IMMUNIZATION PROTOCOLS FOR PHARMACISTS

Guidelines for Managing Severe Adverse Events Following Immunization

Revision as of 09/06:

- Having oxygen supplied on site at all pharmacies is now optional. However, in outlying areas of the state where a 911 response from emergency medical technicians (EMT) or paramedics might be delayed in supporting pharmacists with an adverse event, having oxygen available would be advisable. (Sect IV, p. 6)

I. **ORDER:** All pharmacists should have "basic knowledge" in how to recognize and initiate "first-aid" treatment of anaphylaxis. They should hold current CPR certification.

Note: It is assumed that universal precaution equipment and supplies are available (see Section IV).

ALL adverse events following immunization must be reported to the Vaccine Adverse Event Reporting System (VAERS).

The list of adverse events that must be reported for each vaccine can be found in each model standing order; but please note that reporting is not limited to these events alone. Should you have questions as to which events need to be reported, review the information on reporting in the *Epidemiology and Prevention of Vaccine-Preventable Diseases* text; contact VAERS at (800) 822-7967; visit the agency's website www.vaers.org.

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Pharmacist signature   Date

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II. VASOVAGAL RESPONSE TO INJECTION:

A. Signs and Symptoms:

Individual:

1. Becomes pale.
2. Feels faint, light headed, dizzy, nauseated, or reports a cold sweat (diaphoretic).
3. Collapses suddenly to unconsciousness, BUT maintains a slow, steady, strong pulse, normal respirations and blood pressure.

B. Treatment:

1. If the individual “feels faint”:
   - Have patient lie flat with feet elevated or sit with their head down for several minutes.
   - Ammonia capsules may be used as needed.
2. Unconsciousness:
   - Place flat on back, with feet elevated;
   - Unconsciousness from fainting should only last seconds;
   - May use an ammonia ampule (crush and wave near patient's nose).
3. Have patient rest in a quiet area for 10 minutes after regaining consciousness

III. ANAPHYLAXIS:

A. Symptoms:

1. Symptoms usually occur within the first 15 minutes following the injection, but may occur as soon as 30 seconds afterwards.
2. The more rapid that symptoms appear after an injection/administration, the more serious the reaction.
3. Anaphylaxis can be distinguished from a vasovagal response by quality of pulse. In the case of anaphylaxis, the pulse may be rapid, thready, and weak. The patient's blood pressure may be falling.

B. Early signs and symptoms (may include one or more of the following):

Cardiac:

- Rapid, weak pulse
- Hypotension
- Irregular heartbeat

Respiratory:

- Rapid, shallow breathing
- Tightness in throat/chest
- Hoarseness or stridor
- Congestion, sneezing, wheezing, or coughing

Cutaneous:

- Flushing, pallor, or cyanosis

Other:

- Swelling of lips and tongue, inability to swallow
- Anxiety, restlessness, apprehension, or a "sense of doom"
- Feeling of warmth
- Irritability
- Weakness
- Diaphoresis
- Headache
- "Pins and Needles" sensation on skin
- Flushing, pallor, or cyanosis
- Itching/edema
- Nausea, vomiting, diarrhea, or abdominal pain

ANAPHYLAXIS, continued

C. These signs and symptoms may lead to life-threatening manifestations:

1. Progressive Dyspnea: with or without stridor or wheezing. The upper airway may swell and become obstructed.
2. Shock: Hypotension, weak, fast, irregular pulse.
3. Collapse/unconsciousness; altered mental status, which may include seizures.

NOTE: Anaphylaxis may present with one, some or all of the life-threatening components.

D. TREATMENT OF ANAPHYLAXIS:

1. ASK SOMEONE TO CALL 911 FOR AN AMBULANCE IMMEDIATELY.
2. DO NOT WAIT FOR MILD SYMPTOMS TO SUBSIDE.
3. LAY PATIENT FLAT AND PROCEED WITH THE FOLLOWING:
   Quickly assess the ABC'S:
   - A = Airway;
   - B = Breathing and
   - C = Circulation.

• If at any time the adolescent or adult > 12 years of age suffers Respiratory or Cardiac Arrest, start CPR immediately.

4. **Inject EPINEPHRINE 1:1000, 0.3 ml subcutaneously or intramuscularly at the same site as where the vaccine was administered.**

   - If the antigen causing the anaphylactoid reaction was given by injection, the administration of epinephrine into the same site will slow the absorption of the antigen.

   - Observe until paramedics arrive; if no improvement in condition, repeat epinephrine dose every 10 minutes until symptoms subside.

5. Epinephrine dosage for use with pre-measured EPIPENS[1, 2]

EPIPEN®	Dose	Weight	Approximate age
Older child or adult	0.3 ml	>60 lbs (>27 kg)	>10 years

[1]The manufacturer recommends that the Epipen® should be injected IM into the anterolateral aspect of the thigh.

[2]Epipens expire frequently

ANAPHYLAXIS, continued

E. For severe urticaria (hives) or edema, particularly edema of the larynx:

1. Administer in addition to Epinephrine: DIPHENHYDRAMINE HYDROCHLORIDE (Benadryl®): 25-50 mg, IM (at a different site) as follows:

2. A tourniquet may be applied proximal to the site for 15-20 minutes, briefly releasing it every 3-5 minutes.

3. Apply ice to the site where the vaccine was administered. If more than one site is involved, apply ice to the sites that appear to be red, warm, and/or swelling.

4. Record all medications administered including the time, dosage, response, and the name of the pharmacist who administered the medication.

5. Take and record the patient's vital signs at the initial assessment, and at minimum - every 15 minutes, and following the administration of any additional medication.

6. If the patient is wheezing because of respiratory difficulty, elevate the head and chest slightly; If the patient's blood pressure is decreased and pulse is weak, lay them flat with feet elevated.

7. Any patient who develops signs and symptoms of anaphylaxis MUST be examined by a physician or transported via a fully equipped emergency vehicle to an emergency room before being released.

ASSURE THAT THE PHYSICIAN OR PERSON ACCEPTING RESPONSIBILITY OF THE PATIENT'S CARE KNOWS WHAT MEDICATIONS WERE GIVEN.

IV. EQUIPMENT AND SUPPLIES:

Equipment and supplies must be kept in a location convenient to the pharmacy clinic staff. Quarterly reviews must be completed and recorded to assure that the supplies are complete and that none of the medications will expire sooner than one month after the date of the next review.

A. Recommended Equipment and Supplies:
   1. Oral Airways (small, medium, and large).
   2. Oxygen (O_2): Optional
      a. In outlying areas of the state where a 911 response from emergency medical technicians (EMT) or paramedics might be delayed in supporting pharmacists with an adverse event, having oxygen available would be advisable. An O_2 container with nasal cannula, and face mask should be available. When using the nasal cannula, the regulator should be set as not to exceed 6 liters of O_2/minute. When using the facemask, the regulator should be set at 10-12 liters of O_2/minute with a minimum of 5 liters of O_2/minute.
   3. Breathing Bag with mask (If connected to O_2, regulator should be set between 12-15 liters/minute).
   4. Sphygmomanometer and Stethoscope.
   5. Band-Aids
   6. Alcohol Wipes
   7. Paper and Pen

B. Medications:
   1. Epinephrine solutions:
      a. Ampules of 1:1000 Epinephrine and syringes; <u>or</u>
      b. Pre-measured sources are available:
         The EpiPen® and the Epi auto-injectors are marketed by Dey. The EpiPen® (0.3 ml) auto-injectors are always ready for immediate use. They require no filling, assembly, or preparation. They are not calibrated for doses other than 0.3 ml or 0.15 ml. The concealed needle of the EpiPen® devices is activated by a simple push when held against the thigh and instantly delivers the appropriate dose of epinephrine. A safety cap prevents accidental discharge or injection.
   2. Diphenhydramine hydrochloride (Benadryl® 50 mg/ml).
   3. Ammonia ampules (smelling salts) for fainting only.

V. ADVERSE EVENT REPORTING:

Adverse events following immunization must be reported to the Vaccine Adverse Events Reporting System (VAERS) by calling 1-800-822-7967 or filling the form out on-line at www.vaers.org. In addition, a copy of the reporting form should be reported to the patient's primary health-care provider, per ORS 855-041-0510.

REFERENCES:

1. Crain, E, Gershel, J *Clinical Manual of Emergency Pediatrics*. (Chapter 1). 1997;McGraw-Hill: New York, NY.
2. Corey, EC. Treatment for anaphylaxis. Emergency 1993; 25 (10): 48-93.
3. Freeman, TM. Anaphylaxis: Diagnosis and treatment. Primary Care: Clinics in Office Practice 1998; 25(4): 809-817.
4. Lieberman P. Anaphylaxis: Guidelines for prevention and management. The Journal of Respiratory Diseases May 1995;16(5):456-62.
5. Lieberman P. Distinguishing anaphylaxis from other serious disorders. The Journal of Respiratory Diseases April 1995;16(4):411-91.
6. McKenry, LM, Salerno, E. *Mosby's Pharmacology in Nursing.* (Chapter 38). 1997;Mosby: St. Louis, MO.
7. Thompson, JM, McFarland, GK, Hirsh, JE, & Tucker, SM (1997). *Mosby's Clinical Nursing.* Mosby: St. Louis.
8. Wyatt, R. Anaphylaxis: How to recognize, treat, and prevent potentially fatal attacks. Postgraduate Medicine, 1996; 100 (2), 87.

For more information or to clarify any part of the above order, consult with the vaccine recipient's health-care provider or a consulting physician, or contact Health Services, Immunization Program, (971) 673-0300.

Electronic copy of this protocol available at:
http://www.oregon.gov/dhs/ph/imm/provider/pharmpro.shtml
To request material in an alternate format (e.g., Braille), call (971) 673-0300.