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# Communicable Disease Control Manual

## Chapter 2: Immunization

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

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# 1. Anaphylaxis

## 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.

As 20% of anaphylaxis episodes follow a biphasic course with recurrence of the reaction after a 2 to 9 hour asymptomatic period, hospitalization or a long period of observation is recommended for monitoring. 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, and neck and in the throat.

Features of early or mild anaphylaxis may include swelling and hives at 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 <sup>A</sup>

Signs and symptoms	Approximate frequency
<b>Cutaneous</b>	<b>90%</b>
• Generalized urticaria (hives) and/or angioedema (welts)	85-90%
• Flushing	45-55%
• Pruritus (itchiness) with or without rash	2-5%
<b>Respiratory</b>	<b>40-60%</b>
• Upper airway angioedema	50-60%
• Dyspnea (difficulty breathing), wheeze	45-50%
• Rhinitis (nasal congestion)	15-20%
<b>Dizziness, syncope (fainting), hypotension</b>	<b>30-35%</b>
<b>Abdominal</b>	
• Nausea, vomiting, diarrhea, cramping pain	25-30%
<b>Miscellaneous</b>	
• Headache	5-8%
• Substernal (chest) pain	4-6%
• Seizure	1-2%

### 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)
- Gastrointestinal system (nausea, vomiting, or diarrhea)
- Injection site(s). Observe for redness, swelling, or hives.

Record full details of the assessment including signs/symptoms to allow for classification of the event according to the Brighton Case Definition for anaphylaxis. Use the [Worksheet for Events Managed as Anaphylaxis Following Immunization](#).

In general, the sooner the onset, the more rapid and severe the anaphylactic reaction.

<sup>A</sup> The diagnosis and management of anaphylaxis: an updated practice parameter. Journal of Allergy and Clinical Immunology. 2005;115:S483-523.

## 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).

Intramuscular (IM) epinephrine injections into the thigh (vastus lateralis) have been reported to provide more rapid absorption and higher plasma epinephrine levels in both children and adults than IM or subcutaneous (SC) injections administered into the arm. Therefore, IM is the preferred route for the administration of epinephrine and the thigh is the preferred site for its administration.

When epinephrine is administered intramuscularly, it acts on beta adrenergic receptors found in the skeletal muscle vasculature causing vasodilation. Thus, when IM immunization is given and epinephrine is indicated, it should not be administered into the same muscle mass as the vaccine was administered. The epinephrine will produce vasodilation locally at the site, increase vascular permeability, and may increase absorption of the offending antigen.

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.

## 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.

Prior to immunization, ask the client about history of fainting with previous immunizations.

To reduce the likelihood of fainting (and the possibility of injuries), consider the following measures to lower stress in those awaiting immunization:

- Seat every client prior to immunization
- Maintain a comfortably cool room temperature and if possible, plenty of fresh air
- Avoid long line ups in mass immunization clinics
- Prepare vaccine(s) out of view of recipients
- Provide privacy during vaccination
- If client is anxious and pale, have them lie down with legs elevated, reassure, and apply cold wet cloth to face.

If person was lying down, have them sit for a few minutes before standing.

## **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.

### 2.3 Anaphylaxis versus Fainting and Anxiety

	<b>Anaphylaxis</b>	<b>Fainting</b>	<b>Anxiety</b>
<b>Definition</b>	An acute systemic and potentially fatal allergic reaction to a foreign substance. IgE-mediated antibody induces histamine release from tissue cells.	A 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.
<b>Onset</b>	Usually slower, most instances begin within 30 minutes after immunization.	Sudden, occurs before, during or shortly after immunization; recovery occurs within 1-2 minutes.	Sudden, occurs before, during, or shortly after immunization; recovery occurs within 1-2 minutes.
<b>Skin</b>	<ul style="list-style-type: none"> <li>flushed, red blotchy areas (not necessarily itchy)</li> <li>itchy, generalized hive-like rash</li> <li>tingling sensation often first felt about the face and mouth</li> <li>progressive, painless swelling about the face, mouth, and tongue</li> </ul>	<ul style="list-style-type: none"> <li>pale</li> <li>excessive perspiration</li> <li>cold, clammy</li> </ul>	<ul style="list-style-type: none"> <li>pale</li> <li>excessive perspiration</li> <li>cold, clammy</li> </ul>
<b>Breathing</b>	<ul style="list-style-type: none"> <li>sneezing, coughing, wheezing, laboured breathing</li> <li>upper airway swelling (indicated by hoarseness and/or difficulty swallowing) possibly causing airway obstruction</li> </ul>	<ul style="list-style-type: none"> <li>normal or shallow, irregular, laboured</li> </ul>	<ul style="list-style-type: none"> <li>rapid and shallow (hyperventilation)</li> </ul>
<b>Pulse</b>	<ul style="list-style-type: none"> <li>rapid, weak</li> </ul>	<ul style="list-style-type: none"> <li>slow, steady</li> </ul>	<ul style="list-style-type: none"> <li>rapid</li> </ul>
<b>Blood Pressure</b>	<ul style="list-style-type: none"> <li>decreased systolic and diastolic</li> </ul>	<ul style="list-style-type: none"> <li>decreased systolic and diastolic</li> </ul>	<ul style="list-style-type: none"> <li>normal or elevated systolic</li> </ul>
<b>Symptoms and Behaviours</b>	<ul style="list-style-type: none"> <li>uneasiness, restlessness, agitation</li> <li>hypotension, which generally develops later and can progress to cause shock and collapse</li> <li>not all signs/symptoms will be exhibited in each person; usually one body system predominates</li> </ul>	<ul style="list-style-type: none"> <li>fearfulness</li> <li>light-headedness</li> <li>dizziness</li> <li>numbness, weakness</li> <li>sometimes accompanied by brief clonic seizure activity</li> </ul>	<ul style="list-style-type: none"> <li>fearfulness</li> <li>light-headedness</li> <li>dizziness</li> <li>numbness, weakness</li> <li>tingling around lips and spasm in the hands and feet associated with hyperventilation</li> <li>hyperventilation</li> </ul>
<b>Gastrointestinal</b>	<ul style="list-style-type: none"> <li>nausea and vomiting</li> <li>abdominal pain, diarrhea</li> </ul>	<ul style="list-style-type: none"> <li>nausea</li> </ul>	<ul style="list-style-type: none"> <li>nausea</li> </ul>
<b>Other Symptoms</b>	<ul style="list-style-type: none"> <li>loss of consciousness</li> <li>progression of injection site reaction beyond hives and swelling</li> </ul>		

## 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 (i.e., vaccine, immune globulin, TB skin test) 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.** See [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. Administration of Epinephrine

Call 911 or ambulance.

Administer epinephrine **IM** immediately. The most important step in the management of anaphylaxis is the immediate administration of aqueous epinephrine 1:1,000. Failure to use epinephrine promptly is more dangerous than its improper use. Use the epinephrine dosing chart outlined in [10. Emergency Treatment of Anaphylaxis](#).

**IM** injection of epinephrine into the thigh is the preferred route for administration.

**DO NOT** inject epinephrine into the same muscle mass (e.g., thigh) as the vaccine was administered.

If child is < 12 months of age and has received an **IM** vaccine in each thigh, give epinephrine **SC** into the upper outer triceps area of the infants arm(s).

If the thigh cannot be used in a child  $\geq$  12 months of age or an adult (e.g., client has received **IM** injections in both thighs), give epinephrine **IM** into the deltoid muscle(s).

If both arms and both legs have been used for **IM** immunizations, administer epinephrine **SC** into the upper outer triceps area of the arm(s), or into the fatty area of the anterolateral thigh.

Injection of epinephrine can be made through clothing, if necessary.

Repeat epinephrine at 5-minute intervals twice as needed (i.e., if breathing becomes more laboured or level of consciousness decreases). Note: Administer a maximum of three doses of epinephrine.

Alternate right and left thigh or arm sites for repeat doses of epinephrine (to maximum absorption of epinephrine).

**Note:** An epinephrine self-injector (Epipen® or Twinject™) can also be used in the situation when the immunization provider is not present and if the layperson who administers the self-injector is knowledgeable about proper use. The regular preparations contain 0.3 mL of epinephrine 1:1,000 and can be used for individuals over 6 years of age. If a vaccinee or their parent/guardian refuses the administration of epinephrine when it is indicated, inform them of the risk and immediately call 911 or an ambulance to arrange transfer to an acute care facility. The administration of diphenhydramine hydrochloride (Benadryl®) is not appropriate in this situation. **Diphenhydramine hydrochloride (Benadryl®) is considered second-line therapy to epinephrine and should never be administered alone in treatment of anaphylaxis.**

## 5. Administration of Diphenhydramine Hydrochloride (Benadryl®)

Give **one dose** of diphenhydramine hydrochloride (Benadryl®) **IM** as an **adjunct** to epinephrine when the person is not responding well to epinephrine, or to maintain symptom control in those who have responded (as epinephrine is a short-acting agent). Its use is recommended when transfer to an acute care facility cannot be done within 30 minutes. **Its use is considered second-line therapy to epinephrine and should never be administered alone in the treatment of anaphylaxis.**

The approximate doses for injection (50 mg/mL solution) are outlined in [10. Emergency Treatment of Anaphylaxis](#). Note: Benadryl® is painful when given IM.

When administering diphenhydramine hydrochloride (Benadryl®) **IM**, preferably administer at a different site to that in which epinephrine was given. However, if necessary, give diphenhydramine hydrochloride (Benadryl®) in the same thigh as that in which epinephrine was given.

Diphenhydramine hydrochloride (Benadryl®) can be given into the same muscle mass as the vaccine was given.

Diphenhydramine hydrochloride (Benadryl®) can be given at any time interval either after the initial or repeat doses of epinephrine, as indicated by the person’s condition.

## 6. 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.

Refer to Table 2 for pulse and respiratory rates.

Table 2: Pulse and Respiratory Rates <sup>A</sup>

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

<sup>A</sup> Emergency Medicine: A comprehensive study guide. 6<sup>th</sup> edition. McGraw Hill. 2004

## 7. Client Transport

Arrange for rapid transport by emergency vehicle to an emergency department. Since 20% of anaphylaxis episodes follow a biphasic course with recurrence of the reaction after a 2-9 hour asymptomatic period, hospitalization or a long period of observation is recommended for monitoring.

## 8. Record

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 Panorama and should also be recorded by Vancouver Coastal Health reporters using PARIS (in comments fields if not available as categorical variables). 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 (i.e., Panorama or PARIS).

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 future.

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

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

Discuss with the client the MHO recommendation regarding subsequent immunization.

## 9. Maintenance of Epinephrine Vials and Other Emergency Supplies

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

Protect epinephrine and diphenhydramine hydrochloride (Benadryl®) from light and open vial(s) only when ready to use.

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: Sections 2.3, 10, and 11.
- 3 – 1 cc syringes and needles (25-27 gauge, 1” needle)
- 1 – 1 cc syringe and needle (25-27 gauge, 1½” needle)
- 2 – 3 cc syringes and needles (25-27 gauge, 1” and 1½” needles)
- 2 – 1 cc syringes and needles (25-27 gauge, 5/8” needles) for **SC** route
- extra needles
- 4 ampoules of epinephrine 1:1,000 (within expiration time frame)
- 2 vials of diphenhydramine hydrochloride (Benadryl®) 50 mg/mL (within expiration time frame)
- alcohol swabs
- pens/paper

## 10. Emergency Treatment of Anaphylaxis

### IMMEDIATELY

- Call 911 or ambulance
- Give epinephrine (1:1,000) **IM** into an unimmunized thigh.
- If both thighs were used for immunization:
  - give epinephrine **IM** into deltoid if client is ≥ 12 months of age
  - give epinephrine **SC** into upper outer triceps area of the arm(s) if client is < 12 months of age
- If both thighs and both arms were used for IM immunizations, give epinephrine **SC** into upper outer triceps area of the arm(s) or into the fatty area of the anterolateral thigh.
- **DO NOT** give epinephrine into the same muscle mass as vaccine was given.

Dose: 0.01 mL/kg to maximum of 0.5 mL	
OR:	
Age	Epinephrine
2-6 months	0.07 mL
7-12 months	0.10 mL
13 months-4 years	0.15 mL
5 years	0.20 mL
6-9 years	0.30 mL
10-13 years	0.40 mL
≥ 14 years	0.50 mL

- Position client in recumbent position and elevate legs, as tolerated symptomatically.
- Monitor respiratory effort, pulse, and level of consciousness.

**IF PERSON'S BREATHING IS MORE LABOURED OR LEVEL OF CONSCIOUSNESS DECREASES**

- Repeat epinephrine twice at 5-minute intervals, as needed (maximum 3 doses).
- Alternate right and left thigh or arm sites for repeat doses of epinephrine.
- Elevate head and chest slightly.
- If airway is impaired, use head tilt, chin lift, or jaw thrust.
- If vomiting is likely, turn person to side lying position.

**IF SYMPTOMS ARE NOT CONTROLLED OR TO MAINTAIN SYMPTOM CONTROL IF CLIENT CANNOT BE TRANSFERRED TO ACUTE CARE FACILITY WITHIN 30 MINUTES**

- Give **one dose** of diphenhydramine hydrochloride (Benadryl®) 50 mg/mL **IM preferably** at a different site to that in which epinephrine was given. If necessary, use same thigh as the one in which epinephrine was given. Can also be given into same muscle mass as vaccine was given.
- Can give at any time interval, either after the initial or repeat doses of epinephrine.

Age	Diphenhydramine Hydrochloride (Benadryl®)
< 2 years	0.25 mL
2-4 years	0.50 mL
5-11 years	0.50-1 mL
≥ 12 years	1 mL

**11. Enhanced Surveillance of Suspected Anaphylaxis Following Vaccination**

The form titled [Worksheet for Events Managed as Anaphylaxis Following Immunization](http://www.bccdc.ca/health-professionals/professional-resources/surveillance-forms), found on the BCCDC website at <http://www.bccdc.ca/health-professionals/professional-resources/surveillance-forms>, should be completed by the health care professional who observed and treated the anaphylaxis episode. The information should be added to the AEFI report in the public health information system (i.e., Panorama or PARIS) to allow the MHO/MHO delegate to assess the event, and will allow for application of the Brighton anaphylaxis case definition.

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