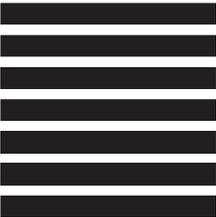


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VAERS
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Rockville MD 20849-1100



DIRECTIONS FOR COMPLETING FORM

(Additional pages may be attached if more space is needed.)

GENERAL

- Use a separate form for each patient. Complete the form to the best of your abilities. Items 3, 4, 7, 8, 10, 11, and 13 are considered essential and should be completed whenever possible. Parents/Guardians may need to consult the facility where the vaccine was administered for some of the information (such as manufacturer, lot number or laboratory data.)
- Refer to the Reportable Events Table (RET) for events mandated for reporting by law. Reporting for other serious events felt to be related but not on the RET is encouraged.
- Health care providers other than the vaccine administrator (VA) treating a patient for a suspected adverse event should notify the VA and provide the information about the adverse event to allow the VA to complete the form to meet the VA's legal responsibility.
- These data will be used to increase understanding of adverse events following vaccination and will become part of CDC Privacy Act System 09-20-0136, "Epidemiologic Studies and Surveillance of Disease Problems". Information identifying the person who received the vaccine or that person's legal representative will not be made available to the public, but may be available to the vaccinee or legal representative.
- Postage will be paid by addressee. Forms may be photocopied (must be front & back on same sheet).

SPECIFIC INSTRUCTIONS

Form Completed By: To be used by parents/guardians, vaccine manufacturers/distributors, vaccine administrators, and/or the person completing the form on behalf of the patient or the health professional who administered the vaccine.

- Item 7: Describe the suspected adverse event. Such things as temperature, local and general signs and symptoms, time course, duration of symptoms, diagnosis, treatment and recovery should be noted.
- Item 9: Check "YES" if the patient's health condition is the same as it was prior to the vaccine, "NO" if the patient has not returned to the pre-vaccination state of health, or "UNKNOWN" if the patient's condition is not known.
- Item 10: Give dates and times as specifically as you can remember. If you do not know the exact time, please
- and 11: indicate "AM" or "PM" when possible if this information is known. If more than one adverse event, give the onset date and time for the most serious event.
- Item 12: Include "negative" or "normal" results of any relevant tests performed as well as abnormal findings.
- Item 13: List ONLY those vaccines given on the day listed in Item 10.
- Item 14: List any other vaccines that the patient received within 4 weeks prior to the date listed in Item 10.
- Item 16: This section refers to how the person who gave the vaccine purchased it, not to the patient's insurance.
- Item 17: List any prescription or non-prescription medications the patient was taking when the vaccine(s) was given.
- Item 18: List any short term illnesses the patient had on the date the vaccine(s) was given (i.e., cold, flu, ear infection).
- Item 19: List any pre-existing physician-diagnosed allergies, birth defects, medical conditions (including developmental and/or neurologic disorders) for the patient.
- Item 21: List any suspected adverse events the patient, or the patient's brothers or sisters, may have had to previous vaccinations. If more than one brother or sister, or if the patient has reacted to more than one prior vaccine, use additional pages to explain completely. For the onset age of a patient, provide the age in months if less than two years old.
- Item 26: This space is for manufacturers' use only.

Medical Management of Vaccine Reactions in Children and Teens

All vaccines have the potential to cause an adverse reaction. To minimize adverse reactions, patients should be carefully screened for precautions and contraindications before vaccine is administered. Even with careful screening, reactions can occur. These reactions can vary from trivial and inconvenient (e.g., soreness, itching) to severe and life threatening (e.g., anaphylaxis). If reactions occur, staff should be prepared with procedures for their management. The table below describes procedures to follow if various reactions occur.

Reaction	Symptoms	Management
Localized	Soreness, redness, itching, or swelling at the injection site	Apply a cold compress to the injection site. Consider giving an analgesic (pain reliever) or antipruritic (anti-itch) medication.
	Slight bleeding	Apply an adhesive compress over the injection site.
	Continuous bleeding	Place thick layer of gauze pads over site and maintain direct and firm pressure; raise the bleeding injection site (e.g., arm) above the level of the patient's heart.
Psychological fright and syncope (fainting)	Fright before injection is given	Have patient sit or lie down for the vaccination.
	Extreme paleness, sweating, coldness of the hands and feet, nausea, light-headedness, dizziness, weakness, or visual disturbances	Have patient lie flat or sit with head between knees for several minutes. Loosen any tight clothing and maintain an open airway. Apply cool, damp cloths to patient's face and neck.
	Fall, without loss of consciousness	Examine the patient to determine if injury is present before attempting to move the patient. Place patient flat on back with feet elevated.
	Loss of consciousness	Check the patient to determine if injury is present before attempting to move the patient. Place patient flat on back with feet elevated. Call 911 if patient does not recover immediately.
Anaphylaxis	Sudden or gradual onset of generalized itching, erythema (redness), or urticaria (hives); angioedema (swelling of the lips, face, or throat); severe bronchospasm (wheezing); shortness of breath; shock; abdominal cramping; or cardiovascular collapse	See "Emergency Medical Protocol for Management of Anaphylactic Reactions in Children and Teens" on the next page for detailed steps to follow in treating anaphylaxis.

Supplies you may need at a community immunization clinic

- | | | |
|---|--|---|
| <ul style="list-style-type: none"> <input type="checkbox"/> First-line treatment: Aqueous epinephrine 1:1000 dilution, in ampules, vials of solution, or prefilled syringes, including epinephrine auto-injectors (e.g., EpiPen). If EpiPens are to be stocked, both EpiPen Jr. (0.15 mg) and adult EpiPens (0.30 mg) should be available. <input type="checkbox"/> Secondary treatment option: Diphenhydramine (Benadryl) injectable (50 mg/mL solution) or oral (12.5 mg/5 mL liquid, 25 or 50 mg capsules/tablets) | <ul style="list-style-type: none"> <input type="checkbox"/> Syringes: 1 and 3 cc, 22–25g, 1", 1½", and 2" needles for epinephrine and diphenhydramine (Benadryl) <input type="checkbox"/> Alcohol wipes <input type="checkbox"/> Tourniquet <input type="checkbox"/> Pediatric & adult airways (small, medium, and large) <input type="checkbox"/> Pediatric & adult size pocket masks with one-way valve <input type="checkbox"/> Oxygen (if available) <input type="checkbox"/> Stethoscope | <ul style="list-style-type: none"> <input type="checkbox"/> Sphygmomanometer (blood pressure measuring device) child, adult and extra-large cuffs) <input type="checkbox"/> Tongue depressors <input type="checkbox"/> Flashlight with extra batteries (for examination of mouth and throat) <input type="checkbox"/> Wrist watch with ability to count seconds <input type="checkbox"/> Cell phone or access to an onsite phone |
|---|--|---|

Emergency medical protocol for management of anaphylactic reactions in children and teens

1. If itching and swelling are confined to the injection site where the vaccination was given, observe patient closely for the development of generalized symptoms.
2. If symptoms are generalized, activate the emergency medical system (EMS; e.g., call 911) and notify the on-call physician. This should be done by a second person, while the primary nurse assesses the airway, breathing, circulation, and level of consciousness of the patient.
3. Drug Dosing Information:
 - a. **First-line treatment:** Administer aqueous epinephrine 1:1000 dilution (i.e., 1 mg/mL) intramuscularly; the standard dose is 0.01 mg/kg body weight, up to 0.3 mg maximum single dose in children and 0.5 mg maximum in adolescents (see chart on next page).
 - b. **Secondary treatment option:** For hives or itching, you may also administer diphenhydramine either orally or by intramuscular injection; the standard dose is 1–2 mg/kg body weight, up to 30 mg maximum dose in children and 50 mg maximum dose in adolescents (see chart on next page).
4. Monitor the patient closely until EMS arrives. Perform cardiopulmonary resuscitation (CPR), if necessary, and maintain airway. Keep patient in supine position (flat on back) unless he or she 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. Monitor blood pressure and pulse every 5 minutes.
5. If EMS has not arrived and symptoms are still present, repeat dose of epinephrine every 5–15 minutes for up to 3 doses, depending on patient’s response.
6. Record all vital signs, medications administered to the patient, including the time, dosage, response, and the name of the medical personnel who administered the medication, and other relevant clinical information.
7. Notify the patient’s primary care physician.

For your convenience, approximate dosages based on weight and age are provided in the charts below. Please confirm that you are administering the correct dose for your patient.

First-Line Treatment: Epinephrine (the recommended dose for epinephrine is 0.01 mg/kg body weight)					
	Age Group	Range of weight (lb)	Range of weight (kg)*	Epinephrine Dose	
				1 mg/mL injectable (1:1000 dilution) intramuscular Minimum dose: 0.05 mL	EpiPen (Dey, L.P.) Epinephrine auto-injector 0.15 mg or 0.3 mg
Infants and Children	1–6 months	9–19 lb	4–8.5 kg	0.05 mL (or mg)	off label
	7–36 months	20–32 lb	9–14.5 kg	0.1 mL (or mg)	off label
	37–59 months	33–39 lb	15–17.5 kg	0.15 mL (or mg)	0.15 mg
	5–7 years	40–56 lb	18–25.5 kg	0.2–0.25 mL (or mg)	0.15 mg
	8–10 years	57–76 lb	26–34.5 kg	0.25–0.3 mL [†] (or mg)	0.15 mg or 0.3 mg
Teens	11–12 years	77–99 lb	35–45 kg	0.35–0.4 mL (or mg)	0.3 mg
	13 years & older	100+ lb	46+ kg	0.5 mL (or mg) [‡]	0.3 mg

Note: If body weight is known, then dosing by weight is preferred. If weight is not known or not readily available, dosing by age is appropriate.

*Rounded weight at the 50th percentile for each age range

[†]Maximum dose for children

[‡]Maximum dose for teens

Secondary Treatment Option: Diphenhydramine (the recommended dose for diphenhydramine [Benadryl] is 1–2 mg/kg body weight)				
	Age Group	Range of weight (lb)	Range of weight (kg)*	Diphenhydramine Dose
				12.5 mg/5 mL liquid 25 mg or 50 mg tablets 50 mg/mL injectable (IV or IM)
Infants and Children	7–36 months	20–32 lb	9–14.5 kg	10 mg–20 mg
	37–59 months	33–39 lb	15–17.5 kg	15 mg–30 mg [†]
	5–7 years	40–56 lb	18–25.5 kg	20 mg–30 mg [†]
	8–12 years	57–99 lb	26–45 kg	30 mg [†]
Teens	13 years & older	100+ lb	46+ kg	50 mg [‡]

Note: If body weight is known, then dosing by weight is preferred. If weight is not known or not readily available, dosing by age is appropriate.

*Rounded weight at the 50th percentile for each age range

[†]Maximum dose for children

[‡]Maximum dose for teens

Sources

Boyce JA, Assa'ad A, Burks AW, et al. Guidelines for the Diagnosis and Management of Food Allergy in the United States: Report of the NIAID-Sponsored Expert Panel. *Allergy Clin Immunol* 2010; 126(6):S1–S57.

Simons FE, Camargo CA. Anaphylaxis: Rapid recognition and treatment. In: UpToDate, Bochner BS (Ed). UpToDate: Waltham, MA, 2010.

These standing orders for the medical management of vaccine reactions in child and teenage patients shall remain in effect for patients of the _____ until rescinded or until _____.

name of clinic *date*

Medical Director's signature _____ Effective date _____

Medical Management of Vaccine Reactions in Adult Patients

All vaccines have the potential to cause an adverse reaction. In order to minimize adverse reactions, patients should be carefully screened for precautions and contraindications before vaccine is administered. Even with careful screening, reactions may occur. These reactions can vary from trivial and inconvenient (e.g., soreness, itching) to severe and life threatening (e.g., anaphylaxis). If reactions occur, staff should be prepared with procedures for their management. The table below describes procedures to follow if various reactions occur.

Reaction	Symptoms	Management
Localized	Soreness, redness, itching, or swelling at the injection site	Apply a cold compress to the injection site. Consider giving an analgesic (pain reliever) or antipruritic (anti-itch) medication.
	Slight bleeding	Apply an adhesive compress over the injection site.
	Continuous bleeding	Place thick layer of gauze pads over site and maintain direct and firm pressure; raise the bleeding injection site (e.g., arm) above the level of the patient's heart.
Psychological fright and syncope (fainting)	Fright before injection is given	Have patient sit or lie down for the vaccination.
	Extreme paleness, sweating, coldness of the hands and feet, nausea, light-headedness, dizziness, weakness, or visual disturbances	Have patient lie flat or sit with head between knees for several minutes. Loosen any tight clothing and maintain an open airway. Apply cool, damp cloths to patient's face and neck.
	Fall, without loss of consciousness	Examine the patient to determine if injury is present before attempting to move the patient. Place patient flat on back with feet elevated.
	Loss of consciousness	Check the patient to determine if injury is present before attempting to move the patient. Place patient flat on back with feet elevated. Call 911 if patient does not recover immediately.
Anaphylaxis	Sudden or gradual onset of generalized itching, erythema (redness), or urticaria (hives); angioedema (swelling of the lips, face, or throat); severe bronchospasm (wheezing); shortness of breath; shock; abdominal cramping; or cardiovascular collapse.	See "Emergency Medical Protocol for Management of Anaphylactic Reactions in Adults" on the next page for detailed steps to follow in treating anaphylaxis.

(continued on page 2)

Supplies you may need at a community immunization clinic

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| <p><input type="checkbox"/> First-line treatment: Aqueous epinephrine 1:1000 (i.e., 1 mg/mL) dilution, in ampules, vials of solution, or prefilled syringes, including epinephrine autoinjectors (e.g., EpiPen). If EpiPens are stocked, at least three adult EpiPens (0.30 mg) should be available.</p> <p><input type="checkbox"/> Secondary treatment option: Diphenhydramine (Benadryl) injectable (50 mg/mL solution) or oral (12.5 mg/5 mL liquid, 25 or 50 mg capsules/tablets)</p> | <p><input type="checkbox"/> Syringes: 1 and 3 cc, 22 and 25g, 1", 1½", and 2" needles for epinephrine and diphenhydramine (Benadryl)</p> <p><input type="checkbox"/> Alcohol wipes</p> <p><input type="checkbox"/> Tourniquet</p> <p><input type="checkbox"/> Adult airways (small, medium, and large)</p> <p><input type="checkbox"/> Adult size pocket mask with one-way valve</p> <p><input type="checkbox"/> Oxygen (if available)</p> <p><input type="checkbox"/> Stethoscope</p> | <p><input type="checkbox"/> Sphygmomanometer (blood pressure measuring device) with adult-size and extra-large cuffs</p> <p><input type="checkbox"/> Tongue depressors</p> <p><input type="checkbox"/> Flashlight with extra batteries (for examination of the mouth and throat)</p> <p><input type="checkbox"/> Wristwatch with ability to count seconds</p> <p><input type="checkbox"/> Cell phone or access to onsite phone</p> |
|--|--|--|

Emergency medical protocol for management of anaphylactic reactions in adults

1. If itching and swelling are confined to the injection site where the vaccination was given, observe patient closely for the development of generalized symptoms.
2. If symptoms are generalized, activate the emergency medical system (EMS; e.g., call 911) and notify the on-call physician. This should be done by a second person, while the primary nurse assesses the airway, breathing, circulation, and level of consciousness of the patient.
3. Drug Dosing Information:
 - a. **First-line treatment:** Administer aqueous epinephrine 1:1000 dilution intramuscularly, 0.01 mL/kg/dose (adult dose ranges from 0.3 mL to 0.5 mL, with maximum single dose of 0.5 mL).
 - b. **Secondary treatment option:** For hives or itching, you may also administer diphenhydramine either orally or by intramuscular injection; the standard dose is 1–2 mg/kg, up to 50 mg maximum single dose.
4. Monitor the patient closely until EMS arrives. Perform cardiopulmonary resuscitation (CPR), if necessary, and maintain airway. Keep patient in supine position (flat on back) unless he or she 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. Monitor blood pressure and pulse every 5 minutes.
5. If EMS has not arrived and symptoms are still present, repeat dose of epinephrine every 5–15 minutes for up to 3 doses, depending on patient’s response.
6. Record all vital signs, medications administered to the patient, including the time, dosage, response, and the name of the medical personnel who administered the medication, and other relevant clinical information.
7. Notify the patient’s primary care physician.

Sources

Boyce JA, Assa’ad A, Burks AW, et al. Guidelines for the Diagnosis and Management of Food Allergy in the United States: Report of the NIAID- Sponsored Expert Panel. *Allergy Clin Immunol* 2010; 126(6):S1–S57.

Simons FE, Camargo CA. Anaphylaxis: Rapid recognition and treatment. In: UpToDate, Bochner BS (Ed). UpToDate: Waltham, MA, 2010.

American Pharmacists Association, Grabenstein, JD, *Pharmacy-Based Immunization Delivery*, 2002.

These standing orders for the medical management of vaccine reactions in adult patients shall remain in effect for patients of the _____ until rescinded or until _____.

name of clinic date

Medical Director’s signature

Effective date