

**PREVENTATIVE CARE**  
**STANDARD VACCINATION PROTOCOL**  
**MANAGING ADVERSE REACTIONS**  
**PROTOCOL for the OREGON PHARMACIST**

**AUTHORITY and PURPOSE:**

- Per [ORS 689.645](#), a pharmacist may prescribe and administer medications for the management of adverse reactions following immunization pursuant to a statewide drug therapy management protocol.

**STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:**

- Utilize the standardized Managing Adverse Events Assessment and Treatment Care Pathway (pg.2)
- Utilize Managing Adverse Events Protocol (see pages 3-7)
- Utilize Adverse Event Record Tool (Appendix A) & Emergency Kit Medications & Equipment List (Appendix B)
- Refer to Recognizing & Responding to Anaphylaxis (Appendix C)

**PRESCRIBING PARAMETERS:**

- Following all elements outlined in [OAR 855-115-0330](#) and [OAR 855-115-0335](#), a Pharmacist licensed and located in Oregon may prescribe and administer medications used in the management of adverse reactions following immunization in adherence with current CDC ACIP recommendations and Epidemiology, Prevention of Vaccine Preventable Diseases (Pink Book), and CDC Yellow Book: Health Information for International Travel information.

**PHARMACIST TRAINING/EDUCATION:**

- Prior to any Oregon licensed pharmacist administering a vaccine, in accordance with [OAR 855-115-0305](#), the pharmacist must:
  - Receive practical training on the injection site and administration technique that is utilized;
  - Complete training regarding hands-on injection technique, clinical evaluation of indications and contradictions of vaccines and the recognition and treatment of emergency reactions to vaccines;
  - Hold an 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 is specific to the age and population receiving the vaccine, drug or device, contains a hands-on training component, and is valid for not more than three years; and
  - Ensure any vaccine administered was stored in accordance with the drug storage rules for pharmacies in [OAR 855-041-1036](#)
- An Oregon licensed pharmacist practicing in Oregon may allow a Pharmacy Intern to perform the following duties related to vaccines:
  - An appropriately trained and qualified Intern may perform the same duties as a pharmacist except as prohibited in [OAR 855-120-0150](#).

## RESOURCES

- CDC ACIP General Best Practice Guidelines: Preventing and Managing Adverse Reactions- <https://www.cdc.gov/vaccines/hcp/imz-best-practices/preventing-managing-adverse-reactions.html>
- Epidemiology and Prevention of Vaccine-Preventable Diseases (Pink Book): Vaccine Administration- [https://www.cdc.gov/pinkbook/hcp/table-of-contents/chapter-6-vaccine-administration.html?CDC\\_AAref\\_Val=https://www.cdc.gov/vaccines/pubs/pinkbook/vac-admin.html](https://www.cdc.gov/pinkbook/hcp/table-of-contents/chapter-6-vaccine-administration.html?CDC_AAref_Val=https://www.cdc.gov/vaccines/pubs/pinkbook/vac-admin.html)
- Medical Management of Vaccine Reactions in Adults in a Community Setting- <https://www.immunize.org/catg.d/p3082.pdf>
- Medical Management of Vaccine Reactions in Children and Teens in a Community Setting- <https://www.immunize.org/catg.d/p3082a.pdf>
- Vaccine Adverse Event Reporting System (VAERS) <https://vaers.hhs.gov/index>



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**Assessment and Treatment Care Pathway**

**STEP 1: COLLECT**

- Observe patient's signs and symptoms
- Obtain prepared Emergency Kit (E-Kit)

**STEP 2: ASSESS**

- Assess patient's blood pressure and vital signs
- Anaphylaxis should be considered when signs or symptoms are generalized (i.e., if there are generalized hives or more than one body system is involved) or are serious or life-threatening in nature, even if they involve a single body system (e.g., hypotension, respiratory distress, or significant swelling of the tongue or lips)
- Activate emergency response (Call 911) if signs and symptoms indicate progression towards anaphylaxis

**STEP 3: PLAN**

- Prepare treatment medications if indicated
- Prepare for CPR

**STEP 4: IMPLEMENT**

- Apply treatment plan and/or administer treatment medications per protocol
- If at any time the patient suffers Respiratory or Cardiac Arrest, start CPR immediately and apply AED if available

**STEP 5: FOLLOW-UP**

- Continue assessing vitals and monitor per protocol until Emergency Medical Services arrive
- Document actions using Adverse Event Record Tool
- Report anaphylaxis and vasovagal syncope to the Vaccine Adverse Events Reporting System (VAERS) online at <https://vaers.hhs.gov/reportevent.html>.
- VAERS Reporting Table: <https://vaers.hhs.gov/resources/infoproviders.html>.

Event and Interval From Vaccination
A. Anaphylaxis or anaphylactic shock (7 days)
B. Vasovagal syncope (7 days)
C. Shoulder Injury Related to Vaccine Administration (7 days)
D. Any acute complication or sequelae (including death) of above events (interval – not applicable)
E. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval – see package insert)



**1. Anaphylaxis Protocol (Generalized Symptoms)**

- If symptoms are generalized, call 9-1-1 immediately. This should be done by a second person if available, while the primary healthcare professional assesses the airway, breathing, circulation, and level of consciousness of the patient. Do not delay transport; DO NOT WAIT FOR MILD SYMPTOMS TO SUBSIDE.
- Keep patient in recumbent position (flat on back) unless patient is having breathing difficulty. If breathing is difficult, patient's head may be elevated, provided blood pressure is adequate to prevent loss of consciousness. If blood pressure is low, elevate legs.
- Take and record the patients' blood pressure and vital signs (pulse, respirations) at the initial assessment, and at minimum – every 5 minutes, and following the administration of any medication.

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- D. The first-line and most important therapy in anaphylaxis is epinephrine. There are NO absolute contraindications to epinephrine in the setting of anaphylaxis.
- E. Administer 1mg/mL epinephrine intramuscularly (IM) into the anterolateral thigh (all ages), through clothing if necessary, with the correct needle length for the patient's age and size according to the dosage chart in Table 1.
- F. If no improvement in condition, repeat epinephrine dose every 5–15 minutes for up to 3 doses, depending on patient's response.
- G. Complete the Adverse Event Record Tool.
- H. If at any time the patient suffers Respiratory or Cardiac Arrest, start CPR immediately. Apply AED if available.
- I. Monitor until Emergency Medical Services arrive.
- J. Any patient who develops signs and symptoms of anaphylaxis MUST be transported via a fully equipped emergency vehicle to an emergency department. Any refusal of transport must be handled by EMS personnel.
- K. Give report and list of medications given to emergency medical personnel upon arrival.
- L. Medication Schedule:

**Table 1: Anaphylaxis**

<b>Inject EPINEPHRINE</b> (1mg/mL): 0.01 mg/kg of body weight up to 0.5mg maximum dose. <u>May be repeated every 5–15 minutes for a total of 3 doses.</u> Give intramuscularly (IM) in the vastus lateralis muscle of the thigh, <u>regardless of age</u> , either by auto injector or by syringe and needle, <u>through the clothing if necessary.</u> <sup>1</sup>				
<b>Suggested dosing of Epinephrine for children<sup>2</sup> and adults: consider needle length</b>				
Age Group	Weight in lb <sup>#</sup>	Weight in kg <sup>#</sup>	Epinephrine injectable (1:1000 dilution); IM =(1mg/mL) [Minimum dose: 0.05mL]	Epinephrine auto-injector 0.1mg (7.5-14.5 kg), 0.15mg (15-29.5 kg) or 0.3 mg (≥30 kg)
<b>6 months (use only for dosing by weight)</b>	9-16 lb	4-7 kg	0.05 mL (or mg)	Off-Label
	16.5-19 lb	7.5-8.5 kg		0.1mg/dose <sup>*</sup>
<b>7-36 months (use only for dosing by weight)</b>	20-32 lb	9-14.5 kg	0.1 mL (or mg)	0.1mg/dose <sup>*</sup>
<b>37-59 months</b>	33-39 lb	15-17.5 kg	0.15 mL (or mg)	0.15mg/dose
<b>5-7 years</b>	40–56 lb	18–25.5 kg	0.25 mL (or mg)	0.15mg/dose
<b>8–10 years</b>	57–76 lb	26–34.5 kg	0.3 mL <sup>†</sup> (or mg)	0.15 mg/dose or 0.3mg/dose
<b>11–12 years</b>	77–99 lb	35–45.5 kg	0.4 mL (or mg)	0.3mg/dose
<b>≥13 years</b>	100+ lb	46+ kg	0.5 mL <sup>‡</sup> (or mg)	0.3mg/dose

<sup>#</sup>Dose by weight is preferred. If weight is not known, dosing by age is appropriate for ages >36 months. Round kg to nearest 0.5 kg.

<sup>\*</sup> The 0.15mg epinephrine autoinjector can also be used for children 7.5 kg (16.5 lb) to 14.5 kg (32 lb) when other alternatives are not available.

<sup>†</sup>Maximum dose for children (prepubertal)<sup>1</sup>

<sup>‡</sup>Maximum dose for adolescents and adults<sup>1</sup>

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**2. Urticaria Protocol (Localized Symptoms)**

- A. If itching and swelling are confined to the injection site where the vaccination was given, observe patient closely for the development of generalized symptoms.
- B. 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.
- C. Administer diphenhydramine intramuscularly (IM) with the correct needle length for the patient's age and size according to the dosage chart in Table 2.
- D. Administer hydroxyzine hydrochloride orally if diphenhydramine unavailable according to patient's age and size in the dosage chart in Table 3.
- E. Complete the Adverse Event Record Tool.
- F. Take and record the patient's blood pressure and vital signs at the initial assessment, and at minimum - every 10 minutes, and following the administration of any additional medication
- G. Continue to monitor for and treat signs and symptoms progressing towards anaphylaxis when indicated. If signs and symptoms present, immediately initiate anaphylaxis protocol.
- H. Medication Schedule:

**Table 2: Urticaria**

<b>First-Line Treatment for Urticaria: Give Diphenhydramine IM as follows:</b>			
<b>Suggested dosing of Diphenhydramine for children<sup>2</sup> and adults</b>			
<b>Age Group Dose</b>	<b>Weight in lbs<sup>#</sup></b>	<b>Weight in kg<sup>#</sup></b>	<b>Injectable: 50mg/mL IM<sup>†</sup></b>
<b>6 months</b> (use only for dosing by weight)	9-19 lb	4-8.5 kg	5-10 mg (0.1 - 0.2 mL)
<b>7-36 months</b> (use only for dosing by weight)	20-32 lbs	9-14.5 kg	10-15 mg (0.2 - 0.3 mL)
<b>37-59 months</b>	33-39 lbs	15-17.5 kg	15-20 mg (0.3 - 0.4 mL)
<b>5-7 years</b>	40-56 lbs	18-25.5 kg	20-25 mg (0.4 - 0.5 mL)
<b>8-12 years</b>	57-99 lbs	26-45.5 kg	25-50 mg (0.5 - 1.0 mL)
<b>≥13 years<sup>‡</sup></b>	100+ lbs	46+ kg	50 -100 mg (1 - 2 mL) <sup>*</sup>

<sup>#</sup> Dose by weight is preferred. If weight is not known, dosing by age is appropriate for ages >36 months.

<sup>†</sup> Pediatric dose is 1-2mg/kg

<sup>‡</sup> Maximum single dose is 100mg for persons ≥13 years<sup>2-3</sup>

<sup>\*</sup> No more than 1 mL per injection site

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**Table 3: Optional Treatment: Hydroxyzine Hydrochloride**

Hydroxyzine Hydrochloride for urticaria when Diphenhydramine is unavailable: Give PO as follows:			
Suggested dosing of Hydroxyzine Hydrochloride for children <sup>2</sup> and adults			
Age Group Dose	Weight in lbs <sup>#</sup>	Weight in Kg <sup>#</sup>	Liquid: 10mg/5mL or 25mg/5mL <sup>†</sup>
6 months (use only for dosing by weight)	9-19 lb	4-8.5 kg	2.5-5 mg/dose
7-36 months (use only for dosing by weight)	20-32 lbs	9-14.5 kg	5-7.5 mg/dose
37-59 months	33-39 lbs	15-17.5 kg	7.5-10 mg/dose
5-7 years	40-56 lbs	18-25.5 kg	10-12.5 mg/dose
8-10 years	57-76 lbs	26-34.5 kg	12.5-15 mg/dose
11-12 years	77-99 lbs	35-45.5 kg	15-25 mg/dose
≥13 years	≥100 lbs	≥46 kg	25 mg/dose

<sup>#</sup> Dose by weight is preferred. If weight is not known, dosing by age is appropriate for ages >36 months.

<sup>†</sup> Pediatric dose is 0.5-1 mg/kg

\* Maximum single dose is 25mg for persons ≥13 years<sup>2-3</sup>

### 3. Loss of Consciousness/Syncope Protocol

- A. If the individual “feels faint”, ammonia ampules should be used if available. Crush and wave near patient’s nose.
- B. Have patient lie flat with feet elevated or sit with their head down for several minutes.
- C. If the patient loses consciousness, place flat on back, with feet elevated.
- D. Unconsciousness from fainting should only last seconds. In a vasovagal response, the pulse should be slow. A weak, thready or rapid pulse may indicate anaphylaxis. Continue to monitor for signs and symptoms progressing towards anaphylaxis. If signs and symptoms present, immediately initiate anaphylaxis protocol.
- E. 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.
- F. Complete the Adverse Event Record Tool.

### 4. Contraindications

- A. There are **no** contraindications for the use of epinephrine to treat anaphylaxis
- B. Previous hypersensitivity is a contraindication for diphenhydramine and hydroxyzine.
- C. Do not administer epinephrine auto-injector to children weighing less than 16.5 lbs.

### 5. Other Considerations

- A. Required Documentation:
  - Current Healthcare Provider CPR Card as required by OAR855-019-0270
  - Completed Adverse Event Record Tool for each event (Appendix A).
- B. Required Medications & Equipment: See Emergency Kit Medications & Equipment List (Appendix B)

### 6. Storage and Handling

- A. Store medications according to OAR 855-041-1036.

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**7. Adverse Events Reporting**

- A. Anaphylaxis and vasovagal syncope must be reported to the Vaccine Adverse Events Reporting System (VAERS) online at: <https://vaers.hhs.gov/index>
- B. VAERS Table of Reportable Events Following Vaccination:  
[https://vaers.hhs.gov/docs/VAERS\\_Table\\_of\\_Reportable\\_Events\\_Following\\_Vaccination.pdf](https://vaers.hhs.gov/docs/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf)

**8. References**

- 1. CDC. Management of Anaphylaxis at a COVID-19 Vaccination Location. Last updated 11 February 2022. Available at: <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html> Accessed 23 August 2022.
- 2. Immunization Action Coalition Website: Medical Management of Vaccine Reactions in Children and Teens in a Community Setting. July 2019. Available at: <https://www.immunize.org/catg.d/p3082a.pdf>. Accessed 23 August 2022.
- 3. Immunization Action Coalition Website: Medical Management of Vaccine Reactions in Adults in a Community Setting. July 2019. Available at: <https://www.immunize.org/catg.d/p3082.pdf>. Accessed 23 August 2022.

**9. Appendix**

- A. [Adverse Event Record Tool](#)
- B. [Emergency Kit Medications & Equipment](#)
- C. [Recognizing & Responding to Anaphylaxis Reference](#)