Revised 6/27/11
Approved IDPH Protocol Subcommittee 2/27/12
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NERVE GAS AUTO-INJECTOR GUIDELINES

Purpose:

To provide Illinois EMS agencies with guidelines on the appropriate use of **Mark I and DuoDote** kits. The **Mark I** and DuoDote kits contain antidotes to be used in instances of exposure to nerve agents (Sarin, Soman, Tabun, VX) or to organophosphate agents (Lorsban, Cygon, Delnav malathion, Supracide parathion, carbopenthion).

Equipment:

Each **Mark I** kit consists of two autoinjectors and the DuoDote kit consists of one autoinjector containing:

- Atropine Sulfate (**Atropine**) 2 mg in .7cc's
- Pralidoxime Chloride (**2 PAM**) 600mg in 2 cc's

Key Provisions:

Only those licensed emergency EMS providers that are governed by the State of Illinois EMS Act (210 ILCS 50/) are authorized by an EMS Medical Director to utilize the specialized equipment and medications needed in WMD incidents including **Mark I** and DuoDote auto-injectors. When appropriate conditions warrant, contact medical control. Other organized response teams not governed by the EMS Act may use the **Mark I** and DuoDote auto-injectors on themselves or other team members when acting under the Illinois Emergency Management Agency Act (20 ILCS 3305).

Guidelines:

The guidelines for the use of the **Mark I** and DuoDote kits were developed by the EMS Committee of the Illinois College of Emergency Physicians (ICEP). They were then adopted by the Illinois Medical Directors, Illinois Department of Public Health, and Mutual Aid Box Alarm System (MABAS), and the Illinois Terrorism Task Force to provide guidance to EMS agencies and providers who are a part of an EMS System.

There are ten provisions in the guidelines:

1. To utilize these kits you must be an EMS agency or provider within an Illinois EMS System and participate within an EMS disaster preparedness plan.

2. The decision to utilize the Mark I and DuoDote antidote is authorized by this State protocol.

3. At a minimum, an EMS provider must be an Illinois EMT at any level including First Responder with additional training in the use of the auto-injector

4. **The Mark I and DuoDote kits are not to be used for prophylaxis.** The injectors are antidotes, not a preventative device. **Mark I** and DuoDote kits may be self-

administered if you become exposed and are symptomatic. Exit immediately to the Safe Zone for further medical attention.

5. **Use of the Mark I and DuoDote kits are to be based on signs and symptoms of the patient. The suspicion or identified presence of a nerve agent is not sufficient reason to administer these medications.**

6. Atropine may be administered IM/IV in situations where **Mark I** or DuoDote kits are not available.

7. Auto-injectors are **NOT** to be used on children under 88 pounds (40 Kg).

8. If available Diazepam (Valium) or Versed may be cautiously given under direct medical control or by standing medical orders if convulsions are not controlled.

9. When a nerve agent has been ingested, symptoms may continue for some time due to slow absorption from the lower bowel and fatal relapses have been reported after initial improvement. Continued medical monitoring and transport is mandatory.

10. If dermal exposure has occurred, decontamination is critical and should be done with standard decontamination procedures. Patient monitoring should be directed to the signs and symptoms as with all nerve or organophosphate exposures. Continued medical monitoring and transport is mandatory.

Personal Protection

The first priority when encountering a potential nerve-agent victim is self protection. Personal protective equipment (PPE) and decontamination are key elements in the successful management of exposed casualties. All people entering a Hot Zone or working a decontamination station must wear full protective ensembles including full-body and respiratory protection. Do not cross contaminate yourself when handling patients in triage, treatment and staging areas or if have begun treatment in the Hot Zone.

Pre-hospital Management

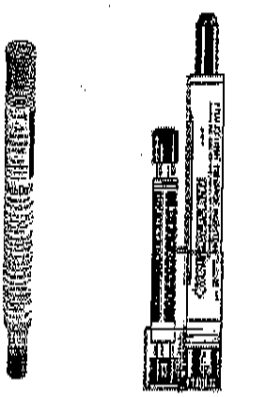
Pre-hospital management for nerve agent or organophosphate poisoning is a two pronged attack focusing on countering the poison with antidotes and preventing death by supporting respirations and controlling seizures. Because the primary cause of death from these agents is respiratory failure, aggressive airway control and ventilation are top priorities. With antidotal therapy, spontaneous respirations should resume within a short period of time.

Please notify the receiving hospitals prior to transport so they can prepare their facilities for your arrival and also consider activating local mass casualty protocols. Use prudent judgment in transferring patients to the hospitals.

At times of disaster Chem Pacs may be deployed for pre hospital use.

Attached to this guideline is the State of Illinois "Mark I / DuoDote Protocol" based upon various federal agency recommendations for administration. **This Protocol is intended for EMS licensed health care professionals.** It may be used only with medical authorization and participation of the agency in an EMS disaster preparedness plan.

STATE OF ILLINOIS PROTOCOL FOR THE USE OF MARK I / DuoDote KITS



Duodote Mark I

Introduction:

Mark I and DuoDote kits are auto-injector antidotes to be used when:

- first responders are exposed to nerve agents/ organophosphate
- signsor symptoms of nerve agent exposure,
- when first responders treat victims in a MCI situation in the hot zone.

Use:

NOTE: The Mark I and DuoDote kits are not to be used for prophylaxis. The injectors are antidotes, not a preventative device. **Mark I** and DuoDote kits may be self-administered if you become exposed and are symptomatic. Medical treatment is directed to relieving respiratory distress and alleviating seizures.

Contents: **Mark I** and DuoDote auto-injectors antidote kit contains:
Atropine (2 mg in .7cc total dose per injection)
2 PAM (pralidoxime chloride) 600 mg in 2 cc total dose per injection.

Indications for use of the Mark I and DuoDote auto-injectors:

It is a concern that the use of auto-injectors could lead to administration of inappropriate and harmful **Mark I or DuoDote** doses during a non-chemical agent or minimal exposure situations. The auto-injectors are to be used only if the patient presents with signs and symptoms consistent with exposure to nerve or organophosphate agents.

Mnemonic for Nerve Agent Exposure
Salivation (*excessive production of saliva*)
Lacrimation (*excessive tearing*)
Urination (*uncontrolled urine production*)
Defecation (*uncontrolled bowel movements*)
Gastrointestinal distress (*cramps*)
Emesis (*excessive vomiting*)
Breathing Difficulty
Arrhythmias
Myosis (pinpoint pupils)

Signs and Symptoms of Nerve Agent Exposure

(from mild to severe)

Exposure

Signs & Symptoms

- ✓ Unexplained runny nose
- ✓ Tightness in the chest
- ✓ Difficulty breathing
- ✓ Bronchospasm
- ✓ Pinpoint pupils resulting in blurred vision
- ✓ Drooling
- ✓ Excessive sweating
- ✓ Nausea and/or vomiting
- ✓ Abdominal cramps
- ✓ Involuntary urination and/or defecation
- ✓ Jerking, twitching and staggering
- ✓ Headache
- ✓ Drowsiness
- ✓ Coma
- ✓ Convulsions
- ✓ Apnea

If symptoms resolve, then only monitoring is necessary.

If severe signs and symptoms are present; three (3) Atropine auto-injectors and (3) three 2 PAM injectors should be administered in rapid succession (stacked).

1. Remove secretions
2. Maintain an open airway
3. Use artificial ventilation if necessary when possible (ie. limited resources available; excessive oral secretions)
4. Repeat Atropine immediately as directed

Pralidoxime (2 PAM) is most effective if administered immediately after the poisoning but not before Atropine, especially for severe exposures.

If available Diazepam (Valium) or Versed may be cautiously given, under direct medical control, if convulsions are not controlled.

When the nerve agent has been ingested, symptoms may continue for some time due to slow absorption from the lower bowel, and fatal relapses have been reported after initial improvement. Continued medical monitoring and transport is mandatory.

If dermal exposure has occurred, decontamination is critical and should be done with standard decontamination procedures. Patient monitoring should be directed to the same signs and symptoms as with all nerve or organophosphate exposures.

ANTIDOTE DOSING:

Refer to Appendix A: Recommendations fro Nerve Agent Therapy – Prehospital Management for antidotes based on patient's age.

1. If available through the distribution of Chem Pac: 2-PAM solution needs to be prepared from the ampule containing 1 gram of desiccated (powder) 2-PAM: Inject 3 ml of NS, 5% distilled or sterile water into ampule and mix without shaking. The resulting solution is 3.3 ml of 300 mg/ml.
2. Mild/moderate: Localized sweating, muscle fasciculations, nausea, vomiting, weakness, dyspnea
3. Severe symptoms: Unconsciousness, seizures, apnea, flaccid paralysis - see earlier charts.

MARK I PROCEDURE:

If you experience any or all of the nerve agent poisoning symptoms, you must IMMEDIATELY self-administer the nerve gas antidote.

Injection Site Selection

- The injection site for administration is normally in the **outer thigh muscle** (Figure 1). It is important that the injections be given into a large muscle area.
- If the individual is thinly-built, then the injections should be administered into the **upper outer quadrant of the buttocks** (Figure 2).

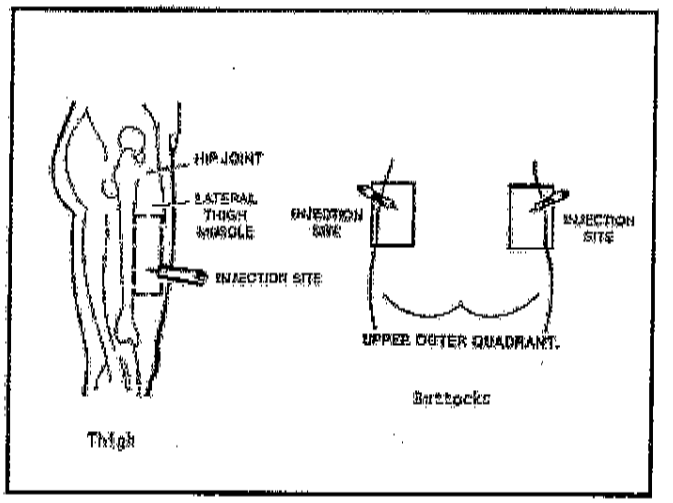
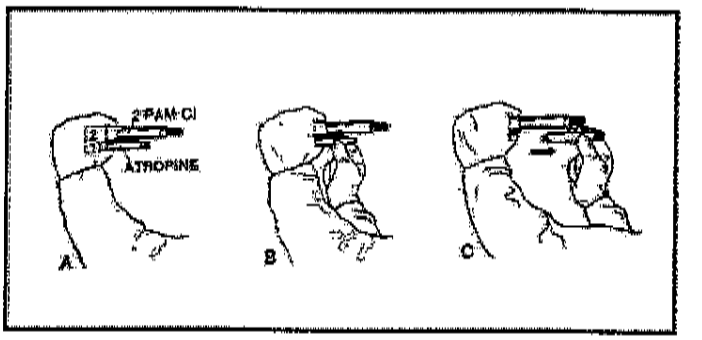


Figure 1 – Thigh injection site **Figure 2** – Buttocks injection site

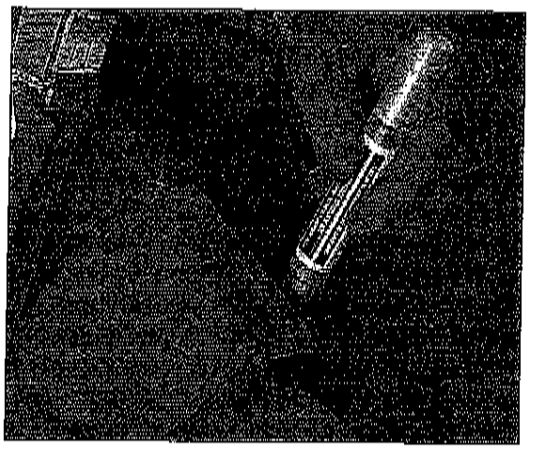
Arming the Auto-injector:



- Immediately put on your protective mask.
- Remove the antidote kit.
- With your non-dominant hand, hold the auto-injectors by the plastic clip so that the larger auto-injector is on top (Figure 3A) and both are positioned at eye level.
- With your dominant hand grasp the atropine auto-injector (the smaller of the two) with the thumb and first two fingers (Figure 3B). DO NOT cover or hold the needle end with your hand, thumb or fingers – you might accidentally inject yourself. An accidental injection into the hand **WILL NOT** deliver an effective dose of the antidote, especially if the needle goes through the hand.
- Pull the injector out of the clip with a smooth motion (Figure 3C). **The auto-injector is now armed.**

Self-Administration of the Antidote:

- Hold the auto-injector with your thumb and two fingers (pencil writing position). Be careful not to inject yourself in the hand!



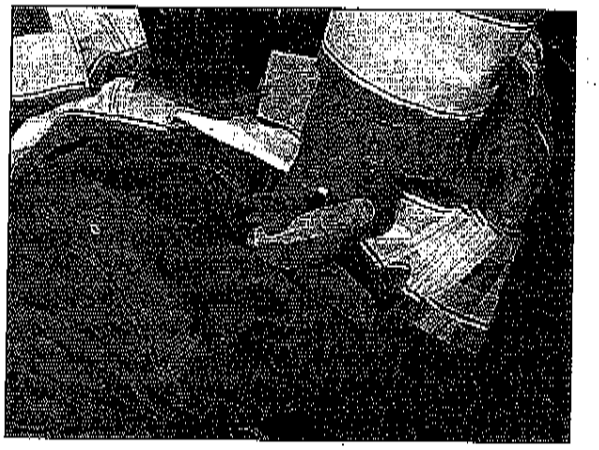


Figure 4

- Position the green (needle) end of the injector against the injection site (thigh or buttock) (Figure 4). DO NOT inject into areas close to the hip, knee or thigh bone.
- Apply firm, even pressure (not jabbing motion) to the injector until it pushes the needle into your thigh (or buttocks). Using a jabbing motion may result in an improper injection or injury to the thigh or buttocks.
- Hold the injector firmly in place for at least 10 seconds. Firm pressure automatically triggers the coiled spring mechanism. This plunges the needle through the clothing into the muscle and at the same time injects the antidote into the muscle tissue.
- Carefully remove the auto-injector from your injection site.
- Next pull the 2 PAM auto-injector (the larger of the two) out of the clip (Figure 5).

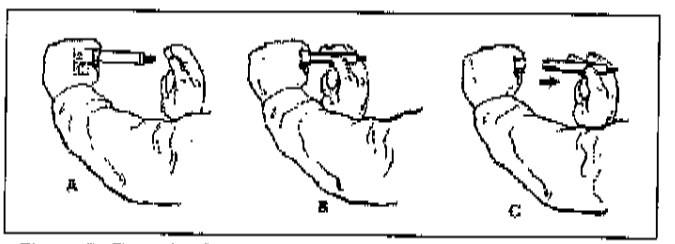


Figure 5 - Removing 2 PAM autoinjector from clip.

- Inject yourself in the same manner as the steps above, holding the black (needle) end against you outer thigh (or buttocks).
- Massage the injection site, if time permits.
- After administering the first set of injections, wait 5 to 10 minutes. After administering one set of injections, you should initiate decontamination procedures, as necessary, and put on any additional protective clothing.
- Once stabilized with Mark I dosages, Atropine only may be repeated every 10 – 15 minutes as patient condition warrants. (Note: multiple doses of atropine may be needed.)

Administering The Antidote To Another In The Hot Zone:

- Squat, DO NOT kneel, when masking the victim or administering the nerve agent antidotes to the victim. Kneeling may force the chemical agent into or through your protective clothing.
- Mask the victim when available.
- Position thevictim on his or her side (recovery position).
- Position yourself near the vicitm's thigh.

- The procedure for site selection and medication administration is the same as above.
- Atropine only should be administered as needed.
- Mark, label or tag victims who have been given **Mark I** or DuoDote injector antidote kits in a way that rescuers in the Warm Zone or triage areas can identify medication and dosage amounts given to the victim.

Figure 6 – Thigh and buttock administration to a casualty

DuoDote PROCEDURE:

If you experience any or all of the nerve agent poisoning symptoms, you must IMMEDIATELY self-administer the nerve gas antidote.

Injection Site Selection

- The injection site for administration is normally in the **outer thigh muscle** (Figure 1). It is important that the injections be given into a large muscle area.
- If the individual is thinly-built, then the injections should be administered into the **upper outer quadrant of the buttocks** (Figure 2).

IMPORTANT: Do Not Remove Gray Safety Release until ready to use

CAUTION: NEVER touch the Green Tip (Needle End)!

1. Tear open the plastic pouch at any of the notches. Remove the DuoDote Auto-injector from the pouch.
2. Place the DuoDote Auto-injector in your dominant hand. (If you are right-handed, your right hand is dominant.) Firmly grasp the center of the Duodote Auto-Injector with the Green Tip (needle end) pointing down.

3. With your other hand, pull off the Gray Safety Release. The DuoDote Auto-Injector is now ready to be administered.
4. The injection site is the mid-outer thigh area. The DuoDote Auto-injector can inject through clothing. **However, make sure pockets at the injection site are empty.**
5. Swing and firmly push the Green Tip straight down (a 90° angle) against the mid- outer thigh. Continue to firmly push until you feel the DuoDote Auto-injector trigger.

   IMPORTANT: After the auto-injector triggers, hold the DuoDote Auto-Injector firmly in place against the injection site for approximately 10 seconds.
6. Remove the DuoDote Auto-Injector from the thigh and look at the Green Tip. If the needle is visible, the drug has been administered. If the needle is not visible, check to be sure the Gray Safety Release has been removed, and then repeat above steps beginning with Step 4, but push harder in Step 5.
7. After the drug has been administered, push the needle against the hard surface to bend the needle back against the DuoDote Auto-Injector.
8. Put the used DuoDote Auto-Injector back into the plastic pouch, If available. Leave used DuoDote Auto-Injector(s) with the patient to allow other medical personnel to see the number of DuoDote Auto-Injector(s) administered.
9. Immediately move yourself and the patient away from the contaminated area and seek definitive medical care for the patient.

INSTRUCTIONS FOR THE USE OF THE DUODOTE AUTO-INJECTOR

(Also see the Illustrated Instruction Sheet for Emergency Medical Personnel)

IMPORTANT: Do Not Remove Gray Safety Release until ready to use.

CAUTION: Never touch the Green Tip (Needle End)!

1) Tear open the plastic pouch at any of the notches. Remove the DuoDote Auto-Injector from the pouch.

2) Place the DuoDote Auto-Injector in your dominant hand. (If you are right-handed, your right hand is dominant.) Firmly grasp the center of the DuoDote Auto-Injector with the Green Tip (needle end) pointing down.

3) With your other hand, pull off the Gray Safety Release. The DuoDote Auto-Injector is now ready to be administered.

4) The injection site is the mid-outer thigh area. The DuoDote Auto-Injector can inject through clothing. **However, make sure pockets at the injection site are empty.**

5) Swing and firmly push the Green Tip straight down (a 90° angle) against the mid-outer thigh. Continue to firmly push until you feel the DuoDote Auto-Injector trigger.
IMPORTANT: After the auto-injector triggers, hold the DuoDote Auto-Injector firmly in place against the injection site for approximately 10 seconds.

6) Remove the DuoDote Auto-Injector from the thigh and look at the Green Tip. If the needle is visible, the drug has been administered. If the needle is not visible, check to be sure the Gray Safety Release has been removed, and then repeat above steps beginning with Step 4, but push harder in Step 5.

7) After the drug has been administered, push the needle against a hard surface to bend the needle back against the DuoDote Auto-Injector.

8) Put the used DuoDote Auto-Injector back into the plastic pouch, if available. Leave used DuoDote Auto-Injector(s) with the patient to allow other medical personnel to see the number of DuoDote Auto-Injector(s) administered.

9) Immediately move yourself and the patient away from the contaminated area and seek definitive medical care for the patient.

HOW SUPPLIED

Each DuoDote Auto-Injector contains a sterile solution of atropine (2.1 mg/0.7 mL) and a sterile solution of pralidoxime chloride (600 mg/2 mL) in two separate internal chambers. When activated, the DuoDote Auto-Injector sequentially administers both drugs intramuscularly through a single needle in one injection.

DuoDote is available in a single unit carton, NDC-11704-620-01.

Each DuoDote is supplied in a pouch that provides protection from light.

Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F) [See USP Controlled Room Temperature]. Contains no latex. Keep from freezing. Protect from light.

Manufactured by:
Meridian Medical Technologies™, Inc.
Columbia, MD 21046

A wholly owned subsidiary of King Pharmaceuticals®, Inc.
1-800-776-3637

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Recommendations* for Nerve Agent Therapy - Prehospital Management

Patient Age		Antidotes[1] Mild/Moderate Symptoms[2]	Severe Symptoms[3]
Infant	(0-6 months) < 7 kg	Atropine: 0.25 mg IM 2-PAM Cl: 15 mg/kg IM	Atropine: 0.5 mg IM 2-PAM Cl: 25 mg/kg IM
Infant	(7 months - 2 yrs) 7-13 kg	Atropine: 0.5 mg IM 2-PAM Cl: 15 mg/kg IM	Atropine: 1 mg IM 2-PAM Cl: 300 mg IM
Child	(3 - 7 yrs) 14-25 kg	Atropine: 1 mg IM 2-PAM Cl: 300 mg IM	Atropine: 2 mg IM 2-PAM Cl: 600 mg IM
Child	(8 - 14 yrs) 26-50 kg	Atropine: 2 mg IM 2-PAM Cl: 600 mg IM	Atropine: 4 mg IM 2-PAM Cl: 1200 mg IM
Adolescent	(>14 yrs) > 51 kg	Atropine: 2-4 mg IM 2-PAM Cl: 600-1200 mg IM	Atropine: 4-6 mg IM 2-PAM Cl: 1200-1800 mg IM
Adult		Atropine: 2-4 mg IM 2-PAM Cl: 600-1200 mg IM	Atropine: 6 mg IM 2-PAM Cl: 1800 mg IM
Elderly, frail		Atropine: 1 mg IM 2-PAM Cl: 10 mg/kg IM	Atropine: 2-4 mg IM 2-PAM Cl: 25 mg/kg IM

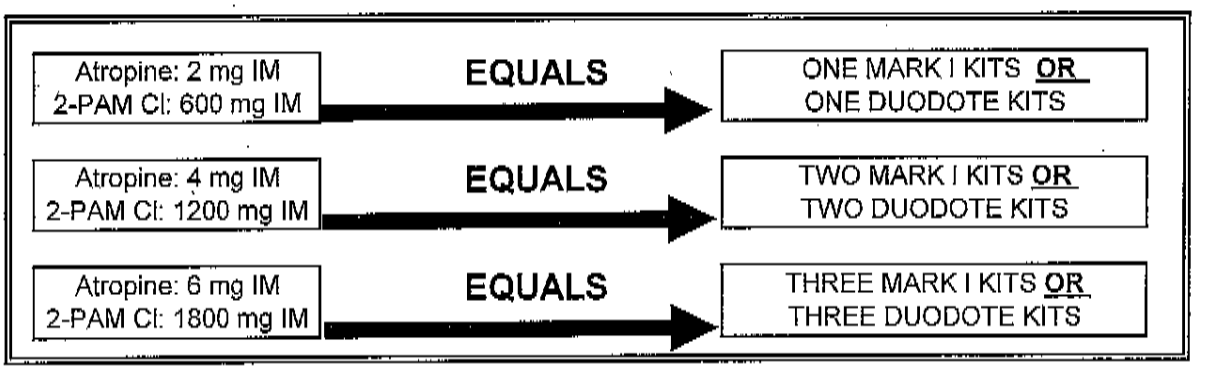
*** Weight based chart, then age of patient to determine dosing category.**

[1] 2-PAM Cl solution needs to be prepared from the ampule containing 1 gram of desiccated 2-PAM Cl: inject 3 ml of saline, 5% distilled or sterile water into ampule and shake well. Resulting solution is 3.3 ml of 300 mg/ml.

Symptoms:

[2] **Mild/Moderate: localized sweating, muscle fasciculations, nausea, vomiting, weakness, dyspnea**

[3] **Severe: unconsciousness, convulsions, apnea, flaccid paralysis.**



Other Treatment:

** Assisted ventilation should be started after adminstration of antidotes for severe exposures.

** Repeat Atropine at 5-10 min intervals until secretions diminished, breathing comfortable or airway resistance near normal

References:

Agency for Toxic Substances and Disease Registry (ATSDR). Prehospital Management: Nerve Agents, 2001: 10-16.

Columbia University. Info Brief Volume 1, No. 1, Spring, 2004. Atropine Use in Children after Nerve Gas Exposure: 1.

Columbia University. Info Brief Volume 1, No. 1, Spring, 2004. Pediatric Expert Advisory Panel (PEAP). Recommendations and Guidelines: What you need to know. 2-7.

Duodote Package Insert

Illinois EMSC Pediatric Prehospital Protocol Manual, 2008. Nerve Agent Antidote Guideline: 36.

Roumig M.D. FAAP, FACEP, Lou. Atropine Autoinjector Use in Children, 2006.

This document was revised and updated in consultation with the following organizations and individuals:

1. Illinois Emergency Medical Services for Children (EMSC)
    - Susan Fuchs, MD
    - Evelyn Lyons, RN
2. Poison Control
    - Mike Wahl, MD