

IMMUNIZATION PROGRAM
Guidelines for Managing Severe Adverse Events
Following Immunization

Revisions as of 04-30-2016

- Clarification of epinephrine for anaphylaxis: 1, 2, 3, 4, 5, 6
- **ANAPHYLAXIS: Inject EPINEPHRINE 1:1,000 (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:*

- either by auto injector or
- by syringe and needle for infants and children weighing less than 15 kg.
- through the clothing if necessary.^{1, 2, 3, 4, 5, 6}

- Option for automatic blood pressure cuff with calibration requirements

I. OREGON IMMUNIZATION MODEL STANDING ORDER:

1. **Anaphylaxis**; Section II A Pages 2–3; signs and symptoms, Appendix A, pages 10–11
2. **Severe urticaria (hives) or edema**, particularly edema of the larynx; Section II. B–C. Pages 4–5; signs and symptoms, Appendix A, pages 10–11
3. **Vasovagal Response, Syncope**; Section III. Page 6; signs and symptoms, appendix A pages 10–11.
4. **Required emergency equipment and supplies (E-Kit)** Section IV. A. Page 7
5. **Adverse Events Reporting**; Section VI. Page 12

*Or to dose large teens and adults accurately

Health Officer Signature

Date

Health Officer Signature

Date

This order expires July 31, 2017

II. TREATMENT OF ANAPHYLAXIS:

1. IMMEDIATELY do the following:
 - a. Ask someone to call 911 and assess ABCs
 - b. Lay patient flat to prevent empty ventricle syndrome
 - c. Administer epinephrine using correct needle length for client²
2. If no improvement in condition, repeat epinephrine dose every 5–15 minutes for up to 3 doses, depending on patient's response.
3. **Do not delay transport**
4. 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.⁵ See optional Adverse Event Record Tool on page 12.
5. Monitor until Emergency Medical Services arrive.
6. Give report and list of medications given to emergency medical personnel upon arrival.
7. Complete your documentation.

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

* DO NOT WAIT FOR MILD SYMPTOMS TO SUBSIDE.

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 10 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, regardless of age, either by auto injector or by syringe and needle, through the clothing if necessary.^{1, 2, 3, 4, 5}

Suggested dosing of Epinephrine for children and adults: consider needle length ²				
Age Group	Weight in lbs	Weight in Kg	Epinephrine injectable (1:1000 dilution); IM =(1mg/mL) Minimum dose: 0.05mL ^{*, ‡}	Epinephrine auto-injector 0.15mg or 0.3 mg*
1–6 mos	9–19 lbs	4–8.5 kg	0.05 ml (or mg)	N/A
7–36 mos	20–32 lbs	9–14.5 kg	0.1 ml (or mg)	N/A
37–59 mos	33–39 lbs	15–17.5 kg	0.15 ml (or mg)	0.15mg/dose
5–7 yrs	40–56 lbs	18–25.5 kg	0.25 ml (or mg)	0.15mg/dose
8–10 yrs	57–76 lbs	26–34.5 kg	0.3 ml [◇] (or mg)	0.15 mg/dose or 0.3mg/dose
11–12 yrs	77–99 lbs	35–45 kg	0.4 ml (or mg)	0.3mg/dose
≥13 yrs	100+ lbs	46+ kg	0.5 ml [§] (or mg)	0.3mg/dose

Note: Dose by weight is preferred. If weight is not known, dosing by age is appropriate.⁵

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

◇ Maximum dose for children.

§ Maximum dose for teens and adults.

‡ Subcutaneous injection is no longer recommended.^{3, 4, 5}

II. B. URTICARIA: First-Line Treatment for Urticaria:

- Give Benadryl[®] IM as follows:

Suggested dosing of Diphenhydramine (Benadryl [®]) for children and adults			
Age Group Dose	Weight in lbs [◇]	Weight in Kg [◇]	Injectable: 50mg/mL IM
7–36 months	20–32 lbs	9–14.5 kg	10 mg–15 mg
37–59 months	33–39 lbs	15–17.5 kg	15 mg–20 mg
5–7 years	40–56 lbs	18–25.5 kg	20 mg–25 mg
8–12 years	57–99 lbs	26–45 kg	25–50 mg ^{1, 3}
≥13 years [§]	100+ lbs	46+ kg	50mg ² –100 mg ⁴

*** This order does not authorize use of Benadryl[®] in children ≤6 months of age.**

[◇] Dose by weight is preferred. If weight is not known, dosing by age is appropriate.⁵

[§]Children age ≥13 years, maximum single dose is 100mg.¹

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, 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 department before being released.**

II. C. Optional Treatment: Hydroxyzine Hydrochloride ^{1, 2, 3, 4, 5} (Atarax[®] or Vistaril[®]) for severe urticaria (hives) when Benadryl[®] is unavailable:

>Administer when Benadryl[®] is unavailable<

- Give **PO** as follows:

Suggested dosing of Hydroxyzine Hydrochloride (Atarax [®] , Vistaril [®]) for children and adults			
Age Group Dose	Weight in lbs	Weight in Kg	Liquid: 10mg/5mL or 25mg/5mL
7–36 mos	20–32 lbs	9–14.5 kg	5–7.5mg/dose
37–59 mos	33–39 lbs	15–17.5 kg	7.5–10mg/dose
5–7 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.⁵**

III. 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 10–11 for additional signs and symptoms of vasovagal response.

IV. 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: Consider needle length

1. Epinephrine solution(s): Keep at least 3 doses available for both adult and pediatric use
 - Multi-dose vial (MDV) or unit dose vial of 1:1,000 Epinephrine and syringes; 22 or 25 gauge, 1 to 1 ½ inch Needle²

OR

 - Epinephrine auto-injector system approved for use [exposed needle is only 0.16 mm (0.62 inches for adult) or 13 mm (0.51 inches for a child) length³];
 - ≥3 adult units
 - ≥3 pediatric units
2. Diphenhydramine (Benadryl[®]): Keep 2 doses available for both adult and pediatric use
 - Injectable: 50mg/mL IM for use in severe urticaria

B. Optional Medications:

1. Hydroxyzine (Atarax[®] or Vistaril[®]): Do not stock if using Benadryl[®]
 - Liquid: 10mg/5mL or 25mg/5mL
2. 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 Epinephrine and Diphenhydramine injection only:
- 1cc U-100 syringe, 22–25g, 1”, 1½” needles for epinephrine administration
- 3cc syringes with 1–1½” needles for diphenhydramine (Benadryl[®]) administration

- Sterile adhesive bandage, alcohol wipes
- Gloves (Regular size), several pairs

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

OPTIONAL OXYGEN (O₂) and SUPPLIES⁵

- A. Having oxygen available may be advisable in areas of the state where a 911 response from emergency medical personnel might be delayed. An O₂ 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 O₂/minute. When using the facemask, the regulator should be set at 10–12 liters of O₂/minute with a minimum of 5 liters of O₂/minute.
- B. Breathing bag with mask (If connected to O₂ regulator should be set between 12–15 liters/minute).
- C. Oral airways (small, medium, and large).

V. ADVERSE EVENTS REPORTING

Public providers are to complete the Vaccine Adverse Events Reporting System (VAERS) report online at <https://vaers.hhs.gov/esub/step1>. Save a copy of the report number for your records, and send copies of the report and VAERS ID number to the Oregon Immunization Program Vaccine Safety Coordinator via confidential email at ORVAERS.Reports@state.or.us or fax (971-673-0278). Private providers are to report events directly to VAERS and can read about options on how to do so at <http://vaers.hhs.gov/index>.

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 standing order is available at:

<http://1.usa.gov/OregonStandingOrders>

VII. REFERENCES:

1. American Academy of Pediatrics. Red Book: 2015 Report of the Committee on Infectious Diseases. Pickering LK, ed. 30th ed. Elk Grove Village, IL: American Academy of Pediatrics; 2015: 66–68.
2. Immunization Action Coalition Website: How to Administer Intramuscular and Subcutaneous Vaccine Injections to Adults. (2015). Available at: <http://www.immunize.org/catg.d/p2020a.pdf>. Accessed 08 March 2016.
3. Simons KJ, Simons ER: Epinephrine and its uses in anaphylaxis: current issues. Current Opinion in Allergy and Clinical Immunology: 2010; 10(4):354–361. Available at: <http://www.medscape.com/viewarticle/726456>. Accessed 2 March 2016.
4. Wood JP, Traub SJ, Lipinski C: Safety of epinephrine for anaphylaxis in the emergency setting: World Journal of Emergency Medicine: 2013; 4(4):245–251. Available at: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4129903/>. Accessed 2 March 2016.
5. Immunization Action Coalition Website: Medical Management of Vaccine Reactions in Children and Adults.(2014) Available at: www.immunize.org/catg.d/p3082a.pdf. Accessed 28 July 2015.
6. EpiPen® EpiPen® Jr. Adrenaline auto-injectors 0.3/0.15mg. EpiPen® frequently asked questions. Available at: <http://www.epipen.co.uk/hcp/faqs/>. Accessed 4 March 2016.
7. Merck Manual. Available at: <http://www.merckmanuals.com/professional/dermatologic-disorders/approach-to-the-dermatologic-patient/urticaria> Accessed 28 July 2015.

8. 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 symptoms⁷



- 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, lay client flat to prevent empty ventricle syndrome.
- Administer epinephrine IM in thigh (vastus lateralis) using correct needle length.² If no improvement in condition, repeat epinephrine every 5–15 minutes for up to 3 doses depending on patient’s response.
- **Do not delay transport.**
- Take Vitals.
- Repeat vitals every 5 minutes, and after each medication given until emergency help arrives.
- Perform CPR if needed. Use AED if available.
- See Urticaria standing order/protocol for diphenhydramine use and dosage.

INFORMATION

Patient Name: _____	Allergies: _____
Date of Birth: _____	Vaccine Given: _____
Date: _____	Site: _____
Signature: _____	Route: _____

Anaphylaxis – Urticaria – Syncope (circle one)

VITALS

Time	Pulse	Respirations	Blood Pressure	Medication	Dose	Site-Route	Initials

Notes: