OREGON HEALTH AUTHORITY
IMMUNIZATION PROTOCOL FOR PHARMACISTS
MANAGING SEVERE ADVERSE EVENTS

Revisions as of 02-27-2015

- Clarification of aqueous epinephrine for injection, page 3
- Addition of epinephrine auto-injector options, page 4
- Update to required medications and dosages; diphenhydramine hydrochloride (Benedryl®), page 5
- Addition of hydroxyzine hydrochloride (Atarax® or Vistaril®) as a treatment option, page 6
- Manual blood pressure cuff and stethoscope required for E-kit
- Required check list for E-kit contents, attachment

I. ORDER:

1. Anaphylaxis; Section II pages 2–4; signs and symptoms, Appendix A, page 12

2. Severe urticaria (hives) or edema, particularly edema of the larynx; Section III. A, pages 5–7; signs and symptoms, Appendix A, page 13

3. Vasovagal Response, Syncope; Section IV. A. page 8; signs and symptoms, appendix A page 13

4. Required emergency equipment and supplies (E-Kit) Section V. A. pages 9–10

5. Adverse Events Reporting; Section VI, page 10

Immunizing Pharmacist Signature Date
For multiple signatures see: http://1.usa.gov/PharmacyImmunizationProtocols

Revised 02–2015
II. TREATMENT OF ANAPHYLAXIS:

1. **IMMEDIATELY** ASK SOMEONE TO CALL 911 FOR AN AMBULANCE

2. DO NOT WAIT FOR MILD SYMPTOMS TO SUBSIDE.

3. LAY PATIENT FLAT AND PROCEED WITH THE FOLLOWING:

4. Quickly assess the ABCs:
   a. A = Airway
   b. B = Breathing
   c. C = Circulation

5. Take and record the patients’ vital signs (pulse, respirations and blood pressure) at the initial assessment, and at minimum – every 5 minutes, and following the administration of any additional medication.

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

7. Start epinephrine. See Section 7A on page 3 and Section 7B on page 4 for dosing tables.

8. Monitor until Emergency Medical Services arrives. If no improvement in condition, repeat epinephrine dose every 5–15 minutes for up to 3 doses, depending on patient’s response.

9. Record pulse, respiration, blood pressure and medications administered to the patient, including time, dosage, response, and the names of the medical personnel administering medications.

10. Give report to emergency medical personnel upon arrival.

If at any time the patient suffers Respiratory or Cardiac Arrest, start CPR immediately.
### 7. A. First-line Treatment: Inject **EPINEPHRINE** 1:1000 (aqueous): 0.01 mg/kg of body weight up to 0.5mg maximum dose. May be repeated every 5–15 minutes for a total of 3 doses. Give intramuscularly (IM) **at site of injection reaction.** Subcutaneous injection is no longer recommended.¹ ²

<table>
<thead>
<tr>
<th>Age Group Dose</th>
<th>Weight in lbs</th>
<th>Weight in Kg</th>
<th>Epinephrine injectable (1:1000 dilution); IM = (1mg/mL) Minimum dose: 0.05mL</th>
<th>Epinephrine auto–injector 0.15mg or 0.3 mg</th>
</tr>
</thead>
<tbody>
<tr>
<td>1–6 mos</td>
<td>9–19 lbs</td>
<td>4–8.5 kg</td>
<td>0.05 ml (or mg)</td>
<td>Off label</td>
</tr>
<tr>
<td>7–36 mos</td>
<td>20–32 lbs</td>
<td>9–14.5 kg</td>
<td>0.1 ml (or mg)</td>
<td>Off label</td>
</tr>
<tr>
<td>37–59 mos</td>
<td>33–39 lbs</td>
<td>15–17.5 kg</td>
<td>0.15 ml (or mg)</td>
<td>0.15mg/dose</td>
</tr>
<tr>
<td>5–7 yrs</td>
<td>40–56 lbs</td>
<td>18–25.5 kg</td>
<td>0.25 ml (or mg)</td>
<td>0.15mg/dose</td>
</tr>
<tr>
<td>8–10 yrs</td>
<td>57–76 lbs</td>
<td>26–34.5 kg</td>
<td>0.3 ml † (or mg)</td>
<td>0.15 mg/dose or 0.3mg/dose</td>
</tr>
<tr>
<td>11–12 yrs</td>
<td>77–99 lbs</td>
<td>35–45 kg</td>
<td>0.4 ml (or mg)</td>
<td>0.3mg/dose</td>
</tr>
<tr>
<td>≥13 yrs</td>
<td>100+ lbs</td>
<td>46+ kg</td>
<td>0.5 ml § (or mg)</td>
<td>0.3mg/dose</td>
</tr>
</tbody>
</table>

Note: Dose by weight is preferred. If weight is not known, dosing by age is appropriate.
* Administration of epinephrine into the antigen injection site will slow absorption of the antigen.
† Maximum dose for children
§ Maximum dose for teens and adults
### 7. B. Epinephrine dosage for use with pre-measured EPIPENS \(^3, 4, 5\)

<table>
<thead>
<tr>
<th>Weight lbs</th>
<th>Weight Kg</th>
<th>EpiPen® Jr (^*\d)</th>
<th>EpiPen®</th>
<th>Auvi®-Q (^*\d) (child)</th>
<th>Auvi®-Q (^*) (adult)</th>
</tr>
</thead>
<tbody>
<tr>
<td>33–66 lbs</td>
<td>15–30kg</td>
<td>0.15mg (1:2000)</td>
<td></td>
<td>0.15mg (1:1000)</td>
<td></td>
</tr>
<tr>
<td>≥66 lbs</td>
<td>≥30kg</td>
<td>0.3mg (1:1000)</td>
<td></td>
<td>0.3mg (1:1000)</td>
<td></td>
</tr>
</tbody>
</table>

*EpiPen®s expire frequently. Keep at least three (3) EpiPen®s in stock.\(^4\)

\(^\d\) The manufacturers for both Auvi-Q® and EpiPen® recommend injection IM into the anterolateral aspect of the thigh.

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 EMERGENCY MEDICAL PERSONNEL ACCEPTING RESPONSIBILITY OF THE PATIENT’S CARE KNOWS WHAT MEDICATIONS WERE GIVEN.**

See APPENDIX A on page 12 for signs and symptoms of anaphylaxis.
III. A. Treatment: Diphenhydramine for severe urticaria (hives) or edema, particularly edema of the larynx:

Administer in addition to Epinephrine: **DIPHENHYDRAMINE HYDROCHLORIDE (Benadryl®):** IM (at a different site) as follows:

- **Infants** = 1.0 mg/kg body weight
- **Young child** = 1.25 mg/kg body weight
- **Adult** = 50–100 mg

<table>
<thead>
<tr>
<th>Age Group Dose</th>
<th>Weight in lbs*</th>
<th>Weight in Kg*</th>
<th>Injectable: 50mg/mL IM Liquid: 12.5mg/5mL Tablets: 25mg or 50mg</th>
</tr>
</thead>
<tbody>
<tr>
<td>7–36 months</td>
<td>20–32 lbs</td>
<td>9–14.5 kg</td>
<td>10 mg–15 mg</td>
</tr>
<tr>
<td>37–59 months</td>
<td>33–39 lbs</td>
<td>15–17.5 kg</td>
<td>15 mg–20 mg</td>
</tr>
<tr>
<td>5–7 years</td>
<td>40–56 lbs</td>
<td>18–25.5 kg</td>
<td>20 mg–25 mg</td>
</tr>
<tr>
<td>8–12† years</td>
<td>57–99 lbs</td>
<td>26–45 kg</td>
<td>25–50 mg&lt;sup&gt;1, 2&lt;/sup&gt;</td>
</tr>
<tr>
<td>≥13 years</td>
<td>100+ lbs</td>
<td>46+ kg</td>
<td>50mg&lt;sup&gt;2&lt;/sup&gt; –100 mg&lt;sup&gt;3&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

*NOTE:* Dose by weight is preferred. If weight is not known, dosing by age is appropriate.

† Children age ≥12 years, maximum single dose is 100mg<sup>1</sup>.  

<sup>1</sup> Administer in addition to Epinephrine.  
<sup>2</sup> Use with caution in children.  
<sup>3</sup> Use with caution in children and adults.
III. B. Optional Treatment: Hydroxyzine Hydrochloride\(^1,2\) (Atarax® or Vistaril®) for severe urticaria (hives) or edema, particularly edema of the larynx when Benadryl® is unavailable:

Administer in addition to Epinephrine:

**HYDROXYZINE HYDROCHLORIDE** (Atarax®, Vistaril®): Give by mouth as follows:

*NOTE:* Dose by weight is preferred. If weight is not known, dosing by age is appropriate.  

<table>
<thead>
<tr>
<th>Age Group Dose</th>
<th>Weight in lbs</th>
<th>Weight in Kg</th>
<th>Liquid: 10mg/5mL or 25mg/5mL</th>
<th>Tablets: 10mg or 25 mg</th>
<th>Capsules: 25mg</th>
</tr>
</thead>
<tbody>
<tr>
<td>7–36 mos</td>
<td>20–32 lbs</td>
<td>9–14.5 kg</td>
<td>5–7.5mg/dose</td>
<td></td>
<td></td>
</tr>
<tr>
<td>37–59 mos</td>
<td>33–39 lbs</td>
<td>15–17.5 kg</td>
<td>7.5–10mg/dose</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5–7 yrs</td>
<td>40–56 lbs</td>
<td>18–25.5 kg</td>
<td>10–12.5mg/dose</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8–10 yrs</td>
<td>57–76 lbs</td>
<td>26–34.5 kg</td>
<td>12.5–15mg/dose</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11–12 yrs</td>
<td>77–99 lbs</td>
<td>35–45 kg</td>
<td>15–25mg/dose</td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥13 yrs</td>
<td>≥100 lbs</td>
<td>≥46 kg</td>
<td>25mg/dose (50–100mg, maximum per day)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
III. C. Additional treatment for severe urticaria:

1. 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.

2. Record all medications administered including the time, dosage, response, and the name of the medical personnel who administered the medication.

3. Take and record the patient’s vital signs at the initial assessment, and at minimum - every 10 minutes, and following the administration of any additional medication.

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

5. 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.

See APPENDIX A on page 13 for signs and symptoms of urticaria.

**ASSURE THAT THE PHYSICIAN OR EMERGENCY MEDICAL PERSONNEL ACCEPTING RESPONSIBILITY OF THE PATIENT’S CARE KNOWS WHAT MEDICATIONS WERE GIVEN.**
IV. VASOVAGAL RESPONSE TO INJECTION:

A. Treatment: Ammonia capsule if needed.

1. If the individual “feels faint”:
   • Ammonia capsules may be used as needed.
   • Have patient lie flat with feet elevated or sit with their head down for several minutes.

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. Slowly have patient move to a sitting position and then standing, checking to make sure no symptoms recur.

Anaphylaxis can be distinguished from a vasovagal response by the quality of the pulse. In the case of anaphylaxis, the pulse may be rapid, thready, and weak. The patient’s blood pressure may be falling.

See APPENDIX A on page 13 for additional signs and symptoms of vasovagal response.
V. REQUIRED EMERGENCY EQUIPMENT AND SUPPLIES (E-KIT):

The properly stocked E-Kit expedites access to the contents reducing the time to assemble them in an emergency.

A. Minimum Required Equipment and Supplies:

- Current CPR Card
- Copy of Adverse Events Protocol
- 1 each: Pediatric and Adult size resuscitation face masks with one-way valve
- Sphygmomanometer and Stethoscope (Must be Manually Operated – NO AUTOMATIC DEVICES)
- Paper and pen(s)
- Syringes: For Epinephrine and Diphenhydramine injection only:
  - 1cc tuberculin syringe, 22–25g, 1”,1½” needles for epinephrine administration
  - 3cc syringes with 1–1½” needles for diphenhydramine (Benadryl®) administration
- Band-Aids, alcohol wipes, bottle of water for oral antihistamines
- Gloves

B. Minimum Required Medications

1. Epinephrine solution(s): Keep 2 doses available for both adult and pediatric use
   - Multi-dose vial or unit dose vial of 1:1000 Epinephrine and syringes;
   OR
   - Epinephrine Auto-injectors
     - EpiPen® 0.3mL of 1:1000 epinephrine=0.3mg
     - EpiPen® Jr. 0.3mL of 1:2000 epinephrine=0.15mg
     - Auvi-Q® 0.3mL of 1:1000 epinephrine=0.3mg
     - Auvi-Q®0.15mL of 1:1000 epinephrine=0.15mg

2. Diphenhydramine (Benadryl®): Keep 2 doses available for both adult and pediatric use
   - Injectable: 50mg/mL IM
   - Liquid: 12.5mg/5mL
   - Tablets: 25mg or 50mg
   OR

3. Hydroxyzine (Atarax® or Vistaril®):
   - Liquid: 10mg/5mL or 25mg/5mL
   - Tablets: 10mg or 25 mg
   - Capsules: 25mg

4. Ammonia ampules (smelling salts) for fainting only. Keep one box
OPTIONAL OXYGEN ($O_2$)$^4$

A. Having oxygen available is advisable in areas of the state where a 911 response from emergency medical personnel might be delayed in supporting pharmacists. 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.

B. Breathing bag with mask (If connected to $O_2$ regulator should be set between 12–15 liters/minute).

C. Oral airways (small, medium, and large).

VI. ADVERSE EVENTS REPORTING

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

Adverse events following immunization must be reported to the Vaccine Adverse Events Reporting System (VAERS) at 1-800-822-7967. Forms and procedures can be found at the VAERS website available at [www.vaers.hhs.gov](http://www.vaers.hhs.gov). In addition, a copy of the reporting form should be reported to the patient’s primary provider, per Oregon Revised Statute (ORS) 855-019-0280(4).  

To request this material in an alternative format (e.g., Braille) or to clarify any part of the above order, contact the Oregon Health Authority Immunization Program at 971.673.0300 and 711 for TTY. For other questions, consult with the vaccine recipient’s primary health care provider or a consulting physician.

Electronic copy of this protocol available at:

[1.usa.gov/PharmacyImmunizationProtocols](http://1.usa.gov/PharmacyImmunizationProtocols)
VII. REFERENCES:


APPENDIX A:

ANAPHYLAXIS: signs and symptoms

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 the symptoms appear after an injection or administration of a vaccine, 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 or chest
- Hoarseness or stridor
- Congestion, sneezing, wheezing, or coughing

Cutaneous:
- Flushing, pallor, cyanosis, or a hive-like rash
- "Pins and needles" sensation on skin
- Diaphoresis
- Itching or edema

Other:
- Swelling of lips and tongue, inability to swallow
- Anxiety, restlessness, apprehension or a “sense of doom”
- Feeling of warmth
- Irritability
- Weakness
- Headache
- Nausea, vomiting, diarrhea or abdominal pain
C. These signs and symptoms may lead to life-threatening manifestations:

- Progressive dyspnea: with or without stridor or wheezing. The upper airway may swell and become obstructed.
- Shock: hypotension, weak, fast, irregular pulse
- Collapse/unconsciousness; altered mental status, which may include seizures.
- **NOTE:** Anaphylaxis may present with one, some or all of the life-threatening components.

**Urticaria (hives): signs and symptoms**

- Migratory
- Well-circumscribed
- Erythematous (red)
- Pruritic plaques on the skin (itchy)

**Vasovagal Response or Syncope: signs and symptoms**

- Client becomes pale.
- Client feels faint, light headed, and dizzy, nauseated, or reports a cold sweat (diaphoretic).
- Client collapses suddenly to unconsciousness, BUT maintains a slow, steady, strong pulse, normal respirations and blood pressure.