Communicable Disease Control

Guidelines for the Management of Anaphylaxis Related to Immunizations

Version 2021-2022

Table of Contents

1. Background **4**

2. Staff Preparation **4**

2.1 Education 4

2.2 Screening 5

3. Anaphylaxis **6**

3.1 Description 6

3.2 Presentation 8

3.3 Assessment 9

4. Anaphylaxis vs. Anxiety-related Adverse Events **10**

4.1 Fainting 10

4.2 Anxiety/Pain Reaction 12

4.3 Injection Site Reactions 14

5. Post-Vaccination Observation **14**

6. Anaphylaxis Management **15**

6.1 Administration of Epinephrine 15

a) Considerations on the Use of Epinephrine 15

b) Mechanism of Action 16

c) Product Description and Dosage of Epinephrine 17

d) Site and Route of Administration 17

e) Storage of Epinephrine 18

f) Post-treatment Monitoring and Assessment 18

6.2 Administration of Diphenhydramine Hydrochloride (Benadryl®) 19

a) Considerations on the Use of Diphenhydramine Hydrochloride (Benadryl®) 19

b) Mechanism of Action 19

c) Product Description and Dosage of Diphenhydramine Hydrochloride (Benadryl®) 20

d) Site and Route of Administration 20

e) Storage of Diphenhydramine Hydrochloride (Benadryl®) 21

f) Post-treatment Monitoring and Assessment 21

6.3 Non-Pharmacological Interventions 21

7. Anaphylaxis Follow-Up **22**
7.1 Recording 22
7.2 Reporting 22
7.3 Patient Transport 23
8. References **24**
9. Appendices **27**
Appendix A: Quick Reference Poster and Anaphylaxis Procedure Checklist 27
Appendix B: Differences between Anaphylaxis vs. Vasovagal Syncope vs. Anxiety Chart 31
Appendix C: Anaphylaxis Management Record 33
Appendix D: Healthcare Provider Summary of Steps of CPR 35
Appendix E: Anaphylaxis Kit 37

Please note this document supersedes the *FNIHB Anaphylaxis Management Guidelines December 2012* and will be updated as new information and evidence becomes available.

1. Background

Anaphylaxis is an acute hypersensitivity reaction that can be potentially life-threatening. However, with prompt recognition and appropriate medication, anaphylaxis can be treated effectively. This clinical syndrome is a rare event, but it can and will occur with immunizations. As such, immunizers must possess the competency (knowledge and skills) to identify and manage an anaphylaxis reaction.

The purpose of the guidelines will be to provide immunizers (that include community health nurses and contracted healthcare professionals) a consistent procedure to anticipate, identify, and manage adverse events following immunizations in a community health setting.

2. Staff Preparation

2.1 Education

To ensure that the immunizers have the necessary competencies to anticipate, identify, and manage adverse events following immunizations, they must:

- Complete an annual review of the management of anaphylaxis following immunization which should include the following topics:
    - Physiology of anaphylaxis and allergic reactions
    - Potential causes of anaphylaxis and ways of decreasing the risks
    - Signs and symptoms of and differences between anaphylaxis, fainting, and anxiety
    - Management and treatment of anaphylaxis
        - Equipment and medications required:
            - Anaphylaxis kits
            - Epinephrine (dosages, routes, and sites of administration)
    - Reporting and documentation of adverse events to immunizations
    - Maintenance of current basic life support certification
- Review the ***Anaphylaxis Quick Reference Poster and Anaphylaxis Procedure Checklist*** prior to each immunization clinic
- Assess the anaphylaxis kit for the integrity of supplies, expiration of products, and restock as necessary prior to immunizing

2.2 Screening

Anaphylaxis is a rare complication of immunization. Pre-vaccination screening includes inquiring about an individual's history of anaphylaxis and identifying potential risk factors. People may have risk factors that may potentially increase the probability and severity of anaphylactic events. In addition, immunizers need to determine if an individual is fit to immunize by screening for anaphylaxis.

Table 1: Pre-Vaccine Administration Check List

	Screening Questions for all Vaccines	Yes	No
1.	Is the vaccine indicated? • Recommended immunization schedules • Vaccine recipient's immunization history • Vaccine recipient's eligibility		
2.	Has vaccine-related information been provided to the vaccine recipient? • Information related to the administration of the vaccine • Benefits of receiving the vaccine • Risks of receiving or not receiving the vaccine		
3.	If the vaccine recipient is a woman: • Is she pregnant? • Is there a chance that she may be pregnant?		
4.	Has the vaccine recipient ever had an allergic reaction after receiving a vaccine? • If so, what was the vaccine? • What was the reaction? • Was the reaction severe?		
5.	Is the vaccine recipient aware of any allergies to components of the vaccine?		
6.	For vaccine recipients who have a history of severe allergies, what were they allergic to? • Biologics/Vaccines • Medications/drugs • Polyethylene Glycol (PEG) • Food • Bee stings • Latex		
7.	Has the vaccine recipient or appropriate guardian or substitute decision-maker provided consent to vaccination and been offered an opportunity to ask questions?		

Adapted from "Vaccine administration practices: Canadian Immunization Guide." by Public Health Agency of Canada, 2017.

Risk factors for increased severity of anaphylactic events include:

- Very young or old age
- Pregnancy
- Severe or uncontrolled asthma
- Chronic obstructive pulmonary disease
- Cardiovascular disease
- Concurrent use of certain medications (e.g. angiotensin-converting enzyme inhibitors and beta-blockers)
- Systemic mastocytosis[1]

3. Anaphylaxis

3.1 Description

Anaphylaxis is an acute hypersensitivity reaction that can present suddenly, involve multiple organ systems, and progress rapidly into a life-threatening response. This reaction is triggered by the binding of an allergen to a specific immunoglobulin E (IgE). It implies previous exposure and sensitization to the triggering substance or a cross reactive allergen.

The antigen-antibody reaction produces a sudden systemic release of allergenic mediators (e.g. histamine, leukotrienes, prostaglandins, tryptase) from basophils and mast cells. These mediators cause increased vascular permeability, vasodilation of the arterioles and capillaries, smooth muscle contraction, and over-secretion by mucous glands. In turn, this produces manifestations in the integumentary, respiratory, cardiovascular systems, and gastrointestinal systems.

Immunizers should be aware that symptoms of anaphylaxis might be difficult to recognize in persons with communication difficulties, neurological disease, and those who are taking medications that can cause drowsiness or sedative effects. Immunizers are recommended to monitor closely for cardinal and non-specific signs and symptoms of anaphylaxis (e.g. flushing, sudden increase in secretions, coughing, agitation, or acute change in mental status).

[1] Systemic mastocytosis is a rare disorder that results in too many mast cells, a type of white blood cells, building up in your skin, bone marrow, digestive tract or other body organs. When triggered, these mast cells release substances that can cause signs and symptoms similar to those of an allergic reaction. Common triggers include alcohol, spicy foods, insect stings and certain medications.

Table 2: Criteria for Suspected Anaphylaxis

Allergen Exposure	Body System Involvement	Symptoms may include
After *unknown exposure* presenting with acute onset of illness	• Integumentary system • Plus one (1) symptom from: ○ Respiratory system ○ Cardiovascular system ○ Central nervous system	**Integumentary system** Flushed skin, redness, generalized hives, itchiness, swelling (face, lips, tongue)
		Respiratory system Stridor, hoarseness, vocal voice changes, grunting, drooling/difficulty swallowing, sneezing, rhinorrhea, coughing, dyspnea, bronchospasm, tachypnea, nasal flaring, shortness of breath, respiratory arrest
		Cardiovascular system Tachycardia, hypotension, arrhythmias, diaphoresis, pallor, cyanosis, headache, sweating, cardiac arrest
		Neurological system Irritability, restlessness, drowsiness, dizziness, lethargy, weakness, reduced level of consciousness, confusion
After *exposure to a likely or known allergen* for that patient	• At least one (1) symptom from two (2) or more of the systems: ○ Integumentary system ○ Respiratory system ○ Cardiovascular system ○ Neurologic system ○ Gastrointestinal system *In rare circumstances, the cardiovascular system may be the only one involved. The patient may present with hypotension.	**Integumentary system** Flushed skin, redness, generalized hives, itchiness, swelling (face, lips, tongue)
		Respiratory system Stridor, hoarseness, vocal voice changes, grunting, drooling/difficulty swallowing, sneezing, rhinorrhea, coughing, dyspnea, bronchospasm, tachypnea, nasal flaring, shortness of breath, respiratory arrest
		Cardiovascular system Tachycardia, hypotension, arrhythmias, diaphoresis, pallor, cyanosis, headache, sweating, cardiac arrest
		Neurological system Irritability, restlessness, drowsiness, dizziness, lethargy, weakness, reduced level of consciousness, confusion
		Gastrointestinal system Nausea, vomiting, diarrhea, cramping, abdominal pain, incontinence

Adapted from "Policy: Anaphylaxis Management – Administration of Intramuscular Epinephrine" by AHS, 2020.

3.2 Presentation

Anaphylaxis should be suspected and managed when the vaccine recipient presents with a sudden onset and rapid progression of integumentary, respiratory, cardiovascular, and/or gastrointestinal symptoms. These signs and symptoms tend to begin within a few minutes after exposure to an offending allergen. Most instances are evident within 15-30 minutes after injection of the vaccine; however, some reactions might develop later. Anaphylaxis occurs as part of a continuum where they may be mild initially and progress to a potentially severe and irreversible outcome. As such, rapid intervention can be life-saving.

The common manifestations of anaphylaxis include:

- **Urticaria** – also known as hives, refer to raised, swollen, pale red bumps, and itchy wheals on the surface of the skin
- **Angioedema** – refers to swelling that occurs beneath the skin that is commonly found around the eyes, lips, hands, feet, neck, and in the throat

High Alert Symptoms – Features of early or mild anaphylaxis include:

- Swelling and hives at the injection site
    - Vaccine recipients that exhibit swelling, and hives should be observed for at least 30 minutes to ensure that the reaction remains localized.
    - If swelling and hives disappear or there is no progression to other parts of the body then no further observation is necessary.
    - If swelling and hives progress further or any other symptoms arise, epinephrine should be administered.
- Having a “Lump in the throat”
- Sneezing, nasal congestion, tearing
- Coughing without shortness of breath
- Facial flushing
- Vomiting/diarrhea

Always treat as Anaphylaxis:

- Flushed skin, redness, generalized hives, itchiness, swelling (face, lips, tongue) AND one (1) symptom from the respiratory, cardiovascular, or central nervous system after UNKNOWN ALLERGEN EXPOSURE
- At least two (2) symptoms from the integumentary, respiratory, cardiovascular, neurologic, or gastrointestinal system after LIKELY or KNOWN ALLERGEN EXPOSURE
- Hypotension after KNOWN ALLERGEN EXPOSURE

3.3 Assessment

In the case of suspected anaphylaxis, the immunizer should:

- Assess the vaccine recipient's airway, breathing, circulation, and level of consciousness
- Perform a rapid assessment of the vaccine recipient for signs and symptoms of anaphylaxis
    - Integumentary system
    - Respiratory system
    - Cardiovascular system
    - Gastrointestinal system
    - Neurological system

Table 3: Signs and Symptoms of Anaphylaxis

Body System	Percentage of Episodes	Signs and Symptoms (One or more may be present)
Integumentary	Up to 80%	Flushed skin, redness, generalized hives, itchiness, swelling (face, lips, tongue)
Respiratory	Up to 70%	Stridor, hoarseness, vocal voice changes, grunting, drooling/difficulty swallowing, sneezing, rhinorrhea, coughing, dyspnea, bronchospasm, tachypnea, nasal flaring, shortness of breath, respiratory arrest
Cardiovascular	Up to 45%	Tachycardia, hypotension, arrhythmias, diaphoresis, pallor, cyanosis, headache, sweating, cardiac arrest
Gastrointestinal	Up to 45%	Nausea, vomiting, diarrhea, cramping, abdominal pain, incontinence
Neurological	Up to 15%	Irritability, restlessness, drowsiness, dizziness, lethargy, weakness, reduced level of consciousness, confusion

See ***Quick Reference Poster, page 28; Appendix A: Quick Reference Poster and Anaphylaxis Procedure Checklist***

4. Anaphylaxis vs. Anxiety-related Adverse Events

There are two types of adverse events that occur following immunizations:

- **Anaphylaxis**
  - Definition: an acute hypersensitive reaction to a component of the vaccine or container.
- **Anxiety-related Adverse Events**
  - Definition: a reaction that arises from anxiety about the immunization.

Distinguishing between the two (2) adverse events becomes important to ensure proper management and timely treatment is administered to the vaccine recipient.

4.1 Vasovagal Syncope (Fainting)

Vasovagal syncope (or fainting) is when an individual becomes pale, loses consciousness, and collapses to the ground. Prior to fainting, individuals may complain of feeling faint or light-headed. This may occur during or within minutes of the immunization followed by brief rhythmic jerking of the limbs (clonic seizure activity). Recovery of consciousness and resolution of limb jerking (if present) should occur within a minute or two. If unconsciousness persists for more than two (2) to three (3) minutes, it is strongly recommended that the immunizer activate emergency response by calling the ambulance and proceed with emergency treatment for anaphylaxis.

Treatment and Management of Vasovagal Syncope:

- Place the vaccine recipient in a supine position and elevate the lower extremities
- If vomiting is imminent or has occurred, place the vaccine recipient in a side-lying position
- If the vaccine recipient is pregnant, place her in a side-lying position on her left side
- Prior to the immunization, consider preventative measures to reduce the likelihood of fainting

Table 4: Key Distinguishing Features of Anaphylaxis and Vasovagal Syncope

Clinical Features	Anaphylaxis	Vasovagal Syncope
Definition	Anaphylaxis is an acute hypersensitivity reaction that can present suddenly, involve multiple organ systems, and progress rapidly into a life-threatening response.	Vasovagal syncope occurs when the individual becomes pale, loses consciousness, and collapses to the ground. Recovery of consciousness within a minute or two.
Onset from Time of Immunization	Within minutes up to hours after exposure to trigger	During or within minutes of the immunization
Skin	• 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	• Generalized pallor • Cold and clammy skin • Excessive perspiration
Respiratory	• Laboured 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	• Normal respirations • Respirations may be shallow and irregular but not laboured
Cardiovascular	• Tachycardia • Chest pain • Weak and rapid pulse • Hypotension alone after an exposure can represent anaphylaxis • Shock • Cyanosis	• Slow and steady pulse • Decreased systolic and diastolic
Gastrointestinal	• Nausea and vomiting • Abdominal pain, cramping, diarrhea • Dysphagia and drooling	• Nausea
Neurological/behavioural/other	• Sense of severe anxiety and distress • Loss of consciousness – no improvement once the individual is supine or in head down position	• Sense of light-headedness • Loss of consciousness – improvement once the individual is supine or in head down position • May result in transient jerking of the limbs and eye-rolling • Numbness and weakness

Adapted from "Anaphylaxis and Other Acute Reactions Following Vaccination: Canadian Immunization Guide." by Public Health Agency of Canada, 2020.

4.2 Anxiety/Pain Reaction

Individuals experiencing an anxiety reaction may appear fearful, pale, and diaphoretic. They may complain of feeling light-headed, dizzy, numb, or tingling of the face and extremities. Hyperventilation is usually evident.

Breath holding spells may occur in young children when they are upset, crying hard, and reacting to pain from the injection. This results in facial flushing and perioral cyanosis. These spells may end with the resumption of crying, a brief period of unconsciousness, or brief rhythmic jerking of the limbs (clonic seizure activity).

Treatment and Management of Anxiety:

- Reassurance and encouraging the vaccine recipient to breath slowly and deeply
- Initiate a refocusing activity by asking the vaccine recipient to count to ten (10)
- Address the root cause of the hyperventilation in case there is another condition causing the anxiety

Table 5: Key Distinguishing Features of Anaphylaxis and Anxiety

Clinical Features	Anaphylaxis	Anxiety
Definition	Anaphylaxis is an acute hypersensitivity reaction that can present suddenly, involve multiple organ systems, and progress rapidly into a life-threatening response.	Anxiety is a protective physiological state recognized as fear, apprehension, or worry. Recovery generally occurs within one (1) to two (2) minutes.
Onset from Time of Immunization	Within minutes up to hours after exposure to trigger	During or within minutes of the immunization
Skin	• 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	• Generalized pallor • Cold and clammy skin • Excessive perspiration • Tingling around the lips
Respiratory	• Laboured 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 and stridor	• Respirations are rapid and shallow • Hyperventilation may occur • Breath-holding in children may occur
Cardiovascular	• Tachycardia • Chest pain • Weak and rapid pulse • Hypotension alone after an exposure can represent anaphylaxis • Shock • Cyanosis	• Rapid pulse • Normal or elevated systolic
Gastrointestinal	• Nausea and vomiting • Abdominal pain, cramping, diarrhea • Dysphagia and drooling	• Nausea
Neurological/behavioural/other	• Sense of severe anxiety and distress • Loss of consciousness – no improvement once the individual is supine or in head down position	• Fearfulness • Light-headedness and dizziness • Numbness and weakness • Spasm in the hands and feet associated with hyperventilation

Adapted from "Anaphylaxis and Other Acute Reactions Following Vaccination: Canadian Immunization Guide." by Public Health Agency of Canada, 2020.

See ***Differences between Anaphylaxis vs. Vasovagal Syncope vs. Anxiety, page 30; Appendix B: Differences between Anaphylaxis vs. Vasovagal Syncope vs. Anxiety Chart***

4.3 Injection Site Reactions

Swelling and urticarial rash (or hives) at the injection site may be the first indication of evolving anaphylaxis. As such, the vaccine recipient should be observed for at least 30 minutes to ensure that these signs remain localized. A mild local reaction that resolves within a few minutes does not indicate an allergic reaction and does not require special observation or further assessment. Ice may be applied to the injection site for patient comfort. However, if other symptoms arise (such as sneezing, nasal congestion, tearing, coughing, facial flushing, or swelling to other parts of the body) then **epinephrine IM** should be promptly given.

5. Post-Vaccination Observation

Recommendations for Observation Period Post Immunization:

- Advise the vaccine recipients or guardian to remain in the waiting area for at least 15 minutes after immunization administration
- Advise the vaccine recipients or guardian to remain in the waiting area for at least 30 minutes after immunization if:
    - Vaccine recipients have experienced an anaphylactic reaction previously
    - Vaccine recipients have experienced an allergic reaction to a biological product or component of the biological product related to the administered vaccine
- Provide instructions for vaccine recipients or guardian to ask for medical assistance immediately if they feel unwell
- Advise vaccine recipients or guardian to notify the immunization provider about concerns that arise following immunizations for further follow-up
- The immunizer will remain at an off-site location with:
    - Anaphylactic kit
    - Telephone access
    - Address of the site for at least 15 minutes following immunization of last patient
- For vaccine recipients who choose not to remain under supervision after immunization, they should be:
    - Informed of the signs and symptoms of anaphylaxis
    - Instructed to obtain immediate medical attention should these signs and symptoms occur
- For cases (such as in low-risk situations) where a shortened observation period is being considered, please consult with the ISC-FNIHB Regional CDC Team.

- Vaccine recipients would need to be within a short distance of the immunization provider (ideally within the setting/facility that the immunization is being carried out), in the company of another person, and able to return immediately for further assessment and potential treatment.

- Treatment of minor adverse reactions (e.g. fever or injection site discomfort) following immunizations may include the use of oral analgesics and antipyretics (e.g. acetaminophen or ibuprofen)

6. Anaphylaxis Management

Anaphylaxis is a medical emergency whereby rapid recognition and treatment can be life-saving. Rapid development of anaphylaxis following immunization may result in a more severe reaction and potentially death within minutes. As such, immunizers must be familiar with the identification and management of anaphylaxis. See ***Anaphylaxis Procedure Checklist, page 29; Appendix A: Quick Reference Poster and Anaphylaxis Procedure Checklist.***

6.1 Administration of Epinephrine

a) Considerations on the Use of Epinephrine

Epinephrine is the **first-line treatment** of choice in community and healthcare settings for suspected anaphylaxis. Prompt intramuscular administration of epinephrine should not be delayed as potential anaphylaxis poses a greater risk to the vaccine recipient. If there are uncertainties, the recommendation is to administer epinephrine as soon as possible, as there are no contraindications and if time is lost subsequent management may become more difficult.

Under specific circumstances, a trained HCP following assessment may administer the recommended dose(s) of epinephrine IM as per the directive when:

- The vaccine recipient is experiencing signs and symptoms of suspected anaphylaxis post-immunization,
- Administration of epinephrine is required as a life-saving intervention, and
- The dose of epinephrine IM is administered by the one who prepared it.

b) Mechanism of Action

Epinephrine is an alpha and beta-agonist that is used to treat anaphylaxis and other severe immediate hypersensitivity reactions. Through alpha-1 receptors, epinephrine causes increased vascular resistance in most body organ systems, increased blood pressure, and decreased mucosal edema. On the beta-2 receptors, epinephrine causes bronchodilation, decreased mediator release from mast cells and basophils, and vasodilation in the skeletal muscles.

Main Effects of Epinephrine:

- Increased heart rate
- Increased force of cardiac contractions
- Increased bronchodilation
- Decreased release of histamine
- Decreased release of mediators of inflammation

Common Side Effects of Epinephrine:

- Palpitations
- Pallor
- Syncope
- Anxiety
- Dizziness
- Headache

c) Product Description and Dosage of Epinephrine

Product Description: Epinephrine is available as **1 mg/mL (1:1000) solution**.

Dosage of Epinephrine: 0.01 mL/kg to a maximum of 0.5 mL

- Dose is calculated based on body weight
- In the case that body weight is unknown, the dose will be calculated based on age
- Monitor the vaccine recipient for continued signs and symptoms of anaphylaxis. Epinephrine can be administered every five (5) minutes to a maximum of three (3) doses if the individual's condition does not improve.

Table 6: Dosage of Intramuscular Epinephrine (1mg/mL) Solution, by Age or Weight

Age, use weight if available	**Weight (kg)**	Epinephrine (1 mg/mL) ampoule or vial	
		Dose mg OR mg/kg/dose	**Volume 1 mg/mL (mL)**
Birth to < 5 kg	< 5	0.01 mg/kg/dose OR 0.1 mg	0.01 mL/kg/dose OR 0.1 mL
Greater than 5 kg AND < 2 years	5-10	0.1 mg	0.1 mL
2-3 years	11-15	0.15 mg	0.15 mL
4-6 years	16-20	0.2 mg	0.2 mL
	21-25	0.25 mg	0.25 mL
7-9 years	26-30	0.3 mg	0.3 mL
	31-35	0.35 mg	0.35 mL
10-12 years	36-40	0.4 mg	0.4 mL
	41-45	0.45 mg	0.45 mL
> 12 years	> 46	0.5 mg	0.5 mL

Adapted from "Anaphylaxis and Other Acute Reactions Following Vaccination: Canadian Immunization Guide." by Public Health Agency of Canada, 2020.

Please note: Some healthcare professionals (e.g. primary care paramedics) are permitted to administer up to a maximum dose of epinephrine 0.3 mg (0.3 mL). It is important that trained healthcare professionals practice within their scope of practice and adhere to their profession's standards of practice.

d) Site and Route of Administration

Site of Administration: Vastus lateralis (*Preferred*) or in the most appropriate IM site

- Administer 1 mg/mL solution into the mid-anterior lateral thigh
- If a second dose is required, use the vaccine recipient's alternate thigh.
- If a third dose is required, use a different site in the first thigh used.
- Avoid administration of epinephrine into the same muscle mass that was used for immunization. If the patient has already received immunizations to both legs, administer the epinephrine at least 2.5 cm (or 1 inch) from the original immunization injection site.

Route of Administration: Intramuscular (IM)

- Intramuscular administration of epinephrine into the vastus lateralis is preferred because the rate of absorption is faster than if the drug was given subcutaneously due to the rich vasculature of the thigh muscle.
- May repeat the injection every five (5) to ten (10) minutes, if necessary. Up to maximum of 3 doses
- Please note that repeated local injection can cause necrosis at the injection site.

e) Storage of Epinephrine

Storage of Epinephrine: Store between 20°C to 25°C. Protect from light and extreme temperatures (e.g. freezing and excessive heat).

- Use the solution only if it is clear or pale yellow and contains no precipitate.

f) Post-treatment Monitoring and Assessment

After administration of the epinephrine dose(s), the immunizer shall:

- Continue to monitor and assess the vaccine recipient
    - Take his or her vital signs
    - Monitor for signs and symptoms of anaphylaxis
    - Observe for potential biphasic anaphylactic reaction
        - Biphasic anaphylactic reaction is the recurrence of the reaction within four (4) to six (6) hours (up to 72 hours) after the initial onset of symptoms
- Notify the Medical Officers of Health/Regional CDC Nurse Manager of the anaphylaxis incident and their disposition
    - Use the 24 hour number: 780-218-9929
- Provide education to the vaccine recipient and/or guardian of the importance of assessing for signs and symptoms of anaphylaxis, and the necessary steps to take if another reaction occurs

6.2 Administration of Diphenhydramine Hydrochloride (Benadryl®)

a) Considerations on Use of Diphenhydramine Hydrochloride (Benadryl®)

Diphenhydramine hydrochloride (Benadryl®) is an antihistamine that can be used to relieve less severe cutaneous symptoms of anaphylaxis. It does not prevent airway obstruction, hypotension, or shock. Use of diphenhydramine hydrochloride (Benadryl®) will not mask symptoms of anaphylaxis.

Indication: Single dose of diphenhydramine hydrochloride (Benadryl®) intramuscular injection may be administered according to the guideline in the case of an anaphylactic reaction:

- Epinephrine has already been administered
- Vaccine recipient is stable but still experiencing itching, hives, flushing, angioedema, and nasal/eye symptoms
- If transport to a greater level of care (e.g. acute care facility) cannot occur within 30 minutes

Single dose of diphenhydramine hydrochloride (Benadryl®) oral administration may be considered in the management of an allergic reaction or for patients with high alert symptoms. **Oral diphenhydramine hydrochloride (Benadryl®) should not be used in place of epinephrine in the management of anaphylaxis.**

> **NOTE**: Diphenhydramine hydrochloride (Benadryl®) should **NOT** be given before epinephrine or **NEVER** used alone during management and treatment of anaphylaxis.

b) Mechanism of Action

Diphenhydramine hydrochloride (Benadryl®) competes with histamine for H_1-receptor sites to alleviate urticaria, pruritis, and angioedema. However, it does not reverse histamine-mediated responses in the bronchial tubes, gastrointestinal tract, or blood vessels.

> **NOTE**: Diphenhydramine hydrochloride (Benadryl®) does **NOT** have any effects in preventing or treating respiratory or cardiovascular symptoms. It is **NOT** indicated in the initial emergency management of anaphylaxis and should **NEVER** be used in place of epinephrine.

Common Side Effects of Diphenhydramine hydrochloride (Benadryl®):

- Sleepiness, sedation, and dizziness
- Epigastric distress

c) Product Description and Dosage of Diphenhydramine Hydrochloride (Benadryl®)

Product Description: Diphenhydramine hydrochloride (Benadryl®) is available as 50 mg/mL (injectable), 1.25 mg/mL (oral), and 12.5 mg/tab (oral).

Dosage of Diphenhydramine hydrochloride (Benadryl®):

Injectable (IM): 50 mg/mL

- 1 mg/kg to a maximum of 50 mg
- Dose is calculated based on body weight
- In the case that body weight is unknown, the dose will be calculated based on age

Oral (PO): 1.25 mg/mL or 12.5 mg tablets

- 1 to 2 mg/kg to a maximum single dose of 100 mg
- Dose is calculated based on body weight
- In the case that body weight is unknown, the dose is calculated based on age

Table 7: Dosage of Intramuscular Benadryl® (50 mg/mL) OR Oral Benadryl® (1.25 mg/mL) Solution OR Tablet (12.5 mg/tab), by Age or Weight

Age, use weight if available	**Weight (kg)**	Benadryl® IM (50 mg/mL)		Benadryl® PO (1.25 mg/mL) or 12.5 mg tab		
		Dose (mg)	**Volume (mL)**	**Dose (mg)**	**Volume (mL)**	**Tablets (tab)**
< 2 years	7 kg	7 mg	0.14 mL	6 to 12.5 mg	5 to 10 mL	N/A
	15 kg	12.5 mg	0.25 mL	12.5 to 31.25 mg	10 to 20 mL	1-2 tabs
2 to 4 years	20 kg	25 mg	0.5 mL	19 to 37.5 mg	15 to 30 mL	1-3 tabs
5 to 8 years	30 kg	25 mg	0.5 mL	37.5 to 75 mg	30 to 60 mL	3-6 tabs
9 to 10 years	40 kg	50 mg	1 mL	37.5 to 75 mg	30 to 60 mL	3-6 tabs
≥ 12 years	≥ 50 kg	50 mg	1 mL	93.75 mg	75 mL	7-8 tabs

Adapted from "Guidelines for the Management of Anaphylaxis Related to Immunizations." by First Nations and Inuit Health Branch, 2012.

d) Site and Route of Administration

Site and Route of Administration: Vastus lateralis (*Preferred*) or in the most appropriate IM site OR orally depending on the circumstances.

Intramuscular (IM) Administration

- Administer 50 mg/mL solution into the mid-anterior lateral thigh or the most appropriate IM site.
- Avoid administration of diphenhydramine hydrochloride (Benadryl®) into the same muscle mass that was used for immunization. If the patient has already received immunizations to the IM sites, administer the medication at least 2.5 cm (or 1 inch) from the original immunization injection site to prevent irritation.

Oral (PO) Administration

- Administer 1.25 mg/mL solution orally.
- Give drug with food or mild to reduce gastrointestinal distress.

e) Storage of Diphenhydramine Hydrochloride (Benadryl®)

Storage of Diphenhydramine hydrochloride (Benadryl®): Store between 15°C to 30°C (or at room temperature). Protect from light.

f) Post-treatment Monitoring and Assessment

After administration of the diphenhydramine hydrochloride (Benadryl®) dose, the immunizer shall continue to monitor and assess the vaccine recipient.

6.3 Non-Pharmacological Interventions

In situations where epinephrine is not readily available yet and anaphylaxis is suspected, the PHN or immunization provider should:

- Seek immediate emergency assistance
- Stop exposure to the suspected allergen (if possible)
- Place the vaccine recipient in a supine position with lower extremities elevated
    - Keep the vaccine recipient in this recumbent position until stable, as fatality can occur if he/she stands or sits suddenly
    - If the vaccine recipient is unable to lie supine with lower extremities elevated (due to respiratory distress, obesity, pregnancy, or age), place them in a side-lying position or position of comfort
    - If the vaccine recipient has vomited or vomiting is imminent, place them in a side-lying position
- Monitor pulse, respiratory effort, and level of consciousness to guide interventions
    - If the person experiences respiratory difficulty, elevate the vaccine recipient's head and chest slightly
    - If airway is impaired, improve the vaccine recipient's position by using head tilt and chin lift, or jaw thrust
- Monitor oxygen saturation if the equipment is available and administer oxygen as required

7. Anaphylaxis Follow-Up

7.1 Recording

Use the *Anaphylaxis Management Record* (See ***Appendix C: Anaphylaxis Management Record***) to record information related to the adverse event. It is important to capture as much information as possible related to:

- Onset and progression of signs and symptoms
- Medications administered (including the time of administration, dosage, and number of doses given if applicable)
- Monitoring (e.g. vital signs) and follow-up care

Copies of this *Anaphylaxis Management Record* can be:

- Provided to emergency services personnel
- Attached to the adverse event reporting form
- Attached to the incident report form
- Included in the patient's record or chart

7.2 Reporting

- The immunizer should as soon as reasonably possible:
- Notify the Medical Officers of Health/Regional CDC Nurse Manager either in person or via phone.
    - Use the 24 hour number: 780-218-9929
    - Do not leave a message for the MOH/Regional CDC NM. You must speak with someone after the initial management of the situation.
- Notify parents/guardians, school principal (if applicable), Zone Nurse Manager, Nurse in Charge/Supervisor as soon as reasonably possible, once the situation is under control.
- Attempt to obtain all documents relating to the emergency or physician's visit.
    - Include the patient's record and adverse reaction report
- Complete the *Alberta Adverse Event Following Immunization Report* and forward to First Nations and Inuit Health Branch, Alberta Regional office as soon as reasonably possible
- Notify the patient and family with recommendations for future immunizations as appropriate

NOTE: **Anaphylaxis kits** should be regularly assessed for expiring product(s), integrity of supplies, and restocked, as necessary.

7.3 Patient Transport

All vaccine recipients who have received emergency anaphylaxis treatment (such as administration of IM epinephrine) are strongly encouraged to be transported to an acute care facility (e.g. hospital) immediately for further observation, assessment, and evaluation. An anaphylactic episode can follow a biphasic course after an initial reaction.

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9. Appendices

Appendix A: Quick Reference Poster and Anaphylaxis Procedure Checklist

Please Refer to the Subsequent Pages for the Printable Versions

Anaphylaxis Quick Reference

Anaphylaxis is an acute hypersensitivity reaction that is usually evident within 15 to 30 minutes, may involve multiple organ systems, and may progress rapidly into a life-threatening response.
Failure to use epinephrine promptly is more dangerous than using it improperly.

Criteria for Suspected Anaphylaxis

Criteria	Allergen Exposure	Body System Involvement
1	After unknown exposure presenting with acute onset of illness	• Integumentary system Plus one (1) symptom from: • Respiratory system • Cardiovascular system • Central nervous system
2	After exposure to a likely or known allergen for that patient *In rare circumstances, the cardiovascular system may be the only one involved. The patient may present with hypotension.	At least one (1) symptom from two (2) or more of the systems: • Integumentary system • Respiratory system • Cardiovascular system • Neurologic system • Gastrointestinal system

Signs and Symptoms of Suspected Anaphylaxis

Body System	Integumentary	Respiratory	Cardiovascular	Gastrointestinal	Neurological
Signs and Symptoms	Flushed skin Redness Generalized hives Itchiness Swelling (face, lips, and tongue)	Stridor Hoarseness Vocal voice changes Grunting Drooling/difficulty swallowing Sneezing Rhinorrhea Coughing Dyspnea Bronchospasm Tachypnea Nasal flaring Shortness of breath Respiratory arrest	Tachycardia Hypotension Arrhythmias Diaphoresis Pallor Cyanosis Headache Sweating Cardiac arrest	Nausea Vomiting Diarrhea Cramping Abdominal pain Incontinence	Irritability Restlessness Drowsiness Dizziness Lethargy Weakness Reduced level of consciousness Confusion

If symptoms displayed by the vaccine recipient are exclusively dermatological or gastrointestinal, monitor carefully and ***be prepared to intervene***. Begin treatment if respiratory and/or circulatory symptoms are present.

If an individual appears to have fainted and remains unconscious for more than 5 minutes, activate ***emergency response*** by calling the ambulance and proceed with ***emergency treatment*** for anaphylaxis**.**

Anaphylaxis Procedure Checklist

Steps should be done rapidly or simultaneously: The priority is prompt administration of epinephrine which should not be delayed. Failure to use epinephrine promptly is more dangerous than using it inappropriately.

STEP 1 Promptly administer **epinephrine (1:1000) IM**

EPINEPHRINE FOR SUSPECTED ANAPHYLAXIS
Product: 1 mg/mL ampoule *OR* vial
Route of administration: Intramuscular (IM)
Site: Vastus lateralis *OR* Most appropriate IM site away from the immunization site *OR* If necessary, administered into the same muscle as the immunization with at least 2.5 cm from the original insertion site
Dose: 0.01 mL/kg to a maximum of 0.5 mL
Considerations: Repeat Epinephrine (IM) Q5-10 minutes PRN x two (2) doses (to a maximum of 3 total doses) for ongoing signs and symptoms of anaphylaxis. Alternate legs for multiple doses.

Age, use weight if available	**Weight (kg)**	Epinephrine (1 mg/mL) **Dose (Volume)**
Birth to < 5 kg	< 5	0.01 mg/kg/dose OR 0.1 mg (0.1 mL)
Greater than 5 kg AND < 2 years	5-10	0.1 mg (0.1 mL)
2-3 years	11-15	0.15 mg (0.15 mL)
4-6 years	16-20	0.2 mg (0.2 mL)
	21-25	0.25 mg (0.25 mL)
7-9 years	26-30	0.3 mg (0.3 mL)
	31-35	0.35 mg (0.35 mL)
10-12 years	36-40	0.4 mg (0.4 mL)
	41-45	0.45 mg (0.45 mL)
> 12 years	> 46	0.5 mg (0.5 mL)

STEP 2 Call for HELP. Call **EMS** and arrange for rapid transport to an emergency department.

STEP 3 Place the Client in a SUPINE position, with ***feet elevated*** if possible.

STEP 4 Perform emergency interventions as indicated.

- Maintain airway and ventilation.
  - Monitor oxygen saturation (if equipment is available). Goal: $Sp0_2$ > 92%
  - Administer oxygen for hypoxia (if available)
- Perform CPR (if required).
- Initiate IV access (if possible). Do NOT administer epinephrine via IV route.

STEP 5 Single dose of diphenhydramine hydrochloride (Benadryl®) 50 mg/mL may be given if epinephrine has been administered, vaccine recipient is not responding well to epinephrine and/or still exhibits integumentary symptoms of anaphylaxis, but ***cannot be transferred to an acute care facility within 30 minutes***.

BENADRYL®
Route of administration: Intramuscular (IM)
Product: 50 mg/mL (injectable)
Site: Vastus lateralis *OR* Most appropriate IM site away from the immunization site *OR* If necessary, administered into the same muscle as the immunization with at least 2.5 cm from the original insertion site
Dose: 1 mg/kg to a maximum of 50 mg

Age, use weight if available	**Weight (kg)**	Benadryl® **IM** (50 mg/mL)	Benadryl® **PO** (1.25 mg/mL) or 12.5 mg tab		
		Dose (Volume)	**Dose (mg)**	**Volume(mL)**	**Tablets (tab)**
< 2 years	7 kg	7 mg (0.14 mL)	6 to 12.5 mg	5 to 10 mL	N/A
	15 kg	12.5 mg (0.25 mL)	12.5 to 31.25 mg	10 to 20 mL	1-2 tabs
2 to 4 years	20 kg	25 mg (0.5 mL)	19 to 37.5 mg	15 to 30 mL	1-3 tabs
5 to 8 years	30 kg	25 mg (0.5 mL)	37.5 to 75 mg	30 to 60 mL	3-6 tabs
9 to 10 years	40 kg	50 mg (1 mL)	37.5 to 75 mg	30 to 60 mL	3-6 tabs
≥ 12 years	≥ 50 kg	50 mg (1 mL)	93.75 mg	75 mL	7-8 tabs

STEP 6 Re-assess circulation, airway, breathing, and the situation frequently to guide medication use. Monitor vital signs.

STEP 7 Notify Medical Officer(s) of Health/Regional CDC Nurse Manager as soon as possible.

Appendix B: Differences between Anaphylaxis vs. Vasovagal Syncope vs. Anxiety Chart

Key Distinguishing Features of Anaphylaxis vs. Vasovagal Syncope vs. Anxiety

Clinical Features	Anaphylaxis	Vasovagal Syncope	Anxiety
Definition	Anaphylaxis is an acute hypersensitivity reaction that can present suddenly, involve multiple organ systems, and progress rapidly into a life-threatening response.	Vasovagal syncope occurs when the individual becomes pale, loses consciousness, and collapses to the ground. Recovery of consciousness within a minute or two.	Anxiety is a protective physiological state recognized as fear, apprehension, or worry. Recovery generally occurs within one (1) to two (2) minutes.
Onset from Time of Immunization	Within minutes up to hours after exposure to trigger	During or within minutes of the immunization	During or within minutes of the immunization
Skin	• 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	• Generalized pallor • Cold and clammy skin • Excessive perspiration	• Generalized pallor • Cold and clammy skin • Excessive perspiration Tingling around the lips
Respiratory	• Laboured 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	• Normal respirations • Respirations may be shallow and irregular but not laboured	• Respirations are rapid and shallow • Hyperventilation may occur Breath-holding in children may occur
Cardiovascular	• Tachycardia • Chest pain • Weak and rapid pulse • Hypotension alone after an exposure can represent anaphylaxis • Shock • Cyanosis	• Slow and steady pulse • Decreased systolic and diastolic	• Rapid pulse • Normal or elevated systolic

Clinical Features	Anaphylaxis	Vasovagal Syncope	Anxiety
Gastrointestinal	• Nausea and vomiting • Abdominal pain, cramping, diarrhea • Dysphagia and drooling	• Nausea	• Nausea
Neurological/ behavioural /other	• Sense of severe anxiety and distress • Loss of consciousness – no improvement once the individual is supine or in head down position	• Sense of light-headedness • Loss of consciousness – improvement once the individual is supine or in head down position • May result in transient jerking of the limbs and eye-rolling • Numbness and weakness	• Fearfulness • Light-headedness and dizziness • Numbness and weakness • Spasm in the hands and feet associated with hyperventilation

Adapted from "Anaphylaxis and Other Acute Reactions Following Vaccination: Canadian Immunization Guide." by Public Health Agency of Canada, 2020.

Appendix C: Anaphylaxis Management Record

Client Name: _____ DOB: _____ PHN: _____

Address: _____ Phone Number: _____

Date: _____ Location: _____

Vaccine History:

Vaccine(s) given[1]	Time of Immunization	Site (LLL, LUL, RLL, RUL, LL, RL, LA, RA)[2]	Route (IM, ID, SC, NA)[3]

Incident History:

Onset of Incident (time)
Time EMS called:
EMS arrival time:
Receiving Hospital:

Notes:
1. Record Vaccine as antigen, i.e. DTaP-IPV-Hib instead of Pediacel™ or Infanrix-Hib™
2. LLL=left lower leg; LUL=left upper leg; RLL=right lower leg; RUL=right upper leg; LL=left leg; RL=right leg; LA=left arm; RA=right arm.
3. IM=intramuscular; ID=intradermal; SC=subcutaneous; NA=nasal

Assessment Details (tick all that apply)

SKIN/ MUCOSA

- ☐ Urticaria
  - ○ Injection site
  - ○ Generalized
- ☐ Erythema
- ☐ Pruritis
  - ○ With skin rash
  - ○ Without skin rash
- ☐ Red, itchy eyes
- ☐ Tingling/prickle sensation
  - ○ Generalized
  - ○ Mouth, hands/feet
- ☐ Angioedema
  - ○ Face
  - ○ Limbs
  - ○ other

CARDIOVASCULAR

- ☐ Hypotension
- ☐ Tachycardia
- ☐ Capillary refill > 3 s
- ☐ Decreased level of consciousness
- ☐ Anxiety

RESPIRATORY

- ☐ Sneezing
- ☐ Rhinorrhea
- ☐ Hoarse voice
- ☐ Lump in throat
- ☐ Wheeze
- ☐ Stridor
- ☐ Cyanosis
- ☐ Tachynpoea
- ☐ Grunting
- ☐ Upper airway swelling:
  - ○ Tongue
  - ○ Throat
  - ○ Uvula
  - ○ Larynx
  - ○ Lip
- ☐ Difficulty breathing Indrawing/retractions

GASTROINTESTINAL

- ☐ Diarrhea
- ☐ Nausea
- ☐ Vomiting
- ☐ Abdominal pain

Management Details

Epinephrine *administration Record (1:1000)*
Dose calculation: 0.01 mL/kg to maximum of 0.5 mL

	Time	Site	Amount	Route
Dose 1				
Dose 2				
Dose 3				

Benadryl *administration record (50 mg/mL IM; 1.25 mg/mL PO)*
IM Dose calculation: 1 mg/kg to maximum 50 mg

	Time	Site (IM)	Amount	Route
Dose 1				

Time	BP	Pulse	Resp	Comments

RN *(please print)*:_____ **Recorder** *(Please Print)*_____

Signature: _____ Signature: _____

FNIHB Anaphylaxis Management
December 2012

SEE REVERSE SIDE FOR FURTHER DETAILS

Notifications:

Next of Kin	Y	N	**Name:** _____	**Relationship:** _____				
NIC	Y	N	**Time:** _____	MOH/Designate:	Y	N	**Time** _____	
ZNM	Y	N	**Time:** _____	Other: _____				
Other _____				Other: _____				

Copies of ***Anaphylaxis Management Record*** should be distributed as follows:

EMS: provide copy to accompany client

FAX ASAP to:
- MOH/Designate (780-495-8070)
- ZNM

Call MOH/Designate ASAP: 780-218-9929

Copy Distribution:
- Family physician
- Client Chart
- Attached to Incident report
- Attached to ***"Report of Adverse Reaction to Immunizing Agent"*** form

Note: there is no need to re-copy information contained on AMR onto the incident report.

Completed original should be forwarded to ZNM

FOLLOW-UP OF INCIDENT: *for recording contact with family, hospital, and any other subsequent activities or information.*

FNIHB Anaphylaxis Management
December 2012

Appendix D: Healthcare Provider Summary of Steps of CPR

Component	**Recommendations**		
Audience	**Adults**	**Children**	**Infants/Neonates**
Recognition	Unresponsive (for all ages)		
	No breathing OR no normal breathing (e.g. only gasping)	No breathing or only gasping	
	No pulse felt within 10 seconds		
CPR Sequence	Chest compressions, Airway, Breathing (C-A-B)		
Compression Rate	100 to 120/minute		
Compression Depth	At least 2 inches (5 cm)	At least 1/3 AP diameter (about 2 inches or 5 cm)	At least 1/3 AP diameter (about 1.5 inches or 4 cm)
Chest Wall Recoil	Allow complete recoil between compressions; Rotate compressions every 2 minutes, or sooner if fatigued		
Compression Interruptions	Minimize interruptions in chest compressions; Attempt to limit interruptions to < 10 seconds		
Airway	Head tilt-chin lift; Jaw thrust (use if there is suspected trauma)		
Compression-ventilation Ratio (until advanced airway placed)	30:2 – one to two rescuers	30:2 – single rescuer 15:2 – two rescuers or if there is no advanced airway	
Ventilations with Advanced Airway	1 breath every 6 to 8 seconds (8 to 10 breaths per minute); Asynchronous with chest Compressions; About 1 second per breath; Observe for visible chest rise	1 breath every 2 to 3 seconds; Observe for visible chest rise	
Defibrillation	Attach and use AED as soon as available; Minimize interruptions in chest compressions before and after shock; Resume CPR beginning with compressions immediately after each shock		
Considerations	Full CPR is an AGMP; *Routine practices for hands-only manual chest compressions* include: Call for help, perform point of care risk assessment, hand hygiene, place loose clothing or sheet		

Considerations (Con't)	over the mouth and nose of the patient (as an airway source control), initiate hands-only chest compressions until individuals who are wearing appropriate PPE can assist; Only individuals who are wearing N95 respirators should manage the airway and complete full CPR; *Routine practices for full CPR* include: call for help, perform point of care risk assessment, hand hygiene, provide CPR in a contained space (e.g. room with a closed door), individuals within 2 metres of the person receiving full CPR should don appropriate PPE (gloves, N95 respirator, gown, face shield), use adult size bag/valve mask as recommended

Abbreviations: CPR – Cardiopulmonary resuscitation; AP – anterior-posterior; AED – automated external defibrillator; AGMP – aerosol generating medical procedure; PPE – personal protective equipment

Adapted from "Highlights of the 2020 American Heart Association: Guidelines for CPR and ECC ." by Heart and Stroke Foundation of Canada, 2020.

Appendix E: Anaphylaxis Kits

Anaphylaxis Management Kits

# Required in the kit	Anaphylaxis Kit Contents	Yes	No
1	Anaphylaxis Quick Reference		
1	Emergency Contact Numbers		
1	Anaphylaxis Management Record		
1	Healthcare Provider Summary of Steps of CPR for Adults, Children, and Infants		
2	Ampoules/vials of Epinephrine (1mg/mL)		
2	Vials of Diphenhydramine Hydrochloride (Benadryl®)		
1	Bottle of Diphenhydramine Hydrochloride (Benadryl®)		
4	1 cc Syringes		
2	3 cc Syringes		
6	25 gauge, 5/8” Needle		
6	25 gauge, 1” Needle		
2	22 gauge, 1 ½” Needle		
10	Alcohol Swabs (Optional)		
3	Pens		
3	Boxes of Gloves (Small, Medium, Large)		
1	Disposable Resuscitation Mask or Laerdal Pocket Mask		

Adapted from “Guidelines for the Management of Anaphylaxis Related to Immunizations” by First Nations and Inuit Health Branch, 2012.