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PEDIATRIC EXPERT ADVISORY PANEL (PEAP)
ADDRESSING TERRORISM, DISASTER AND PUBLIC HEALTH EMERGENCY

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ATROPINE USE IN CHILDREN AFTER NERVE GAS EXPOSURE

Following the FDA's approval of a pediatric dosage Atropen®, the Pediatric Expert Advisory Panel was asked to review the existing guidelines and recommendations regarding the treatment of children exposed to nerve agents and the Mark-1 Kit; review the new literature on pediatric nerve agent exposure; and to develop recommendations and guidelines for this new device including modifications to the existing recommendations and guidelines if warranted.

In May 2003, the first nationally accepted pediatric disaster and terrorism preparedness recommendations and treatment guidelines were issued by the Program for Pediatric Preparedness of the National Center for Disaster Preparedness (NCDP). These guidelines were based on a National Consensus Conference sponsored by the Program for Pediatric Preparedness and funded by the Agency for Healthcare Research and Quality and the EMS for Chidlren Program of the Health Resources and Services Administration. At that time, the only available treatment for certain types of nerve gas exposure (predominantly those with anticholinesterase properties) was the Mark 1 kit.

The recommendations were based on established usage of antidotes for cholinergic toxicity and were felt to be both safe and supported by the literature. It was stated that the Mark 1 Autoinjector kits (although not approved for pediatric use) should be used as initial treatment for children with severe, life-threatening nerve agent toxicity for whom IV treatment is not possible or available, or for whom more precise IM (mg/kg) dosing would be logistically impossible.

It was further felt that while not within the published dosage range for cholinergic toxicity, if a Mark 1 kit was the only source of atropine and pralidoxime available after a bona fide exposure it should be used to treat all children, even those younger than 3 years old.

Furthermore, it was felt to be imperative to expedite approval of the pediatric autoinjector kit (which contains both atropine and an oxime and is designed for children) that is currently produced and marketed abroad but not available in the United States.

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Recommendations and Guidelines: What You Need to Know

Antidotes (Atropine & Pralidoxime)

The recommendations regarding this new device, a pediatric dosage AtroPen® and the existing Mark 1 kit (based on the key points listed, information from the consensus conference and on data that have been published since that meeting) are summarized below:

1. **The Mark 1 kit should remain as the preferred emergency treatment for children of any age exposed to a nerve agent with the dosage based on the previously published tables,** *Autoinjector Usage* and *Recommended Treatment and Management of Chemical Agents Used in Terrorism* (Consensus Conference Executive Summary and on pages 3 and 6 of this document).

2. **The Mark 1 kit should remain as the preferred emergency treatment for children younger than 3 years old after bona fide nerve agent exposure if it is the only source of atropine and pralidoxime opperationally feasible or available.**

3. If there are overriding regulations or legislation that explicitly prohibits agencies from using the Mark 1 kits for children, then these agencies should stock and use the pediatric dosage AtroPen® for the treatment of nerve agent exposure in children. It is recognized that the pediatric dosage AtroPen® is not equivalent to the Mark 1 kit and does not treat all children. As a result these agencies must also stock and use atropine in other forms for children weighing less than 15 pounds and pralidoxime for all children (this includes stocking pediatric appropriate administration equipment for these pharmaceuticals).

Anticonvulsants

The following additional recommendations regarding needed anticonvulsant treatment (based on the key points listed above, information from the consensus conference, and on data that have been published since that meeting) was made by the Pediatric Expert Advisory Panel:

1. **The complete treatment of nerve agent exposure would necessitate the usage of anticonvulsants.** All providers, agencies and stockpiles in addition to atropine and pralidoxime must have an anticonvulsant agent in a formulation and concentration that can be administered to children in as rapid a fashion as possible (as available this should include the usage of auto-injectors).

2. The anticonvulsants and the dosage guidelines which can be used to treat children exposed to a nerve agent who have either a severe exposure or who are experiencing a seizure are:

   - Diazepam
     0.05-0.3 mg/kg (max 10 mg) IV or IM
   - Lorazepam
     0.1 mg/kg IV or IM (max 4 mg)
   - Midazolam
     0.1-0.2 mg/kg (max 10 mg) IV or IM

Rationale for Recommendations

The Pediatric Expert Advisory Panel felt the following key points must be considered when making a determination regarding the role of the pediatric dosage AtroPen®:

- AtroPen® is not equivalent to the current Mark 1 kit because it does not include pralidoxime. An oxime should be included for appropriate treatment of nerve agent exposure.
- The pediatric dosage AtroPen® does not have an approved indication for use in children weighing less than 15 pounds, ie, infants and young toddlers.
- The Mark 1 Kit should be used in children 3 years and older. This represents acceptable dosage ranges for the first 60 minutes of treatment based on mg per kg dosing (see table below). The possible risk of use in children younger than 3 years old after bona fide nerve agent exposure would be far outweighed by the benefit of treatment.
- Several stockpiles and organizations, based on legislation or regulation, may only stock and use devices for their FDA approved label indications.
- While significant attention has been focused on the need for atropine and an oxime following a nerve agent exposure, complete treatment will require the usage of anticonvulsants.
- Previous and recent data has shown that even when atropine is administered in doses higher than traditional cholinergic toxicity doses, it has not been shown to cause toxicity in small children and infants.

Autoinjector Usage

Approximate age	Approximate weight	Number of autoinjectors (each type)	Atropine dosage range (mg/kg)	Pralidoxime dosage range (mg/kg)
3-7 yrs	13-25 kg	1	0.08-0.13	24-46
8-14 yrs	26-50 kg	2	0.08-0.13	24-46
>14 yrs	>51 kg	3	0.11 or less	35 or less

NOTE: Each Mark 1 kit contains two autoinjectors (0.8 inch needle insertion depth), one each of atropine 2 mg (0.7 ml) and pralidoxime 600 mg (2 ml); while not approved for pediatric use, they should be used as initial treatment in circumstances for children with severe, life-threatening nerve agent toxicity for whom IV treatment is not possible or available or for whom more precise IM (mg/kg) dosing would be logistically impossible. Suggested dosing guidelines are offered; potential excess of initial atropine and pralidoxime dosage for age/weight, although within general guidelines for recommended total over first 60-90 min of therapy for severe exposures. This table lists usage of the Mark 1 kit only down to age 3 based on adherence to recommended dosages for atropine and pralidoxime. However, if an adult Mark 1 kit is the only available source of atropine and pralidoxime after a nerve agent exposure, it should not be withheld from even the youngest child.

Physiology of Nerve Agents

Nerve agents are liquids under temperate conditions. The most commonly discussed agents are VX, GA (Tabun), GB (Sarin), GD (Soman), and GF. The more volatile ones constitute both a vapor and a liquid hazard when dispersed. Nerve agents are organophosphorus cholinesterase inhibitors. They inhibit butyrylcholinesterase in plasma, acetylcholinesterase on erythrocytes, and acetylcholinesterase at cholinergic receptor sites in tissue. Some commonly used pesticides (for example, the organophosphate [OP] Malathion and the carbamate Sevin) and some common therapeutic drugs (the carbamates pyridostigmine [Mestinon] and physostigmine [Antilirium]) also inhibit acetylcholinesterase and can be considered "nerve agents." However, while the OP pesticides cause the same biological effects as nerve agents, there are some important differences in the duration of biological activity and response to therapy. Acetylcholinesterase (RBC) is most sensitive for nerve agents while Butyrylcholinesterase (plasma) is more sensitive for most insecticides

After a nerve agent inhibits the tissue enzyme, the enzyme cannot hydrolyze acetylcholine, the neurotransmitter, at cholinergic receptor sites. Acetylcholine accumulates and continues to stimulate the affected organ. **The clinical effects from nerve agent exposure are caused by excess acetylcholine.**

The normal physiology is an electrical impulse goes down the nerve. This impulse causes release of the neurotransmitter, acetylcholine (Ach). Then ACh stimulates a receptor site on an organ and causes the organ to act. The ACh is destroyed by acetylcholinesterase (AChE) and once destroyed no more organ activity is noted. Organs with cholinergic receptor sites include the smooth muscles, skeletal muscles, central nervous system (CNS), and most exocrine glands. In addition, cranial efferents and ganglionic afferents are cholinergic nerves. There are different forms of the receptor for Ach which are categorized by their location and whether they are stimulated by either nicotine or muscarine. The muscarinic sites include the smooth muscles and glands. Nicotine will stimulate other cholinergic sites, known as nicotinic sites, which are those in skeletal muscle and ganglia. Because both the muscarinic (vagal) and nicotinic (pre-ganglionic) receptors can affect then heart rate but in different way, following nerve gent exposure a person may have a high, low, or normal heart rate.

Muscarinic	Nicotinic

• Smooth muscles
  o Airways - constrict
  o GI tract - constrict
  o Pupils - constrict
• Glands
  o Eyes, nose, mouth, sweat, airways, GI
• Heart, bradycardis (vagal)
	• Skeletal muscles
	  o Fasciculations, twitching, fatigue, flaccid paralysis
	• Pre-ganglionic
	  o Tachycardia, hypertension

The CNS contains both types of receptors, but the pharmacology in the CNS is more complex and less well understood. We know that an acute, large exposure of a nerve agent can cause loss of consciousness, seizures, apnea, and even death. Whereas an acute but small exposure of a nerve agent can cause minor CNS effects including slowness in thinking and decision making, sleep disturbances, poor concentration, emotional problems and other minor problems.

Treatment of Nerve Agents

The treatment of nerve agents includes decontamination, the traditional priorities of airway, breathing and circulation, supportive care for the symptoms and administration of antidotes. The goals of the antidotes are to reverse the underlying process:

1. Too much acetylcholine
   - Block excess acetylcholine
2. Enzyme inhibited
   - Reactivate enzyme

Atropine is a cholinergic blocking agent. Atropine and similar compounds block the effects of excess acetylcholine more effectively at muscarinic sites than at nicotinic sites. This leads to drying of secretions and reduced smooth muscle constriction. But atropine does not treat the skeletal muscle effects and can not treat the miosis, unless used topically.

The attachment of the agent to the enzyme is permanent (unless removed by therapy). Erythrocyte enzyme activity returns at the rate of erythrocyte turnover, about 1 percent per day. Tissue and plasma enzyme activities return with synthesis of new enzymes. The rate of return of the tissue and plasma enzymes is not the same, nor is the rate the same for all tissue enzymes.

However, the agent can be removed from the enzyme and the enzyme "reactivated" by several types of compounds, the most useful of which are the oximes. If the agent-enzyme complex has not "aged," oximes are useful therapeutically. Aging is a biochemical process by which the agent-enzyme complex becomes refractory to oxime reactivation of the enzyme. For most nerve agents, the aging time is longer than the time within which acute casualties will be seen, allowing time for treatment. However, the aging time of the GD-enzyme complex is about two minutes, and the usefulness of oximes in GD poisoning is greatly decreased after this period.

In addition the oximes via the nictonic sites can increase muscle strength but they have no effect on the muscarinic sites, thus treating effects of nerve agents which are not treated by atropine.

Nerve Agent Clinical Signs. *Vapor Exposure*

Mild

- Eyes: miosis, dim vision, headache
- Nose: rhinorrhea
- Mouth: salivation
- Lungs: Dyspnea ("tightness in the chest")
- Time of onset: seconds to minutes after exposure

Severe

- Same as mild, plus
  - Severe breathing difficulty or cessation of respiration
  - Generalized muscular twitching, weakness, or paralysis
  - Convulsions
  - Loss of consciousness
  - Loss of bladder, bowel control
- Time of onset: seconds to minutes after exposure

Nerve Agents Clinical Signs. *Liquid on Skin*

Mild/moderate

- Muscle twitching at site of exposure
- Sweating at site of exposure
- Nausea, vomiting
- Feeling of weakness
- Time of onset: 10 minutes to 18 hours after exposure

Severe

- Same as mild/moderate, plus
  - Severe breathing difficulty or cessation of breathing
  - Generalized muscular twitching, weakness, or paralysis
  - Convulsions
  - Loss of consciousness
  - Loss of bladder and bowel control
- Time of onset: minutes to an hour after exposure

Antidotes

Atropine is a cholinergic blocking or anticholinergic compound. It is extremely effective in blocking the effects of excess acetylcholine at peripheral muscarinic sites. When small doses (2 mg) are given to healthy individuals without nerve agent intoxication, atropine causes mydriasis, a decrease in secretions (including a decrease in sweating), mild sedation, a decrease in GI motility, and tachycardia.

Pralidoxime chloride (protopam chloride, 2-PAMCl) is an oxime. Oximes attach to the nerve agent that is inhibiting the cholinesterase and break the agent-enzyme bond to restore the normal activity of the enzyme. Clinically, this is noticeable in organs that have nicotinic receptors; abnormal activity in skeletal muscle decreases and normal strength returns.

Auto-Injector

Mark 1 kit Each Mark 1 kit contains two autoinjectors (0.8 inch needle insertion depth), one each of atropine 2 mg (0.7 ml) and pralidoxime 600 mg (2 ml);

Pediatric Dosage AtroPen® (New Device) Earlier this year, the FDA approved pediatric dosages of the AtroPen® (atropine injection), an auto-injector that has an indication for use in children weighing more than 15 pounds. The two dosages approved were 0.5 mg of Atropine for children weighing 15-40 pounds and 1.0mg atropine for children weighing 40-90 pounds. At this time a device with pediatric dosage of 2-PAM is not available. These new devices were presented to the working group for discussion and recommendations for their use in light of the existing Mark-1 device and the absence of a pediatric dosage 2-PAM device.

Recommended Treatment and Management of Chemical Agents Used in Terrorism

Agent	Toxicity	Clinical Findings	Onset	Decontamination	Management
Nerve Agents					
Tabun, sarin soman, VX	Anticholinesterase: muscarinic, nicotinic, and CNS effects	Vapor: miosis, rhinorrhea, dyspnea	Vapor: seconds	Vapor: fresh air, remove clothes, wash hair	Airway, breathing, circulatory support **Atropine** 0.05-0.1 mg/kg IV[b], IM[c] (min 0.1mg, max 5mg), repeatq2-5 min prn for marked secretions, bronchospasm. **Pralidoxime** 25-50 mg/kg IV, IM[d] (max 1 g IV; 2 g IM), may repeat within 30-60 min prn, then again q1h for 1 or 2 doses prn for persistent weakness, high atropine requirements. Diazepam 0.3 mg/kg (max 10 mg) IV, lorazepam 0.1 mg/kg IV or IM (max 4 mg), midazolam 0.2 mg/kg (max 10mg) IM prn for seizures or severe exposure.
		Liquid: Diaphoresis, vomiting Both: coma, paralysis, seizures, apnea	Liquid: Minutes to hours	Liquid: remove clothes, opious washing of skin and hair with sopa	
Vesicants					
Mustard	Alkylation	Skin: erythema, vesicles Eyes: inflammation Respiratory tract: inflammation, respiratory distress, acute respiratory distress synrome	Hours	Skin: soap and water Eyes: irrigation (water) Both: major impact only if done within minutes of exposure	Systomatic care
Lewisite	Arsenical		Immediate Pain		Possibly British anti-lewisite (BAL) 3 mg/kg IM q4-6h for systemic effects of lewisite in severe cases
Pulmonary Agents					
Chlorine, phosgene	Liberate HCI, alkylation	Eyes, nose, throat irrication (especially chlorine)	Minutes	Fresh air Skin: water	Systomatic care
		Bronchospasm, pulmonary edema (especially phosgene)	Bronchospasm: minutes Pulmonary edema: hours		
Cyanide	Cytochrome oxidase inhibition: cellular anoxia, lactic acidosis	Tachypnea, coma, seizures, apnea	Seconds	Fresh air Skin: soap and water	Airway, breathing, circulatory support; 100% oxygen Sodium bicarbonate prn for metabolic acidosis Sodium nitrite (3%) Dosage (ml/kg) — Estimated Hgb (g/dl) for average child 0.27 — 10 0.33 — 12 0.39 — 14 Maximum 10 ml Sodium thiosulfate (25%) 1.65 ml/kg (maximum 50 ml)
Riot Control Agents					
CS,CN (Mace®), capsaicin (pepper spray)	Neuropeptide substance P release, alkylation	Eye: tearing, pain, blepharospasm Nose and throat irritation Pulmonary failure (rare)	Seconds	Fresh air Eye: irrigation (water)	Topical ophthalmics, symptomatic care

a Decontamination, especially for patients with significant exposure to nerve agents or vesicants, should be performed by health care providers dressed in adequate personal protective equipment. For emergency department staff, this consists of a non-encapsulated, chemically resistant body suit, boots, and gloves with a full-face air purifier mask/hood.

b Intraosseous route is likely equivalent to intravenous.

c Atropine might have some benefit via endotracheal tube or inhalation, as might aerosolized ipratropium.

d Pralidoxime is reconstituted to 50 mg/ml (1 g in 20 ml water) for IV administration, and the total dose is infused over 30 min, or it may be given by continuous infusion (loading dose 25 mg/kg over 30 min, then 10 mg/kg/hr). For IM use, it might be diluted to a concentration of 300 mg/ml (1 g added to 3 ml water - by analogy to the Mark 1 autoinjector concentration), to effect a reasonable volume for injection.

Key: Hgb = hemoglobin; prn = as needed

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Note: Although some of these individuals were appointed to represent their organizations and agencies, and the comments contained in this document represent these individuals' input, formal approval of this document was not obtained from the boards of all organizations.

Pediatric Expert Advisory Panel (PEAP)

The purpose of the Pediatric Expert Advisory Panel (PEAP) is to discuss, review the current literature, analyze current issues and to make recommendations for policy and programmatic action on pediatric terrorism, disaster and public health emergency preparedness. The resulting information pieces are then posted to the pediatric section of the National Center for Disaster Preparedness website at www.ncdp.mailman.columbia.edu and distributed to interested parties.

The Pediatric Expert Advisory Panel is a major program of the National Center for Disaster Preparedness (at the Mailman School of Public Health), which is composed of public health experts in epidemiology and program development, clinical scientists and physicians with expertise in relevant areas, healthcare providers from a multitude of fields with pediatric and other relevant experience, bench scientists, public health historians, economists, legal and bioethics professionals, anthropologists, mental health professionals and sociologists, information technologists, communication and media specialists, representatives of national professional organizations and representatives of federal, state and local governmental agencies.

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The National Center for Disaster Preparedness

The National Center for Disaster Preparedness (NCDP) is a major national and international resource in disaster and terrorism readiness. While based in the Mailman School of Public Health, the only accredited school of public health in New York City, senior investigators, program planners and experts are selected from Columbia University Medical Center (College of Physicians & Surgeons, School of Nursing, School of Dental & Oral Surgery, New York Presbyterian Hospital) as well as from across the campus of Columbia University including the schools of Journalism, International Public Affairs, Law, and Teachers College. The Center also actively collaborates with: the Children's Health Fund, the New York City Department of Health and Mental Hygiene, the Office of Emergency Management, FEMA, The Center for Disease Control, Department of Homeland Security, Department of Education and other key federal, state and city agencies. The NCDP works with other academic institutions, as well as advocacy and public policy organizations.

Major Areas of Interest & Expertise:

- Preparedness issues for children, families and special populations
- Hospital and community health systems preparedness & curriculum development
- Public health workforce competencies
- Mental health aspects of disaster preparedness and cons quences of terrorism
- International collaborations
- Community-based preparedness planning
- Individual and family preparedness planning
- Technology applications to enhance preparedness
- Emerging public health crisis
- Public policy implications, costs and impact of preparedness planning

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