

**OREGON HEALTH AUTHORITY**  
**IMMUNIZATION PROTOCOL FOR PHARMACISTS**  
Guidelines for Managing Severe Adverse Events

Following Immunization of individuals  $\geq 7$  years of age

**Revisions as of 01-01-2016**

- Clarification of epinephrine for anaphylaxis: <sup>1, 2</sup>

**ANAPHYLAXIS: 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) in the vastus lateralis muscle of the thigh, regardless of age, by auto injector, through the clothing if necessary.<sup>1</sup>

- Option for automatic blood pressure cuff with calibration requirements
- Optional Emergency Treatment Worksheet, page 14.

**I. OREGON IMMUNIZATION PHARMACY PROTOCOL:**

1. **Anaphylaxis;** Section II A, B and C. Pages 2–4; signs and symptoms, Appendix A, page 12
2. **Severe urticaria (hives) or edema,** particularly edema of the larynx; Section III. A–B. Pages 6–7; signs and symptoms, Appendix A, page 13
3. **Vasovagal Response, Syncope;** Section IV. page 8; signs and symptoms, appendix A page 13
4. **Required emergency equipment and supplies (E-Kit)** Section V. A. Page 9
5. **Adverse Events Reporting;** Section VI. Page 10

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Immunizing Pharmacist Signature

Date

For multiple signatures see: [1.usa.gov/PharmacyImmunizationProtocols](http://1.usa.gov/PharmacyImmunizationProtocols)

## II. TREATMENT OF ANAPHYLAXIS:

1. IMMEDIATELY ASK SOMEONE TO CALL 911 while you assess ABC's<sup>\*◇</sup>
2. Start epinephrine. See Section IIA and B on page 3 and Section IIC on page 4 for dosing tables or easy access page(s).
3. 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.<sup>2</sup> See optional Adverse Event Record Tool, page 14
4. Give diphenhydramine (Benadryl<sup>®</sup>) in the opposite arm from the vaccine reaction. See Section IIB, page 4.
5. Do not delay transport for Benadryl<sup>®</sup> injection.
6. Monitor until Emergency Medical Services arrive. If no improvement in condition, repeat epinephrine dose every 5–15 minutes for up to 3 doses, depending on patient's response.
7. Give report and list of medications given to emergency medical personnel upon arrival.
8. Complete your documentation.

If at any time the patient suffers Respiratory or Cardiac Arrest, start CPR immediately. Apply AED if available.

\* DO NOT WAIT FOR MILD SYMPTOMS TO SUBSIDE.

◇ Lay patient flat.

**Any client who develops signs and symptoms of anaphylaxis MUST be examined by a physician or transported via a fully equipped emergency vehicle to an emergency department. Any refusal of transport must be dealt with by EMS personnel.**

See APPENDIX A on page 12 for signs and symptoms of anaphylaxis.

**II. A. ANAPHYLAXIS: 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) in the vastus lateralis muscle of the thigh, by auto injector, through the clothing if necessary.<sup>1</sup>

Age Group	Weight in lbs	Weight in Kg	Epinephrine auto-injector 0.15mg or 0.3 mg <sup>* ◇</sup>
5–7 yrs	40–56 lbs	18–25.5 kg	0.15mg/dose
8–10 yrs	57–76 lbs	26–34.5 kg	0.15 mg/dose or 0.3mg/dose
11–12 yrs	77–99 lbs	35–45 kg	0.3mg/dose
≥13 yrs	100+ lbs	46+ kg	0.3mg/dose

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

<sup>\*</sup> If the agent causing anaphylactic reaction was given by injection, epinephrine can be injected into the same site to slow absorption.<sup>1</sup>

<sup>◇</sup>Subcutaneous injection is no longer recommended.<sup>2</sup>

**II. B. For Anaphylaxis with edema of the larynx or urticaria: Give Diphenhydramine (Benadryl®) IM in addition to Epinephrine.**

- Administer Benadryl® IM in the deltoid to persons ≥ 7 years:<sup>1, 2</sup>  
**Young child = 1.25 mg/kg body weight**  
**Adult = 50–100 mg**

Suggested dosing of Diphenhydramine (Benadryl®) for children and adults			
Age Group Dose	Weight in lbs *	Weight in Kg *	Injectable: 50mg/mL IM
≥7 years	40–56 lbs	18–25.5 kg	20 mg–25 mg
8–12 years	57–99 lbs	26–45 kg	25–50 mg <sup>1, 2</sup>
≥13 <sup>◇</sup> years	100+ lbs	46+ kg	50mg <sup>2</sup> –100 mg <sup>1</sup>

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

◇ Children age ≥13 years, maximum single dose is 100mg<sup>1</sup>.

**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**

**II. C. Optional Treatment: Hydroxyzine Hydrochloride <sup>1, 2</sup> (Atarax<sup>®</sup> or Vistaril<sup>®</sup>) for severe urticaria (hives) or edema, particularly edema of the larynx when Benadryl<sup>®</sup> is unavailable:**

**>Administer in addition to Epinephrine when Benadryl<sup>®</sup> is unavailable<**

- Give by mouth (PO) as follows:

Suggested dosing of <b>Hydroxyzine Hydrochloride</b> (Atarax <sup>®</sup> , Vistaril <sup>®</sup> ) for <b>children and adults</b>			
Age Group Dose	Weight in lbs	Weight in Kg	Liquid: 10mg/5mL or 25mg/5mL
≥7 yrs	40–56 lbs	18–25.5 kg	10–12.5mg/dose
8–10 yrs	57–76 lbs	26–34.5 kg	12.5–15mg/dose
11–12 yrs	77–99 lbs	35–45 kg	15–25mg/dose
≥13 yrs	≥100 lbs	≥46 kg	25mg/dose (50–100mg, maximum per day)

**\* NOTE: Dose by weight is preferred. If weight is not known, dosing by age is appropriate.<sup>2</sup>**

**III. A. URTICARIA: First-Line Treatment for Urticaria:**

- Give Benadryl<sup>®</sup> IM as follows:

Suggested dosing of Diphenhydramine (Benadryl <sup>®</sup> ) for <b>children and adults</b>			
Age Group Dose	Weight in lbs *	Weight in Kg *	Injectable: 50mg/mL IM
≥7 years	40–56 lbs	18–25.5 kg	20 mg–25 mg
8–12 years	57–99 lbs	26–45 kg	25–50 mg <sup>1, 2</sup>
≥13 years <sup>◇</sup>	100+ lbs	46+ kg	50mg <sup>2</sup> –100 mg <sup>1</sup>

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

◇ Children age ≥13 years, maximum single dose is 100mg. <sup>1</sup>

1. Record all medications administered including the time, dosage, response, and the name of the medical personnel who administered the medication.
2. 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.
3. 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.
4. **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 department before being released.**

**III.B. URTICARIA Optional Treatment: Hydroxyzine Hydrochloride <sup>1, 2</sup> (Atarax<sup>®</sup> or Vistaril<sup>®</sup>)**

- Give by mouth as follows:

**Hydroxyzine 0.5–1mg/kg body weight every 4–6 hrs**

Suggested dosing of <b>Hydroxyzine Hydrochloride</b> (Atarax <sup>®</sup> , Vistaril <sup>®</sup> ) for <b>children and adults</b>			
<b>Age Group Dose</b>	<b>Weight in lbs</b>	<b>Weight in Kg</b>	<b>Liquid: 10mg/5mL or 25mg/5mL</b>
<b>≥7 yrs</b>	40–56 lbs	18–25.5 kg	10–12.5mg/dose
<b>8–10 yrs</b>	57–76 lbs	26–34.5 kg	12.5–15mg/dose
<b>11–12 yrs</b>	77–99 lbs	35–45 kg	15–25mg/dose
<b>≥13 yrs</b>	≥100 lbs	≥46 kg	25mg/dose (50–100mg, maximum per day)

## IV. LOSS OF CONSCIOUSNESS: Syncope

### A. Treatment: Ammonia capsule if needed.

1. If the individual “feels faint”:
  - Ammonia ampules may be used: (crush and wave near patient's nose)
  - 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
  - Ammonia ampules may be used: (crush and wave near patient's nose)
  - 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. In a vasovagal response, the pulse should be slow.

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 Medications

- Epinephrine auto-injector system: keep at least 2 doses available for both adult and pediatric use
- Diphenhydramine (Benadryl<sup>®</sup>): Keep 2 doses available for both adult and pediatric use. Injectable: 50mg/mL IM for use in anaphylaxis and severe urticaria

### B. Optional Medications:

- Hydroxyzine (Atarax<sup>®</sup> or Vistaril<sup>®</sup>): **Do not stock if using Benadryl<sup>®</sup>**
  - Liquid: 10mg/5mL or 25mg/5mL
- Ammonia ampules (smelling salts) for fainting only.

### C. Minimum Required Equipment and Supplies:

- Current healthcare-level CPR Card (on record)
- Copy of current Adverse Events Oregon Model Standing Order in binder if using short forms attached to E-kit for easy access. See optional tool kit resources
- Copy of current E-kit check list
- 1 Adult size resuscitation face mask/shield with one-way valve
- 1 pediatric size resuscitation face/shield mask with one-way valve
- Sphygmomanometer and Stethoscope (Manually Operated OR Automatic Device\*)
- Syringes for Diphenhydramine (Benadryl<sup>®</sup>) injection only: 3cc syringes with 1–1½” needles
- Sterile adhesive bandage, alcohol wipes
- Gloves (Regular size), several pairs

\* Documentation that manufacturer calibration is current and that battery functions.

**OPTIONAL OXYGEN (O<sub>2</sub>) and SUPPLIES<sup>4</sup>**

A. Having oxygen available may be advisable in areas of the state where a 911 response from emergency medical personnel might be delayed. An O<sub>2</sub> 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<sub>2</sub>/minute. When using the facemask, the regulator should be set at 10–12 liters of O<sub>2</sub>/minute with a minimum of 5 liters of O<sub>2</sub>/minute.

B. Breathing bag with mask (if connected to O<sub>2</sub> regulator should be set between 12–15 liters/minute).

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

Adverse events following immunization must be reported to the Vaccine Adverse Events Reporting System (VAERS). The VAERS online report form is available at <https://vaers.hhs.gov/esub/step1>. A pharmacist who administers any vaccine must report to the OHA ALERT Immunization Information System in a manner prescribed by OHA within 15 days of administration. This replaces the former requirement to notify the primary health care provider. A pharmacist is not required to notify the primary health care provider. Oregon Administrative Rule 855-019-0290-(2)(3).<sup>5, 6</sup>

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](https://www.fda.gov/oc/ohrt/1.usa.gov/PharmacyImmunizationProtocols)

**VII. REFERENCES:**

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2. Immunization Action Coalition Website: Medical Management of Vaccine Reactions in Children and Adults.(2014) Available at: [www.immunize.org/catg.d/p3082a.pdf](http://www.immunize.org/catg.d/p3082a.pdf). Accessed 28 July 2015.
3. Oregon Department of Human Services, Public Health Division, Office of Community Health and Health Planning; *Treatment of Severe Allergic Reaction; A Protocol for Training*; April 2013 Available at: [public.health.oregon.gov/ProviderPartnerResources/EMSTraumaSystems/Documents/epinephrine/epinephrine-training-protocol.pdf](http://public.health.oregon.gov/ProviderPartnerResources/EMSTraumaSystems/Documents/epinephrine/epinephrine-training-protocol.pdf) Accessed 28 July 2015.
4. Merck Manual. Available at: <http://www.merckmanuals.com/professional/dermatologic-disorders/approach-to-the-dermatologic-patient/urticaria> Accessed 28 July 2015.
5. State of Oregon, Administration of Vaccines by Pharmacists: 855–019–270. Available at: [www.oregon.gov/pharmacy/Imports/Rules/December10/855-019\\_Perm.pdf](http://www.oregon.gov/pharmacy/Imports/Rules/December10/855-019_Perm.pdf) Accessed 11 August 2015.
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**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<sup>7</sup>



- 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.

## Adverse Event Documentation: EMERGENCY TREATMENT

- Call 911 while assessing ABCs → AIRWAY BREATHING CIRCULATION

- Administer epinephrine IM in thigh (vastus lateralis). If no improvement in condition, repeat epinephrine every 5–15 minutes for up to 3 doses depending on patient’s response.
- Take Vitals.
- Administer diphenhydramine (Benadryl<sup>®</sup>) IM in arm (deltoid) opposite vaccine reaction per flow chart.
- Repeat vitals every 5 minutes, and after each medication given until emergency help arrives.
- Perform CPR if needed. Use AED if available.
- Do not delay transport for Benadryl<sup>®</sup>.

**INFORMATION**

<b>Patient Name:</b> _____	<b>Allergies:</b> _____
<b>Date of Birth:</b> _____	<b>Vaccine Given:</b> _____
<b>Date:</b> _____	<b>Site:</b> _____
<b>Pharmacist:</b> _____	<b>Route:</b> _____

**Anaphylaxis – Urticaria – Syncope (circle one)**

**VITALS**

Time	Pulse	Respirations	Blood Pressure	Medication	Dose	Site–Route	Initials

Notes: