



BC Centre for Disease Control
Provincial Health Services Authority

Immunization Programs and Vaccine Preventable
Diseases Service
655 West 12th Avenue
Vancouver, BC V5Z 4R4

Tel 604.707.2548
Fax 604.707.2515

www.bccdc.ca

Communicable Disease Control Manual

Chapter 2: Immunization

Part 3 - Management of Anaphylaxis in a Non-Hospital Setting

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1. Anaphylaxis

This decision support tool (DST), Management of Anaphylaxis in a Non-Hospital Setting, is intended for use by all immunizing professionals, including all nursing professionals, pharmacists, midwives, physicians and naturopathic physicians. Nursing professionals may also follow the provincial DST, [Anaphylaxis: Initial Emergency Treatment by Nurses \(Adult and Pediatric\)](#). The clinical content and protocol in these two DSTs is identical however this DST, Management of Anaphylaxis in a Non-Hospital Setting, includes important immunization specific information including background information and reporting regulations.

1.1 Description

Anaphylaxis is a potentially life-threatening IgE-mediated reaction that results from the sudden systemic release of allergenic mediators (e.g., histamine, leukotrienes, prostaglandins, tryptase) from mast cells and basophils. Within 10 minutes, increased vascular permeability allows transfer of as much as 50% of the intravascular fluid into the extravascular space. As a result, hemodynamic collapse might occur rapidly with little or no cutaneous or respiratory manifestations.

While anaphylaxis is extremely rare, every immunization carries an associated risk of producing an anaphylactic reaction. The estimated annual reported rate of anaphylaxis ranges from 0.4 to 1.8 reports per 1,000,000 doses of vaccines distributed in Canada.

The more rapidly anaphylaxis occurs after exposure to an offending stimulus, the more likely the reaction is to be severe and potentially life-threatening.

Anaphylaxis often produces signs and symptoms within minutes of exposure to an offending stimulus. Most instances begin within 30 minutes after injection of vaccine, but some reactions might develop later.

Up to 23% of anaphylaxis episodes in adults, and up to 11% in children, follow a biphasic course with recurrence of the reaction anywhere from 1-72 hours after the first onset of symptoms. Most biphasic reactions occur within the first 4-6 hours after the initial onset of symptoms. Hospitalization or a long period of observation is recommended for monitoring of such a recurrence. The presentation of the second phasic reaction may be as pronounced as that of the initial anaphylactic episode.

1.2 Presentation

Changes develop over several minutes and usually involve at least two body systems (affecting the skin, respiration, circulation). Unconsciousness is rarely the sole manifestation of anaphylaxis and occurs only as a late event in severe cases.

Anaphylaxis occurs as part of a continuum. Even when there are mild symptoms initially there is the potential for progression to a severe and even irreversible outcome. Fatalities during anaphylaxis usually result from delayed administration of epinephrine and from severe respiratory complications, cardiovascular complications, or both. **There is no contraindication to epinephrine administration in anaphylaxis.**

Urticaria and angioedema are the most common manifestations of anaphylaxis. Urticaria (hives) are raised, often itchy, wheals on the surface of the skin. Angioedema is a swelling similar to urticaria, but the swelling

is beneath the skin rather than on the surface. The swellings are called welts. The welts usually occur around the eyes and lips. They may also be found on the hands, feet, neck and in the throat.

Features of early or mild anaphylaxis may include swelling and hives at the injection site, sneezing, nasal congestion, tearing, coughing, and facial flushing. These symptoms are generally associated with minimal dysfunction.

Features of moderate to severe anaphylaxis include obstructive swelling of the upper airway, hypotension, and marked bronchospasm (constriction of the air passages of the lung by spasmodic contraction of the bronchial muscles).

Table 1: Frequency of occurrence of signs and symptoms of anaphylaxis ^A

System	Percentage of Episodes	Signs and Symptoms One or more sign or symptom may be present
Skin*	Up to 80%	Hives, swelling (face, lips, tongue), angioedema, itching, warmth, redness, drooling in children
Respiratory	Up to 70%	Coughing, wheezing, shortness of breath, chest pain or tightness, throat tightness, hoarse voice, nasal congestion or hay fever-like symptoms (runny, itchy nose and watery eyes, sneezing), trouble swallowing, drooling in children
Cardiovascular	Up to 45%	Weak pulse, dizziness or light headedness, collapse, hypotension**, shock
Gastrointestinal	Up to 45%	Nausea, pain or cramps, vomiting, diarrhea
Other		Anxiety, sense of doom, headache, uterine cramps, metallic taste Suddenly quiet, sleepy or lethargic in children

*Skin signs, such as hives are present in ~80% of cases, but may develop after other symptoms have already occurred. Patients can have anaphylaxis without having hives.

**Hypotension may be the only sign of anaphylaxis.

1.3 Assessment

Assess:

- Level of consciousness (impairment might reflect hypoxia)
- Upper and lower airways [observe for hoarse cry/voice, stridor (a high-pitched noisy sound occurring during inhalation or exhalation), cough, wheezing, or shortness of breath]
- Respiratory rate
- Pulse rate (assess for rapid, weak pulse). Examine for pallor or cyanosis around perioral area
- Skin (observe for facial flushing, itching, hives, or welts)
- Suddenly quiet, sleepy or lethargic (common in young children)
- Gastrointestinal system (nausea, vomiting, or diarrhea)
- Injection site(s). Observe for redness, swelling, or hives.

^A Simons FER, Arduoso LRF, Bilo MB, El-Gamal YM, Ledford DK, Ring J et al. World Allergy Organization Guidelines for the Assessment and Management of Anaphylaxis. World Allergy Organ J. 2011 Feb;4(2):13-37.

In general, the more rapid the onset, the more severe the anaphylactic reaction. The [Worksheet for Events Managed as Anaphylaxis Following Immunization](#) can be used to assist with assessment and documentation of symptoms.

1.4 Action of Epinephrine

Action of epinephrine:

- Counteracts the histamine-induced vasodilation
- Increases heart rate and cardiac contractility to increase oxygenated blood flow to vital organs
- Acts on smooth muscles of bronchial tree thereby reducing bronchospasm
- Suppresses body's immune response (slows down histamine cascade)

Side effects of excessive doses of epinephrine pose little danger but can add to the person's distress by causing palpitations, tachycardia, flushing, and headache. Cardiac dysrhythmias can occur in older adults but are rare in otherwise healthy children.

NOTE: *Diphenhydramine (Benadryl®) is **not indicated** in the initial emergency management of anaphylaxis.*

H1 antihistamines (e.g., Benadryl®) are not indicated as first line treatment in the emergency management of anaphylaxis. Antihistamines are not life-saving as they have no effect on respiratory or cardiovascular symptoms, and as such, have little clinical importance in life-threatening anaphylaxis. Antihistamines relieve less severe, cutaneous symptoms of anaphylaxis including urticaria, pruritus and angioedema.

Epinephrine is the first line treatment for anaphylaxis and there is no known equivalent substitute. Prompt intramuscular injection of epinephrine should not be delayed by taking the time to administer antihistamines, and thus, these medications are not recommended in the initial emergency management of anaphylaxis.

2. Anaphylaxis versus Fainting, Anxiety, Allergic Reaction, or Injection Site Reaction

Anaphylaxis must be distinguished from fainting (vasovagal syncope), anxiety, and breath-holding spells which are more common and benign reactions. The lack of hives, a slow, steady pulse rate, and cool pale skin distinguishes a vasovagal episode from anaphylaxis.

2.1 Fainting

During fainting, the individual suddenly becomes pale, loses consciousness and collapses to the ground. Fainting is sometimes accompanied by brief clonic seizure activity (i.e., rhythmic jerking of the limbs), but this generally requires no specific treatment or investigation.

Recovery of consciousness occurs within a minute or two, but clients may remain pale, diaphoretic and mildly hypotensive for several more minutes. **If unconsciousness persists for more than 2-3 minutes, call 911/ambulance and proceed as per emergency treatment for anaphylaxis.** Unconsciousness may reflect hypoxia.

To reduce the likelihood of fainting (and the possibility of injuries), consider measures to lower stress in those awaiting immunization. Prior to immunization, ask the client about history of fainting with previous immunizations. Seat every client prior to immunization. If client appears anxious pre-immunization or describes a history of fainting with previous immunization, have them lie down for the immunization if possible. If client appears pale and displays signs of fainting pre-immunization, advise them to lie down and apply a cold wet cloth to their face. If person was lying down, have them sit for a few minutes before standing. Refer to [Appendix D - Reducing Immunization Injection Pain](#) for other strategies to mitigate anxiety.

2.2 Anxiety/Pain Reaction

People experiencing an anxiety reaction may appear fearful, pale and diaphoretic, and complain of light-headedness, dizziness and numbness, as well as tingling of the face and extremities. Hyperventilation is usually evident.

If an individual appears anxious, it may be helpful to have them rebreathe into a paper bag until symptoms subside.

Breath-holding spells occur in some young children when they are upset, crying hard, and reacting to injection pain. The child is suddenly silent but obviously agitated. Facial flushing and perioral cyanosis deepens as breath-holding continues. Some spells end with resumption of crying, but others end with a brief period of unconsciousness during which breathing resumes. Occasionally, the breath-holding spell may be accompanied by brief clonic seizure activity. Similar spells may have been observed in other circumstances. No treatment is required beyond reassurance of the child and parents.

Section 2.3 outlines the key differences between anaphylaxis, fainting, and an anxiety reaction.

For further information on strategies for the reduction of pain and anxiety associated with injections, refer to [Appendix D – Reducing Immunization Injection Pain](#).

2.3 Anaphylaxis versus Fainting and Anxiety

	Anaphylaxis	Fainting	Anxiety
Definition	A potentially life threatening allergic reaction that is rapid in onset and progression of symptoms.	Temporary unconsciousness caused by diminished blood supply to the brain due to painful stimuli or emotional reaction.	A protective physiological state recognized as fear, apprehension, or worry.
Onset	<ul style="list-style-type: none"> rapid onset and progression of symptoms occurs minutes to hours after exposure to trigger recovery dependent on response to treatment 	<ul style="list-style-type: none"> sudden onset occurs before, during or shortly after trigger (e.g., sight of the needle) recovery occurs within 1-2 minutes 	<ul style="list-style-type: none"> sudden onset occurs before, during, or shortly after trigger (e.g., sight of the needle) recovery generally occurs within 1-2 minutes
Skin/Mucosal	<ul style="list-style-type: none"> flushed, red blotchy areas (not necessarily itchy) itchy, generalized hive-like rash tingling sensation often first felt about the face and mouth progressive, painless swelling about the face, mouth, and tongue 	<ul style="list-style-type: none"> pale excessive perspiration cold, clammy 	<ul style="list-style-type: none"> pale excessive perspiration cold, clammy tingling around the lips
Respiratory	<ul style="list-style-type: none"> labored breathing - hoarse voice, throat tightness, rapid breathing, wheezing, coughing, nasal flaring, nasal and chest congestion rhinitis (stuffy or runny nose, itchy watery eyes and sneezing) shortness of breath, stridor, retractions, chest pain and cyanosis 	<ul style="list-style-type: none"> breathing normal or shallow, irregular, laboured 	<ul style="list-style-type: none"> breathing rapid and shallow (hyperventilation) breath-holding in children
Cardiovascular	<ul style="list-style-type: none"> weak and rapid pulse hypotension alone after an exposure can represent anaphylaxis hypotension is less common in children shock 	<ul style="list-style-type: none"> slow, steady pulse decreased systolic and diastolic 	<ul style="list-style-type: none"> rapid pulse normal or elevated systolic
Gastrointestinal	<ul style="list-style-type: none"> nausea, vomiting, diarrhea abdominal pain or cramping dysphagia (difficulty swallowing) drooling in children 	<ul style="list-style-type: none"> nausea 	<ul style="list-style-type: none"> nausea
Other Symptoms and Behaviours	<ul style="list-style-type: none"> anxious or feeling of “impending doom” sudden lack of energy (lethargy) in children quietness or sleepiness in children headache, light-headedness or dizziness, decreased level of consciousness uterine cramps 	<ul style="list-style-type: none"> fearfulness light-headedness dizziness numbness, weakness sometimes accompanied by brief clonic seizure activity 	<ul style="list-style-type: none"> fearfulness light-headedness dizziness numbness, weakness spasm in the hands and feet associated with hyperventilation

2.4 Allergic Reaction

Allergic reactions constitute a spectrum, the extreme end of which is anaphylaxis, but milder forms may involve both the dermatologic/mucosal (e.g., urticaria, pruritis, rhinitis) and/or the respiratory systems (e.g., upper airway swelling, respiratory distress). Anaphylaxis is set apart from simple allergic reactions by the simultaneous involvement of the cardiovascular system and loss of intravascular volume, as well as respiratory obstruction.

2.5 Injection Site Reactions

A mild local reaction resolving by itself within a few minutes does not require special observation.

If swelling and hives occur at the injection site(s):

- Keep client under **direct observation** for at least 30 minutes to ensure the reaction remains localized.
- Observe for any deterioration in condition.
- If hives or swelling disappears, or there is no evidence of any progression to other parts of the body or any other symptoms within the 30-minute observation period, no further observation is necessary. Release the client from observation.
- **If any other symptoms arise**, even if considered mild (e.g., sneezing, nasal congestion, tearing, coughing, facial flushing) or if there is evidence of any progression of the hives or swelling to other parts of the body, **administer epinephrine**.
- There is little risk to the unnecessary use of epinephrine, whereas delay in its administration (when required) may result in difficulty to treat anaphylaxis and in death.
- Apply ice for comfort.

3. Supervision of Vaccinee Post-Immunization

Advise recipients of any biological product (e.g., vaccines and immune globulins), to remain under supervision for at least 15 minutes after immunization; regardless of whether or not they have had the particular product previously. **Thirty (30) minutes is a safer duration when the person has had a prior allergic reaction to the biological product or a component of the biological product. If an individual has such an allergic history, immunization should occur in an emergency room setting according to Health Authority guidelines.** For more information, refer to [Part 5 – Adverse Events Following Immunization](#).

The risk of fainting is the more common reason to keep vaccinees under observation.

Routine supervision should ensure that vaccinees remain within a short distance of the vaccinator with the instruction that they ask someone to obtain the nurse for them immediately for assessment if they feel unwell.

Where vaccinees choose not to remain under supervision after immunization, they (or their parent/guardian) should be informed of the signs and symptoms of anaphylaxis and instructed to obtain immediate medical attention should symptoms occur.

4. Site and Route of Epinephrine Administration

Early administration of intramuscular (IM) epinephrine is first line treatment for anaphylaxis to prevent death and there is no known equivalent substitute.

The recommended route and site of epinephrine administration is ALWAYS intramuscular (IM) injection into the vastus lateralis. This is because the rate of absorption is far quicker than when the drug is given subcutaneously. Administration into the deltoid is not recommended as absorption from the deltoid site is slower than when the drug is given in the vastus lateralis due to the rich vasculature of the thigh muscle. Plasma concentrations of epinephrine may be up to five times higher when administered intramuscularly into the vastus lateralis, as compared to either subcutaneously or intramuscularly into the deltoid.

If possible, avoid administering epinephrine into the same muscle mass recently used to administer an immunization. **If the client has already received immunizations to both legs, give epinephrine IM at least 2.5 cm (1 inch) from the original immunization injection site.**

Alternate legs for multiple epinephrine IM doses.

Administration of epinephrine through the clothing is acceptable in emergency situations.

The standard information provided in the process of obtaining informed consent prior to the administration of biological products includes the provision of emergency treatment of anaphylaxis.

Note: A client-owned epinephrine auto-injector (e.g., EpiPen®) can be used in the situation when the immunization provider is not present and if the layperson who administers the auto-injector is knowledgeable about its proper use. EpiPen® delivers 0.3 mg of epinephrine and EpiPen Junior® delivers 0.15 mg of epinephrine. The weight range for EpiPen Junior® is 15 to 30 kg, however an EpiPen Junior 0.15 mg can be safely administered to children that weigh less than 15 kg.

5. Other Considerations

Position client in the recumbent position and elevate legs, as tolerated symptomatically. This slows progression of circulatory compromise, if present, by preventing orthostatic hypotension and helping to shunt effective circulation from the periphery to the head, heart, and kidneys.

Monitor pulse, respiratory effort, and level of consciousness to guide medication use:

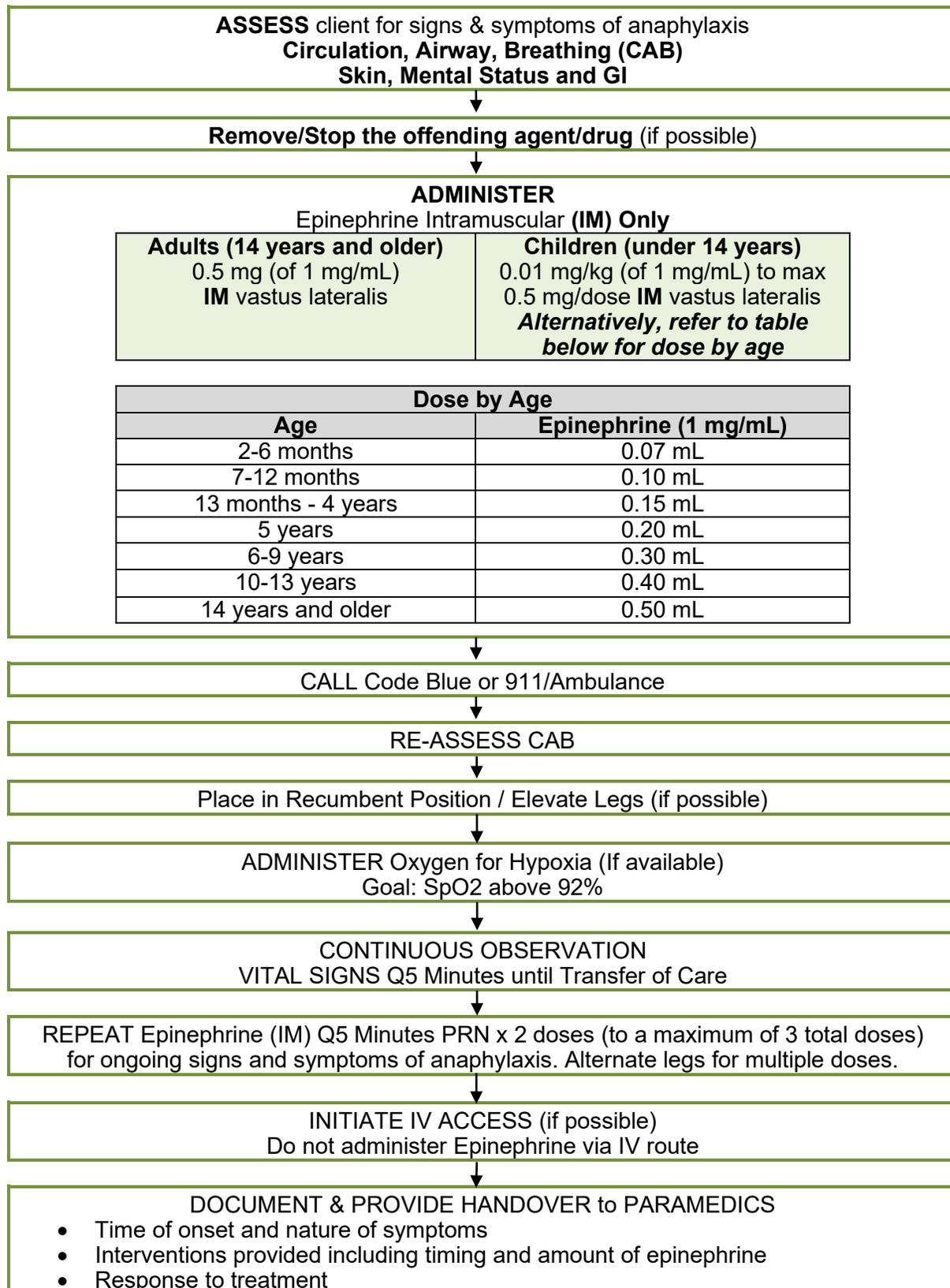
- If person experiences respiratory difficulty, elevate head and chest slightly.
- If airway is impaired, improve position by using head tilt, chin lift, or jaw thrust.
- If vomiting is likely, turn person to side lying position.

Table 2: Pulse and Respiratory Rates ^A

Age	Heart (pulse) rate per minute, Upper Limit	Respiratory rate per minute Upper Limit
0-1 month	180	60
2-12 months	160	50
12-24 months	140	40
2-6 years	120	30
6-12 years	110	20
> 12 years (adult)	100	20

^A Tintinalli's Emergency Medicine: A comprehensive study guide. 8th edition. McGraw Hill. 2016

6. Emergency Treatment of Anaphylaxis



Perform simultaneously

7. Client Transport

Arrange for rapid transport by emergency vehicle to an emergency department (ED). As an anaphylactic episode can follow a biphasic course, hospitalization or a long period of observation is recommended for monitoring.

7.1 Serum Tryptase Testing

Serum tryptase levels should be measured between 30 minutes and 3 hours after symptom onset.^{A, B} The sample for this test should be collected in ED and therefore the “[Request for Serum Tryptase Test](#)” letter needs to be provided to the paramedics for handover to ED staff. The tryptase results will be followed up by the local Medical Health Officer. The results will help with the assessment of the suspected anaphylaxis event following the receipt of a vaccine and inform further management, including recommendations for future vaccination.

For more information, see [Part 5 – Adverse Events Following Immunization](#), Section 9.1 Anaphylaxis.

8. Documentation

The information related to the event managed as anaphylaxis can be recorded on the [Worksheet for Events Managed as Anaphylaxis Following Immunization](#). This worksheet should be completed by the health care professional who observed and treated the client for anaphylaxis.

The worksheet supports recording of the signs and symptoms that correspond to the event codes for reporting of adverse events following immunization (AEFI) in BC using the public health information system. The information will allow the MHO/MHO delegate to assess the event, and will allow for application of the Brighton anaphylaxis case definition.

The [Adverse Event Following Immunization \(AEFI\) Case Report Form](#) can be used for data collection before entry into the public health information system.

Await the MHO/MHO delegate review and recommendation regarding subsequent immunization with the associated biological product(s).

If the reaction is deemed to have been an allergic reaction and not anaphylaxis, the associated biological product(s) can be administered in the future.

If the reaction is deemed to have been anaphylactic, the associated biological product(s) cannot be administered in the future. A history of anaphylaxis is a contraindication to the administration of the associated biological product(s), except in the case of rabies post-exposure prophylaxis.

Record this contraindication in the client’s personal and electronic immunization record.

^A Golden DBK, Wang J, Wasserman S, Akin C, et al. Anaphylaxis: A 2023 practice parameter update. *Ann Allergy Asthma Immunol.* 2024 Feb;132(2):124-176.

^B Platzgummer S, Bizzaro N, Bilo MB, Pravettoni V, et al. Recommendations for the use of tryptase in the diagnosis of anaphylaxis and clonal mastcell disorders. *Eur Ann Allergy Clin Immunol.* 2020 Mar;52(2):51-61.

Discuss with the client the MHO recommendation regarding subsequent immunization.

9. Maintenance of Epinephrine Ampoules and Other Emergency Supplies

Check epinephrine ampoules and other emergency supplies prior to each immunization clinic and replace if outdated.

Protect epinephrine from light and open ampoule(s) only when ready to use. Store epinephrine at room temperature (15°C to 30°C), and do not store epinephrine in the refrigerator.

Do not pre-load a syringe with epinephrine in anticipation of a reaction. Epinephrine rapidly deteriorates and loses potency when exposed to oxygen.

Suggested epinephrine kit contents:

- BCCDC guidelines for the management of anaphylaxis: [Part 3 - Management of Anaphylaxis in a Non-Hospital Setting](#)
- [Worksheet for Events Managed as Anaphylaxis Following Immunization](#)
- “[Request for Serum Tryptase Test](#)” letter
- 4 ampoules of epinephrine (1 mg/mL)
- 4 – 1 mL syringes
- needles (25 to 27 gauge)
 - 4 - 1 inch
 - 4 - 1½ inch
- alcohol swabs
- pens/paper

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