that the unit does have a sharp needle in it. Do not remove the safety cap until you are ready to use the auto-injector. **Never put your fingers over the needle end (orange or red colored) of the device when removing the safety cap or after the safety cap has been removed.** Do not replace the safety cap once it has been removed. After use carefully re-insert the unit - NEEDLE FIRST - into the carrying tube, then re-cap the carrying tube.

To minimize risk of injection-related injury when administering an epinephrine auto-injector to a child, caregivers should hold the child’s leg firmly in place and limit movement prior to and during administration.

12.  **Who can use an epinephrine auto-injector?**

New York State Public Health Law authorizes the possession and use of an epinephrine auto-injector by an eligible person or entity such as a children's camp, a school district, board of cooperative educational services, county vocational education and extension board, charter school, and non-public elementary and secondary school, a sports, entertainment, amusement, education, government, day care or retail facility, an establishment that serves food; and any other person or entity designated or approved, or in a category designated or approved pursuant to regulations of the commissioner in consultation with other appropriate agencies.

This allows a person involved with an eligible entity to administer epinephrine to individuals with or without a history of allergies/allergic reactions who have a severe allergic reaction even if the patient doesn't have his/her prescribed auto-injector with them.

All participating individuals must complete this or another training program in the use of epinephrine auto-injector devices that is conducted by a nationally recognized organization experienced in training laypersons or a program approved by the Commissioner of Health in the recognition of severe anaphylaxis, the steps to administering of an epinephrine auto-injector, calling for EMS and completing the appropriate documentation (see the course objectives above).

13.  **How is the epinephrine auto-injector obtained?**

A health care practitioner or pharmacist who is authorized to prescribe drugs may prescribe, dispense or provide an epinephrine auto-injector device to or for an eligible person or entity by a non-patient-specific prescription.
14. How can a training program be approved by the New York State Commissioner of Health?

New York State PHL Section 3000-c (2)(c) requires that "No one may use an epinephrine auto-injector device on behalf of an eligible person or entity unless he or she has successfully completed a training course in the use of epinephrine auto-injector devices conducted by a nationally recognized organization experienced in training laypersons in emergency health treatment or by an entity or individual approved by the commissioner...."

Any training program submitted for approval must include, but may not be limited to the following objectives and competencies:

1. identify common causes of allergic reactions;
2. identify the signs and symptoms of a mild and severe allergic reaction (anaphylaxis);
3. identify how signs and symptoms of anaphylaxis differ from other medical conditions;
4. demonstrate knowing when epinephrine should be administered and when it should not be administered;
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10. understand the NYS laws that allow an individual to possess and use an epinephrine auto-injector in a life-threatening situation.

Prior to initiating the training program, please submit proposed training programs for approval to:
New York State Department of Health
Bureau of Emergency Medical Services and Trauma Systems
875 Central Avenue
Albany, NY 12206

518-402-0996
518-402-0985
http://www.health.ny.gov/professionals/ems/
For more information:

For more information on the requirements contact the Bureau of Emergency Medical Services at:

New York State Department of Health
Bureau of Emergency Medical Services and Trauma Systems
875 Central Avenue
Albany, NY  12206

518-402-0996
518-402-0985
http://www.health.ny.gov/professionals/ems/

RESOURCES:

New York State Public Health Law, Article 30, Section 3000-c
http://www.health.ny.gov/professionals/ems/art30.htm#BM3000c

New York State Department of Health, Bureau of Emergency Medical Services
Policy Statement 17-02 – Epinephrine Auto-Injectors (Epi-Pen®)

American Academy of Pediatrics
http://www.aap.org

American Red Cross
Anaphylaxis and Epinephrine Auto-Injector - Online Course
http://www.redcross.org/take-a-class/course-dowbt000000000011096

American College of Allergy, Asthma & Immunology
http://acaai.org/

Food Allergy Research and Education
https://www.foodallergy.org/treating-an-allergic-reaction/epinephrine

Asthma and Allergy Foundation
http://www.aafa.org/