Use of “Mark I Kits” (AtroPen® Auto-Injector & Pralidoxime Chloride Injector)

Purpose:

To provide EMS agencies with guidelines on the appropriate use of “Mark I Kits”. The “Mark I Kit” contains antidotes to be used in instances of exposure to a nerve or organophosphate agent. The Mark I kit consists of two autoinjectors containing Atropine Sulfate and Pralidoxime Chloride.

Key Provision:

Only those EMS services that are part of the Metropolitan Medical Response Systems (MMRS) and/or a Municipal response Plans are authorized to purchase and utilize the specialized equipment and medications needed in WMD incidents. This includes “Mark I Kits”.

Guidelines:

The initial guidelines for the use of the “Mark I Kits” were developed by the Bio-Terrorism sub-committee of the State Emergency Medical Advisory Committee (SEMAC). They were then adopted by the SEMAC as well as the State Emergency Medical Services Council (SEMSCO), to provide guidance to EMS agencies who are a part of the Metropolitan Medical Response System (MMRS) and/or a Municipal Response Plan. This updated edition is to provide additional guidance on the use of the Mark I kits.

There are five provisions in the guidelines:

1. An EMS agency must be participating in an MMRS or Municipal Response Plan for WMD incidents.

2. The decision to utilize the “Mark I” antidote must be done under the authority of medical control.

3. At a minimum, an EMS provider must be trained to the WMD awareness level. The
awareness program should be a national training program or modeled after one of the training programs developed by the Department of Defense (DOD), Department of Justice (DOJ) or Federal Emergency Management Agency (FEMA).

An online WMD awareness course is offered through the Domestic Preparedness Campus of Texas A&M University’s web site at:

http://www.teexwmdcampus.com

4. The “Mark I Kit” is not to be used for self-administration or prophylaxis.

5. Use of the “Mark I Kit” is 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.

Antidote Mechanism of Action:

1. The nervous system controls body functions by secreting chemical transmitters which act as “instructions” to nerves, muscles and glands at the nerve endings.

2. These neurological instructions come in two forms:
   1) **stimulate** (move or work)
   2) **relax** (stop or rest).

3. When a nerve agent is present, it interferes with the normal instructions of chemical transmitters that direct the muscle or gland to return to an un-stimulated, relaxed state.

4. By interfering with the normal chemical checks and balances, the action of toxic nerve agents is to over-stimulate the nerve endings and central nervous system.

5. Over-stimulation of the nervous system causes muscles and certain glands to over-react and cause the symptoms of: SLUDGEM + Respirations and Agitation.

6. The initial treatment for a nerve agent exposure consists of a two part antidote:
   1) Atropine, and
   2) 2-PAM Chloride.

**NOTE:** *ATROPINE IS THE PRIMARY DRUG FOR TREATMENT OF NERVE AGENT EXPOSURE!*
7. Atropine stops the effect of the nerve agent by blocking the effects of over-stimulation. It effectively counters the actions of the nerve agent at nerve receptors.

8. Atropine relieves the smooth muscle constriction in the lungs (wheezing, respiratory distress) and gastrointestinal (diarrhea, cramps) tract, and also dries up respiratory tract secretions.

9. The companion drug to Atropine is 2-PAM CL; this drug complements the action of Atropine. 2-Pam Chloride acts to restore normal functions at the nerve ending by removing the nerve agent and affecting toxin irreversibility. This antidote is effective at re-establishing normal skeletal muscle contraction (relieves twitching and paralysis of respiratory muscles).

RECOMMENDED ANTIDOTE DOSING SCHEDULE FOR EXPOSURE TO NERVE AGENT

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

2. If the patient exhibits SLUDGEM but no central nervous system (CNS) findings are present, then two (2) Atropine auto-injectors and one (1) 2-PAM CL injector should be given.

3. In either case, remove secretions, maintain patient’s airway and, if necessary and the situation permits, use artificial ventilation.

4. Repeat dosages will be given as specified in the Extended Re-evaluation and Treatment Schedule (Table 2).

5. If symptoms resolve, then only monitoring is necessary.

6. Pre-measured doses of auto-injectors should be safe in most adults. It should be noted, however that auto-injectors were designed for a military profile: approximate age 18-35, weight 70 kg. Or 154 lbs., healthy and with no preexisting medical conditions.

7. Pralidoxime (2-PAM CL) is most effective if administered immediately after poisoning and following but not before Atropine, especially for severe exposures.

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

10. Diazepam (Valium) may be given cautiously if convulsions are not controlled.

**Antidote Dosing Schedules:**

<table>
<thead>
<tr>
<th>Signs &amp; Symptoms</th>
<th>Atropine Dose Monitor Interval</th>
<th>2-Pam Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severe Respiratory Distress, Agitation, <strong>SLUDGEM</strong></td>
<td>3 Auto-injectors (6 mg) Monitor every 5 minutes</td>
<td>3 Auto-injectors (1.8 gms)</td>
</tr>
<tr>
<td>Respiratory Distress, <strong>SLUDGEM</strong></td>
<td>2 Auto-injectors (4 mg) Monitor every 10 minutes</td>
<td>1 Auto-injector (600 mg)</td>
</tr>
<tr>
<td>Asymptomatic None</td>
<td>Monitor for signs &amp; symptoms every 15 minutes</td>
<td>None</td>
</tr>
</tbody>
</table>

In the initial phase, triage will be initiated in the Hot Zone, continued in the warm zone, and performed only by trained personnel who are wearing appropriate Personal Protective Equipment (as determined by the Incident Commander). Patient decontamination will be simultaneous with and/or prior to treatment. Children should be decontaminated and have expedited transport off scene especially if they are demonstrating any signs and symptoms of exposure.

**Extended Re-Evaluation & Treatment Phase:**

This phase is reached once patients have been initially managed and patient volume allows for more protracted patient assessments.

**Extended Re-evaluation and Treatment Schedule (Table 2)**

<table>
<thead>
<tr>
<th>Signs &amp; Symptoms</th>
<th>Atropine Dose Monitor Interval</th>
<th>2 Pam Dose</th>
<th>Atropine Repeat Dosing Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severe Respiratory Distress, Agitation, <strong>SLUDGEM</strong></td>
<td>2 mg Monitor every 5 minutes</td>
<td>Up to a maximum of 1.8 gms. (3 auto-injectors)</td>
<td>Atropine 3-5 minutes as needed</td>
</tr>
<tr>
<td>Respiratory Distress <strong>SLUDGEM</strong></td>
<td>2 mg Monitor every 5 to 15 minutes</td>
<td>Up to a maximum of 600 mg. (1 auto-injector)</td>
<td>Atropine 5-10 minutes as needed</td>
</tr>
<tr>
<td>Asymptomatic</td>
<td>None Monitor every 15 minutes</td>
<td>None</td>
<td>Atropine 5-15 minutes as needed</td>
</tr>
</tbody>
</table>
Note: Personnel operating in this phase should be aware of the potential for “off-gassing”. Off-gassing is the process by which vapors are given off by chemically contaminated clothing.

Cautions For Use Of Auto-Injectors:

1. Every potential exposure in the immediate vicinity of the incident must be medically evaluated and monitored. Delayed symptoms may present anytime post incident.

   Any patient ill enough to receive even one dose of atropine must be evaluated at an appropriate facility (e.g. casualty collection point, hospital, etc.).

2. Signs or symptoms of nerve agent poisoning may reappear. Serial observations are a critical part of the management process.

3. Auto injectors have been developed for use in the adult population. Safety and effectiveness of 2-PAM CL in children has not been established. The atropine and 2-PAM CL antidote auto injectors should not be used in children 9 years of age or younger.

   For additional information on the treatment of pediatric patients contact medical control or refer to local REMAC developed protocols.

Adverse Reactions:

Note: Adverse reactions may occur but there are no contraindications to treating systematic patients.

1. Atropine may cause chest pain. It may also exacerbate angina or induce a myocardial infarction.

2. Up to one hour after intramuscular injection of 2-PAM CL some pain may be experienced at the site of injection.

3. 2-PAM CL may cause blurred vision, double vision (diplopia), dizziness, headache, drowsiness, nausea, rapid heart rate (tachycardia), increased blood pressure, and hyperventilation.

4. Both (Atropine and 2-Pam CL) should be used with caution (but not withheld) in patients with preexisting cardiac disease, high blood pressure, or strokes, particularly in the Extended Re-evaluation and Treatment Phase.

Auto-Injectors – General:

Note: Use of antidotes will not protect responders from anticipated exposures.
1. Auto-injectors are self-contained, simple, compact injection systems that come equipped with a pre-measured dose (normal adult dose) of antidote.

2. An antidote relieves, counteracts, or reverses the effects of poisons or drugs such as nerve agents.

3. The Mark I kit must be kept at room temperature (about 25°C 77°F) and must be protected from freezing.

4. **Mark 1 antidote kits are to be used only:**
   
   1) when specific signs and symptoms of exposure are present
      
      AND
   
   2) the scene has been declared the site of a nerve agent release by a local competent authority
      
      AND
   
   3) Following consultation with Medical Control and in compliance with any local REMAC Nerve Agent Protocol.
      
      a. The Mark 1 injectors are not to be used as a prophylaxis for personal protection.
      
      b. There is to be no self-administration of antidote.

5. Auto-injectors permit rapid administration of antidote, prevent needle cross-contamination between patients, and enable rapid and accurate administration to a large number of patients (even if the emergency provider and the patient are in chemical protective clothing).

6. Auto-injectors facilitate treatment by providing simple, accurate, drug administration of a pre-measured, controlled dose.

7. Auto-injectors administer a predictable drug dose that is not operator dependent.

8. Auto-injectors contain pre-measured doses of the nerve agent antidotes:
   
   1) Atropine
   
   2) 2-PAM Chloride (2-PAM CL; pralidoxime chloride)

9. Each auto-injector contains pre-measured amounts of Atropine (2 mg total dose per injection) and 2-PAM CL (600 mg total dose per injection).

10. Mark 1 antidote kits are available and are only to be used under the direction of medical control in accordance with a local REMAC approved
Nerve Agent Exposure protocol. EMS agencies must be identified as a participant in a municipal response plan involving nerve agents.

Directions For Use Of Auto-Injector

1. When auto-injector use is indicated, the recommended procedure is to inject the contents of the auto-injector into the muscles of an anterolateral (front and side) thigh (through the pocket).

2. Procedure:
   1) Remove safety cap (yellow on Atropine; gray on 2-PAM CL). Do not touch the colored end of the injector after removing the safety cap.
   2) Caution: The injector can and will inject into the fingers or hand if any pressure is applied to either end of the injector.
   3) Hold injector as you would a pen. Place colored end (green on Atropine, Gray on 2-PAM CL) on thickest part of thigh and press hard until injector is activated.
   4) Pressure automatically activates the spring, which plunges the needle into the muscle and simultaneously forces fluid (Atropine or 2-Pam CL) through it into the muscle tissues.
   5) Hold firmly in place for ten seconds then remove. Massage the area of injection.
   6) After each auto-injector has been activated, the empty container should be disposed of properly. It cannot be refilled nor can the protruding needle be retracted.

IMPORTANT: Physicians and/or other medical personnel and emergency responders assisting evacuated victims of nerve agent exposure should avoid exposing themselves to cross-contamination by ensuring that they do not come into direct contact with the patient’s clothing.

Documentation:

- When a patient has received treatment with the use of a Mark I kit(s) there must be a method to record such information so persons providing subsequent care are aware of that treatment and the amount of medication given.
- If the resources are present it is recommended that a triage tag be placed on each patient and that any treatment given be recorded on that tag.
• If the patient is provided with care prior to decontamination than replace that triage tag following decontamination with a new (dry) tag and copy over any information regarding treatments already provided.

• In the event triage tags are not available, documentation might be provided by affixing a piece of medical tape on the patient indicating what care has been provided. Be sure that if such a system is used that any tape applied prior to decontamination is removed as part of decontamination and the information is exactly copied on any new documents pertaining to the patient.

Sample Protocol:

Sample Protocol:

Attached to this policy and guideline is a model “Mark I PROTOCOL” based upon existing metropolitan response system protocols and various federal agency recommendations for administration. This protocol is not mandated and was not specifically approved by the SEMAC. This protocol is provided to assist a Regional Medical Advisory Committee (REMAC) or municipal system Medical Director in developing a local protocol. This model is not intended for independent use by an EMS agency. It may be used only with medical authorization and participation of the agency in a municipal or MMRS plan.

There are currently five metropolitan areas that are part of the MMRS program in New York State:

- New York City
- Yonkers
- Buffalo
- Rochester
- Syracuse

If your agency is included in an MMRS or municipal response plan you may have received training and formal protocols for WMD response, including the use of the “Mark I Kits”. This guideline, if different from the plan in which you participate, is not meant to supercede your local protocol, medical control or policy.

This policy has been distributed to your REMAC, Regional EMS Councils and County Emergency Management authorities.

Issued and Authorized by:
Edward G. Wronski, Director
Bureau of EMS
MODEL PROTOCOL FOR THE USE OF MARK I KITS

Purpose: These are antidotes to be used in instances of exposure to a nerve or organophosphate agent.

Use: The Mark I is to be used only if you are part of the MMRS and or a Municipal Response Plan.

Contents: (1) Atropine Auto-Injector (2 mg total dose per injection)
(2) 2-PAM (2-PAM CL; pralidoxime chloride) 600 mgs. total dose per injection.

• NOTE: These injectors are not to be used as a prophylactic modality. There is to be no self-administration of the antidote.

I: Mark I Kit

(a) To be used only in a disaster situation and only if you are a part of the MMRS and or a Municipal Response system.
(b) The Mark I Kit is only to be utilized under direct authority of Medical Control.

II: Auto Injector Use

(a) Pre measured doses in auto-injectors should be safe for most adults.
(b) Atropine auto-injector and Pralidoxime (2 PAM CL) may be administered by qualified emergency personnel and designated emergency responders who have had adequate training in on-site recognition and treatment of nerve and or organophosphate agent intoxication in the event of a chemical release. This is specific to the disaster setting.
(c) Medical treatment is directed to relieving respiratory distress and alleviating seizures.

III: Indications for use of the Auto Injectors

(a) It is a concern that the use of auto-injectors could lead to administration of inappropriate and harmful doses during a non-chemical agent or minimal exposure situations. The auto-injectors are to be used only if the patient presents with SLUDGEM + RESPIRATIONS and AGITATION.
(b) The Atropine and 2-PAM CL auto injectors should be used by qualified emergency medical personnel and designated emergency responders only after the following events have occurred:

1) The recognition of the existence of a potential chemical or organophosphate agent release in an area.
2) Some or all of the symptoms of the nerve agent poisoning cited below are present:
SLUDGEM + RESPIRATION and AGITATION

S – salivation (excessive drooling)
L – lacrimation (tearing)
U – urination
D – defecation / diarrhea
G – GI upset (cramps)
E – emesis (vomiting)
M – muscle (twitching, spasm, “bag of worms”)

+ RESPIRATION – difficulty breathing / distress (sob, wheezing)

+ AGITATION + CNS SIGNS – confusion, agitation, seizures, coma.

3) Atropine must be given first, **do not give anything else until the effects of atropine become apparent.** Only when the effects of the atropine have been seen can you then give 2 – PAM CL.
4) If symptoms resolve, then only monitoring is necessary.
5) If severe signs and symptoms are present; three (3) Atropine auto-injectors and three (3) 2-PAM CL injectors should be administered in rapid succession (stacked).

1. Remove secretions
2. Maintain an open airway
3. Use artificial ventilation in necessary and possible
4. Repeat Atropine immediately as directed

6) Pralidoxime (2-PAM CL) is most effective if administered immediately after the poisoning but not before Atropine, especially for severe exposures.
7) If available Diazepam (Valium) may be cautiously given, under direct medical control, if convulsions are not controlled.
8) When the nerve agent has been ingested, exposure 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.
9) 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.

7/2/2002