

OREGON HEALTH AUTHORITY
IMMUNIZATION PROTOCOL FOR PHARMACISTS

Guidelines for Managing Severe Adverse Events Following Immunization	
Last Reviewed	08 May 2019
Last Revised	08 May 2019
This order expires	31 July 2021

May 2019:

Changes to the required emergency kit contents in Section V.

Changes to the anaphylaxis module in Section II A.

Changes to the required emergency kit checklist (separate document)

Changes to the optional Anaphylaxis/Epinephrine worksheet (separate document)

I. OREGON IMMUNIZATION PHARMACY PROTOCOL:

1. Anaphylaxis;

- a. **Treatment:** see Section II A;
- b. **Epinephrine IM injection table:** see Section II B;
- c. Anaphylaxis **signs and symptoms:** see Appendix Section 1, A–C

2. Severe Urticaria (hives);

- a. **Diphenhydramine IM injection table:** see Section III A
- b. **Hydroxyzine Hydrochloride PO table:** see Section III B
- c. Urticaria **signs and symptoms:** see Appendix Section 2

3. Loss of Consciousness: Syncope (fainting);

- a. **Treatment:** see Section IV;
- b. Fainting **signs and symptoms:** see Appendix Section 3.

4. Required emergency equipment and supplies (E-Kit): see Section V.

5. Documentation of adverse event worksheet: see Appendix Section 4.

Immunizing Pharmacist

Date

II. A. 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 client¹
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; DO NOT WAIT FOR MILD SYMPTOMS TO SUBSIDE.**
4. Take and record the patients’ vital signs (pulse, respirations) at the initial assessment, and at minimum – every 5 minutes, and following the administration of any additional medication.⁴ See optional Adverse Event Record Tool.
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.

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 for signs and symptoms of anaphylaxis.

II. B. ANAPHYLAXIS Cont.:

EPINEPHRINE SDV and MDV 1:1000 (aqueous): 0.01 mg/kg of body weight up to 0.5mg maximum dose. **Or** to dose large teens and adults accurately.

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.¹⁻⁴

Suggested dosing of Epinephrine for children and adults: consider needle length ^{1,8}				
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
7 years	40–56 lbs	18–25.5 kg	0.25 ml (or mg)	0.15mg/dose
8–10 years	57–76 lbs	26–34.5 kg	0.3 ml [*] (or mg)	0.15 mg/dose or 0.3mg/dose
11–12 years	77–99 lbs	35–45 kg	0.4 ml (or mg)	0.3mg/dose
≥13 years	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.⁴

^{*} Maximum dose for children.

[◇] Maximum dose for teens and adults. [§] Subcutaneous injection is no longer recommended.²⁻⁴

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

- Give Diphenhydramine **IM** as follows:

Suggested dosing of Diphenhydramine 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 ³
≥13 years [◇]	100+ lbs.	46+ kg	50mg ² –100 mg ⁴

* Dose by weight is preferred. If weight is not known, dosing by age is appropriate.⁴

◇ Children age ≥13 years, maximum single dose is 100mg.

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. Continue to monitor for and treat signs and symptoms progressing towards anaphylaxis when indicated.

III. B. Optional Treatment: Hydroxyzine Hydrochloride¹⁻⁴ for severe urticaria (hives) when diphenhydramine is unavailable:

>Administer when diphenhydramine is unavailable<

- Give **PO** as follows:

Suggested dosing of Hydroxyzine Hydrochloride for children and adults			
Age Group Dose	Weight in lbs*	Weight in Kg*	Liquid: 10mg/5mL or 25mg/5mL
7 years	40–56 lbs	18–25.5 kg	10–12.5mg/dose
8–10 years	57–76 lbs	26–34.5 kg	12.5–15mg/dose
11–12 years	77–99 lbs	35–45 kg	15–25mg/dose
≥13 years	≥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.⁴**

IV. LOSS OF CONSCIOUSNESS: Syncope or Fainting

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 for additional signs and symptoms of syncope or fainting.

V. REQUIRED EMERGENCY EQUIPMENT AND SUPPLIES (E-KIT):

Oregon Pharmacist Immunization Emergency-kit Requirements

Oregon Pharmacist Immunization Emergency Kit Requirements

May 2019

Required Documentation available on site:

- Immunization Training Certificate
- **You must be in possession of a Yellow Fever Stamp to administer this vaccine**
- Current Healthcare Provider CPR Card*
- Copy of Adverse Events Protocol

Required Equipment and Medications Maintained in a Separate Container:

Medications (generic formulations acceptable):

- Epinephrine solutions:
 - 1 multi-dose vial (MDV) of 1:1000 Epinephrine and syringe
OR **EXP: _____**
 - Epinephrine auto-injectors; 3 doses each of adult and pediatric size units
EXP: _____

Syringes: For Epinephrine injection **only**:

- 1-cc U-100 syringes, 22–25g, 1”, 1½” needles for epinephrine administration

Optional Medications and Equipment

- Diphenhydramine (Benadryl®): Keep 1 MDV or 2 SDV vials available
 - Injectable: 50 mg/mL IM
 - Syringes: For diphenhydramine injection only:
 - 3-cc syringes with 1–1½” needles for diphenhydramine (Benadryl®) administration

Optional Medications and Equipment Cont.

- Sphygmomanometer and Stethoscope: electronic devices must show current calibration and batteries as needed.
- Hydroxyzine for use when diphenhydramine is unavailable
 - Liquid: 10 mg/5 mL or 25 mg/5 mL
EXP: _____
 - Tablets: 10-mg or 25-mg
EXP: _____
 - Capsules: 25-mg
EXP: _____
 - Bottle of water for swallowing oral antihistamines
EXP: _____

Oxygen Supplies for Rural Areas or where 911 response may be delayed:

- O₂ Container **Level checked:** _____
- Nasal cannula: the regulator should not be set to exceed 6 liters of O₂/minute
- An oxygen face mask/shield with one-way valve: the regulator should be set at 10–12 liters of O₂/minute with a minimum of 5 liters of O₂/minute
- Breathing bag with mask with O₂ regulator should be set between 12–15 liters/minute
- Oral airways: small, medium and large

By signing below, I acknowledge that I have reviewed the Adverse Events Protocol & met all requirements:

Signature: _____ **Date Reviewed:** _____

*Note: Per OAR 855-019-0270: The pharmacist holds active CPR certification issued by the American Heart Association or the American Red Cross or any other equivalent program intended for a healthcare provider that contains a hands-on training component, is valid for not more than three years and is specific to the age and population the pharmacist treats.

VI. ADVERSE EVENTS REPORTING

Private providers are to report events directly to VAERS and can read about options on how to do so at <https://vaers.hhs.gov/reportevent.html>

A pharmacist who administers any vaccine must report the following elements 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).⁹

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

REFERENCES

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APPENDIX :

1. 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.**

NOTES:

- Both EpiPen® and EpiPen® Jr should be injected intramuscularly into the outside of the thigh, through clothing if necessary. The needle size of both the EpiPen® and the EpiPen® Jr is 22 gauge. The extended needle length after activation is 16 mm (~1 inch+) for the EpiPen® and 13 mm (~7/8 inch+) for the EpiPen® Jr. <http://www.epipen.co.uk/hcp/faqs/>⁶
- Why the Thigh: <http://www.aaaai.org/ask-the-expert/administration-of-epinephrine>

2. Urticaria (hives): signs and symptoms⁷



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

3. 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.

4. APPENDIX Cont. : 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: