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MANAGEMENT OF ANAPHYLAXIS AND OTHER REACTIONS FOLLOWING IMMUNIZATIONS IN NON-HOSPITAL SETTINGS

Department of Health
Public Health New -Brunswick

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1.0 POLICY

This policy is intended to provide guidance for immunizers administering publicly funded vaccines in New Brunswick in non-hospital settings such as Public Health clinics, community health clinics, pharmacies, primary care providers' offices, schools, immunization mass clinics, homebound patients, and similar settings. Its purpose is to ensure a consistent approach to preventing, assessing, and managing suspected or confirmed anaphylactic reactions. Immunizers are authorized to implement emergency management procedures for anaphylaxis as outlined in this guide following an initial clinical assessment.

Epinephrine is the exclusive and effective treatment for anaphylaxis. Rapid **intramuscular (IM) administration** of Epinephrine upon recognizing anaphylaxis is crucial to mitigate the risk of hospitalization or death. Studies show significantly higher peak plasma epinephrine concentrations with IM injection rather than subcutaneous injection (SC). **In non-hospital settings, prioritizing rapid absorption of medication is critical to minimize delays in emergency care. Therefore, IM injection is recommended as the preferred route for the treatment of anaphylaxis.**

Diphenhydramine (Benadryl) is **no longer indicated** in the treatment of anaphylaxis. Based on current evidence, antihistamines are no longer indicated as a treatment in the emergency management of anaphylaxis since they have no effect on respiratory or cardiovascular symptoms and have limited clinical significance in cases of life-threatening anaphylaxis.

Effective anaphylaxis management outside the hospital requires proactive preparation. Vaccine providers must establish, demonstrate, and routinely practice a written protocol. This protocol should clearly define necessary emergency equipment, medication dosages, and the required medical personnel for the safe and efficient handling of anaphylactic reactions.

2.0 MAINTENANCE OF IMMUNIZATION COMPETENCIES

All healthcare professionals administering immunizations are required to demonstrate competence, understanding, clinical skills, and up-to-date evidence-based knowledge in anaphylaxis recognition and management, in accordance with the New-Brunswick Immunization Program Guide (NBIPG) program policy - Immunization Competency Requirements for All Immunization Providers.

Continuous competency in anaphylaxis management, including Cardiopulmonary Resuscitation (CPR) training, is an individual professional responsibility and is guided by professional practice standards, employer policies and evidence- based research.

3.0 PRE-VACCINATION SCREENING

Early identification of risk factors is key. With each vaccine recipient, inquire if any history of anaphylaxis, any known or suspected allergies to vaccine components, and any past adverse reactions to a vaccine.

Regarding COVID-19 vaccines, there is now sufficient evidence regarding management of allergies, hypersensitivities, and contraindications. Healthcare professionals now have guidance for managing individuals with confirmed or suspected allergies to components of a COVID-19 vaccine, found in the section on contraindications and precautions in the COVID-19 vaccine Chapter: Canadian Immunization Guide.

For vaccine histories not related to COVID-19 vaccines or requiring further guidance: If an individual reports experiencing an anaphylactic reaction or another moderate to severe allergic reaction to a previous dose or component, it is important to seek guidance from the prescribing physician, if applicable, to determine the appropriate course of action. For Public Health or community First Nation nurses, contacting the regional Medical Officer of Health (RMOH) is necessary to determine the next steps. If neither a physician nor an RMOH on call can be reached immediately, vaccination should be postponed until the situation can be discussed with the physician/RMOH.

For a complete list of potential allergens in immunizing agents, refer to the Canadian Immunization Guide: Contents of immunizing agents authorized for use in Canada.

For tips on counseling and pre-vaccine administration check lists, refer to the Canadian Immunization Guide chapter on Vaccine Administration Practices.

4.0 POST VACCINATION OBSERVATION

Most occurrences of anaphylaxis begin within minutes after administration. Vaccine recipients are instructed to wait at least 15 minutes post vaccination before leaving the clinic for this reason. Longer wait times may be recommended (30 minutes or more) for those with a history of allergic reaction and/or anaphylaxis or to a specific vaccine (such as COVID-19 vaccines).

If a client chooses not to remain under supervision following immunization, despite having been informed of our recommendations, it is crucial to inform them (or their parent/guardian) about the signs and symptoms of anaphylaxis. They should be instructed to seek immediate medical attention should any symptoms arise. Additionally, it is important document their decision to leave against medical advice in the client's records.

For more information on the post observation period specifically following a COVID-19 vaccine, refer to the Canadian Immunization Guide- Chapter on COVID-19 vaccines.

5.0 DISTINGUISHING ANAPHYLAXIS VERSUS OTHER REACTIONS

Beyond anaphylaxis, immunizations can trigger other acute reactions. These typically fall into two categories: anxiety-related events like fainting (vasovagal syncope), hyperventilation, and breath-holding; or immediate hypersensitivity reactions like injection site reactions. Timely and appropriate treatment depends on accurately distinguishing these symptoms from anaphylaxis.

5.1. Vasovagal syncope (fainting)

While fainting itself may not result in adverse consequences, falls during episodes of fainting could lead to severe head or other injuries. Syncope-related events are more prevalent among adolescents and adults, with fainting being rare among infants and children.

Symptoms may include generalized pallor, cold clammy skin, sense of “lightheadedness”, shallow breathing, bradycardia, weak pulse (except strong carotid pulse), loss of consciousness improved once supine or head down position, may be transient rhythmic jerking of the limbs or eyes rolling. A sudden loss of consciousness in children should be suspected as anaphylaxis, **particularly if they show additional clinical manifestations of anaphylaxis.**

Treatment: No specific treatment needed. Reassure anxious clients, have them lie down with legs elevated, apply cool cloth to face, monitor lying to sitting to standing position slowly, offer water and cool compress to face/neck. If unconscious, turn on their side (left if pregnant). Monitor until recovery, which usually occurs within minutes.

For techniques to decrease anxiety and fainting, refer to the Canadian Immunization Guide - Vaccine Administration Practices in Part 1.

5.2. Hyperventilation

Factors that may trigger a hyperventilation reaction may include immunization anxiety due to fear of needles, past negative immunization experiences, concerns about potential side effects, a lack of trust in the vaccine or healthcare system. Hyperventilation is usually evident.

Symptoms may include: An anxious client appearing fearful, pale, diaphoretic, possibly rapid, shallow breathing, shortness of breath, lightheadedness, or feelings of dizziness, tingling extremities, chest discomfort, sense of panic.

Treatment: No specific treatment needed but the goal is to slow the breathing and provide reassurance. Use simple activities to shift the person's attention, like asking them to count from one to ten or backwards. Initiate a controlled breathing exercise such as inhaling deeply for a count of 10, then exhaling slowly for a count of 10. Repeat this process until breathing becomes slower.

- **Important:** current evidence supports **avoiding using a paper bag** for hyperventilation. Rebreathing exhaled air is ineffective due to the limited CO2 reabsorption and offers little benefit. There is a risk of misdiagnosing serious allergic reactions (anaphylaxis) as they share similar symptoms and could worsen the hypoxia (low oxygen levels) already present.

5.3. Breath-holding spells

Breath-holding is an anxiety related reaction that can occur in some young children when they are upset, crying intensely, and reacting to injection pain. Although breath-holding might look scary, the spells are fairly harmless and do not cause long-term damage. Children with breath-holding spells usually do not have an underlying illness.

Symptoms may include: crying or gasping followed by suddenly silent and no breathing. They may have facial flushing and/or pallor and bluish discoloration around the mouth (perioral cyanosis). Some spells end with crying resumed, but others may end in fainting or brief loss of consciousness during which breathing resumes withing seconds. In very rare cases, transient rhythmic jerking of the limbs may occur. If these movements last for more than one minute, which is rare, call an ambulance and suspect they may be experiencing a seizure.

Treatment: No specific treatment needed. After the spell offer reassurance to the child and parents. If unconscious, turn to side. Monitor until recovery, which usually occurs within minutes.

5.4. Injection site reactions (not considered anaphylaxis)

Allergic reactions exist on a spectrum from mild to moderate localized reactions (like swelling at the injection site) to more severe, systemic reactions (anaphylaxis) affecting multiple body systems at once. Early assessment and understanding of different types of reactions are crucial for timely intervention and differentiating anaphylaxis.

Anaphylaxis is set apart from local allergic reactions by involving the integumentary system simultaneously with **at least another system** such as the cardiovascular system, respiratory and/or gastrointestinal system.

Symptoms may include localized swelling, redness, pain or pruritis (itching) most commonly at the injection site. Symptoms can vary in their severity.

Treatment: Observe for at least 30 minutes to monitor ensuring the reactions remains localized and there is no progression in clinical symptoms. Apply ice for comfort. If hives or swelling subside without progression to other areas or emergence of new symptoms, no further observation is required.

- **Important:** If hives/swelling progress beyond the injection site or new onset of any other clinical symptoms involving other organs in the body, even if mild – **administer Epinephrine.** There is no risk to the use of epinephrine. Failure to administer epinephrine promptly may result in greater risk to the client than using epinephrine improperly. See next section – recognizing anaphylaxis.

6.0 RECOGNIZING ANAPHYLAXIS

6.1. Description and updates to the anaphylaxis definition

Anaphylaxis is a severe allergic reaction when the body's immune system identifies a foreign substance as a threat.

While anaphylaxis is extremely rare, every immunization carries an associated risk of producing an anaphylactic reaction. Based on Canadian surveillance data for vaccine adverse events the annual rate of anaphylaxis ranges from 0.4 to 1.8 reports per 1,000,000 doses of vaccines administered in Canada.

The quicker the onset of anaphylaxis symptoms following exposure to a triggering agent (such as a vaccine) the higher the likelihood that the reaction will be severe and pose a potential risk to life.

Fatalities during anaphylaxis usually result from delay in the administration of Epinephrine and from severe respiratory complications, cardiovascular complications, or both.

The definition of anaphylaxis has evolved since 2022. This update stems from the work of The Brighton Collaboration, a non-profit global vaccine safety research network that provides standardized definitions for Adverse Events Following Immunizations (AEFI), ensuring global acceptance and consistency in reporting. The updates have been reflected in this policy and The Brighton Collaboration's research on anaphylaxis can be further explored in their publication titled 'Anaphylaxis: Revision of the Brighton Collaboration Case Definition,' available at : Anaphylaxis: Revision of the Brighton

collaboration case definition (2022).

6.2. Clinical presentation

Anaphylaxis occurs within minutes to a few hours following immunization and is characterized by a rapid progression of symptoms or signs, usually affecting **at least two or more body systems including skin, respiratory, cardiovascular or gastrointestinal system.**

Table 1: Signs and symptoms of anaphylaxis and their frequency of occurrence:

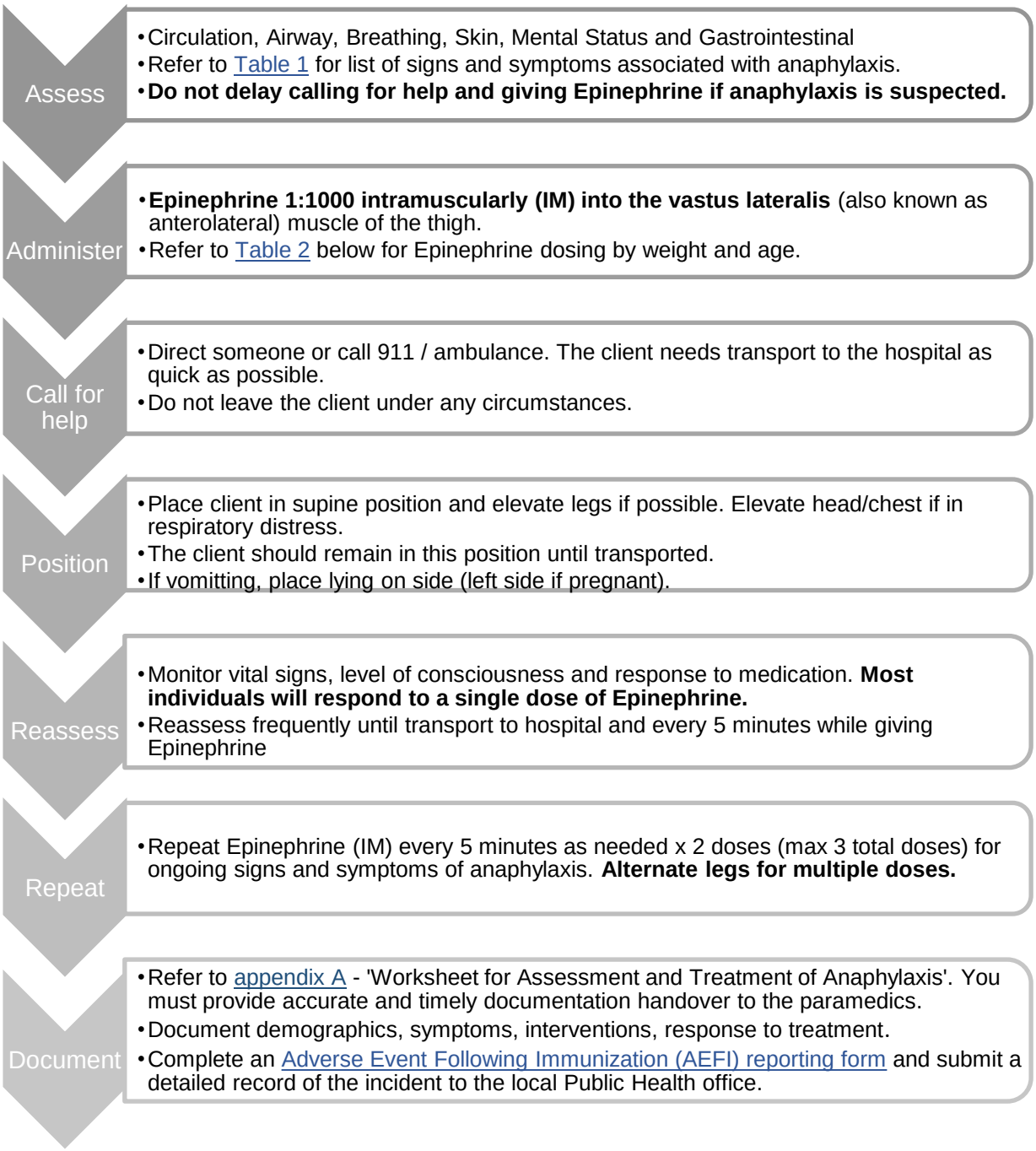
System affected	Frequency of occurrence	Signs and symptoms (Several symptoms may be present)
Skin/Integumentary	Up to 80%	• Urticaria (hives) – localized at injection site or away from injection site • Angioedema (welts) - not at injection site • Generalized erythema - with or without itch • Red and/or itchy eyes - bilateral and new onset • Generalized prickly/itchy sensation • Generalized pruritis with or without rash
Respiratory	Up to 70 %	• Difficulty breathing without wheeze or stridor • Bilateral wheeze - with or without a stethoscope • Stridor - with or without a stethoscope • Upper airway swelling (lip tongue, throat, uvula or pharynx) • Respiratory distress: Tachypnea, use of accessory muscles, chest wall retractions, cyanosis, grunting, drooling in children (measures hypoxia <90% if oxygen saturation equipment available) • Dry cough and/or sneezing and/or runny nose that is new onset and persistent • Hoarse voice • Sensation of throat closure, • Chest tightness/discomfort, sensation of
Cardiovascular	Up to 45 %	Tachycardia Decreased or loss of consciousness – other than a brief self-resolving loss of consciousness (typical of vasovagal reaction) Capillary refill time > 3 seconds Hypotension (equipment on site)
Gastrointestinal	Up to 45 %	Abdominal pain Nausea Vomiting - new onset (infants <12 mo – must be 2 or more episodes and does not apply to oral vaccines) Diarrhea – New onset (infants <12 mo – must be 2 or more episodes)
Updated from: Brighton Collaboration. (2022, Decembre 12). Anaphylaxis: Revision of the Brighton collaboration case definition.		

7.0 EMERGENCY MANAGEMENT OF ANAPHYLAXIS

If uncertain of the client's signs and symptoms, prioritize treatment. There are no contraindications to the use of Epinephrine.

KEY TAKEAWAY: failure to use Epinephrine promptly is more dangerous than improper use.

7.1. Steps for basic anaphylaxis management in a community setting



7.2. Dosage of Epinephrine

Determine the dose based on weight, however if the weight is unknown, use age as a guide. Between the ages of 4 and 12, two doses are available for administration. Immunizers may consider individual factors such as body size and muscle mass however either dose is considered appropriate per the Canadian Immunization Guide.

KEY TAKEAWAY: do not to delay administration of the dose as the failure to administer Epinephrine promptly may result in a great risk to the vaccinee.

Table 2: Dosage of Epinephrine by age or weight adapted from the CIG

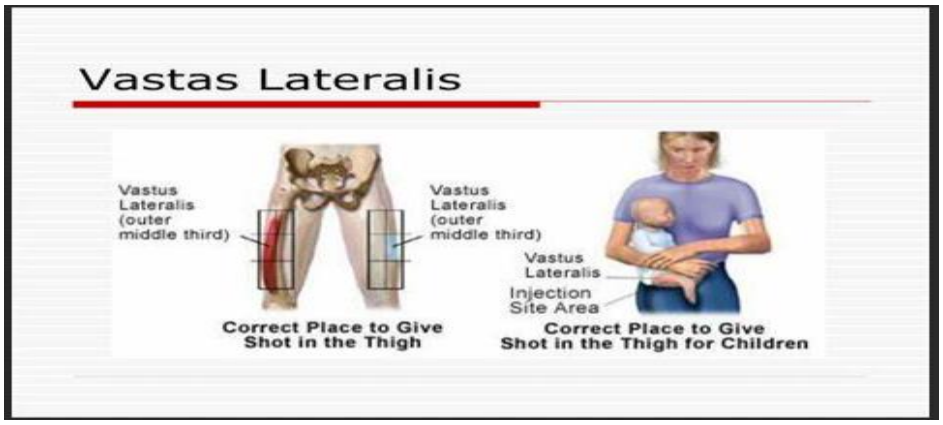
Age (Use weight when available)	Weight (kg)	Epinephrine dose	
		Dosage (mg)	Volume (mL)
Birth to less 5 kg	Less than 5 kg	0.1 mg	0.1 mL
Greater than 5 kg **and** less than 2 years	5 – 10 kg	0.1 mg	0.1 mL
2 to less than 4 years	11 – 15 kg	0.15 mg	0.15 mL
4 to less than 7 years	16 – 20 kg	0.2 mg	0.2 mL
	21 – 25 kg	0.25 mg	0.25 mL
7 to less than 10 years	26 – 30 kg	0.3 mg	0.3 mL
	31 – 35 kg	0.35 mg	0.35 mL
10 to 12 years	36 – 40 kg	0.4 mg	0.4 mL
	41 – 45 kg	0.45 mg	0.45 mL
Older than 12 years	46 kg and above	0.5 mg	0.5 mL

7.3. Injection site of Epinephrine

Epinephrine is always given **intramuscularly (IM)** and into the rich vasculature of the **vastus lateralis muscle** (see photo below). Administration subcutaneously or in the deltoid is not recommended as absorption is much slower.

- Whenever ***possible***, avoid administering epinephrine into the same site recently used and maintain a distance of 1 inch from the original immunization. For multiple doses, alternate the legs.
- When faced with a ***rare*** situation where multiple immunizations and/or epinephrine have been administered in both thigh muscles, exhausting the vastus lateralis sites, immunizers *may consider* an alternative **IM** site based on Vaccine administration practices in the Canadian Immunization Guide.

    - **KEY TAKEAWAY:** in life threatening anaphylactic situations, prioritize prompt administration of the dose intramuscularly in the muscle of the thigh(s), even if it means potentially reusing a previous immunization site or one nearby. Most individuals will respond to a single dose of Epinephrine.



Note: If scissors are not readily available, injection of epinephrine can be made through clothing.

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 0.3mL of Epinephrine 1:1000 and can be used for individuals older than six.

If a client or his or her 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 for transfer to an acute-care facility.

7.4 Pulses and respiratory rates

Age	Pulse rate per minute Upper limit	Respiratory rate per minute Upper limit
0-1 month	180	60
2-12 months	160	50
12-24	140	40
2-6 years	120	30
6-12 years	110	20
>12 years	100	20
From : Tintinalli's Emergency Medicine: A comprehensive study guide. 8th edition. McGraw Hill. 2016		

8.0 ANAPHYLAXIS KITS AND EMERGENCY SUPPLIES

To achieve a favorable outcome in anaphylaxis, it is essential to be well-prepared and have **at least TWO anaphylaxis kits** within your reach when providing any immunizations.

8.1. Regular kit maintenance

- Check your kit prior to each immunization clinic or at least once a month and replace any outdated epinephrine medication, updated contact lists and emergency supply.
- Protect epinephrine from light and open vial(s) only when ready to use.
- Store Epinephrine at room temperature
- Do not pre-load a syringe with epinephrine in anticipation of a reaction. Epinephrine rapidly deteriorates and loses potency when exposed to oxygen.

8.2. Recommended emergency anaphylaxis kit supplies:

- 4 ampules of Epinephrine 1:1000 1mg/ml (4^{th} in case one of the vials drops)
- Needles: 25-27 gauge
    - 4 x 1 inch
    - 4 x 1 ½ inch
- Syringes: 4 x 1 cc
- Alcohol swabs
- Pens/papers
- Scissors
- Up-to-date contact info for:
    - Local Immunization Coordinator
    - The RMOH
    - MOH on-call pager
- A copy of this policy
- Extra and separate blank copies of Appendix A "***Worksheet for Assessment and Treatment of Anaphylaxis***"

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APPENDIX A - WORKSHEET FOR ASSESSMENT AND TREATMENT OF ANAPHYLAXIS

This form is recommended to document suspected cases of anaphylaxis in the field following immunization.

Client Information	**Parent/Legal Guardian**
Name: _____ (Last Name, First Name)	Name: _____ (Last Name, First Name)
Medicare #: _____	Contact Number: _____
Date of Birth: _____ / ____ / ____ YYYY / MM / DD	Relationship to Client: _____
Sex: ☐ Male ☐Female ☐X	Telephone:_____

Attended by ambulance services/Transferred to hospital ☐ Refused ambulance services ☐

Documentation provided to ambulance services ☐ Time of Transfer: _____

Epinephrine and Immunizations given

Epinephrine Administered	**Pulse** (per min)	**Resp** (per min)	**Lot #**	**Route**	**Site**	**Administered by** (Last name, First Name)	**Signature**
Dose #1							
Dose #2							
Dose #3							

Alternatively, provide a copy of the immunization record or consent form

Vaccine(s) Given Today	**Manufacturer**	**Lot #**	**Dose**	**Route**	**Site**	**Approx Time Vaccine Given** (24-hour)

Client History

				Details:
Allergies to any vaccine component(s):	Yes ☐	No ☐	Unknown ☐	
History of anaphylaxis:	Yes ☐	No ☐	Unknown ☐	
History of anaphylaxis in family:	Yes ☐	No ☐	Unknown ☐	
Prior severe reactions to any vaccines:	Yes ☐	No ☐	Unknown ☐	
Recent or concurrent infections:	Yes ☐	No ☐	Unknown ☐	
Known medical conditions	Yes ☐	No ☐	Unknown ☐	
Medications	Yes ☐	No ☐	Unknown ☐	

Client Information: Name: _____ Date of Birth: ___ / _____ / _____
(Last name, First Name) YYYY / MM / DD

Check all symptoms present during course of the episode

Time of first symptom onset: _____ Rapid progression of symptoms: ☐Yes ☐No

	SYMPTOMS	YES	NO	UNKNOWN / DID NOT ASSESS
Skin	Angioedema (swelling), generalized			
	Angioedema (swelling), at the injection site			
	Erythema (redness), generalized with or without itching			
	Erythema (redness), generalized WITHOUT itching			
	Urticaria (hives) localized at injection site			
	Urticaria (hives) NOT at injection site (generalized)			
	Pruritis WITH rash, generalized			
	Pruritis WITHOUT rash, generalized			
	Red and/or itchy eyes - bilateral and NEW onset			
	Generalized prickly/itchy sensation			
Respiratory	Difficulty breathing WITHOUT wheeze or stridor			
	Bilateral wheeze and/or stridor – with or without a stethoscope			
	Upper airway swelling (lip, tongue, throat, uvula, pharynx)			
	Tachypnea			
	Use of accessory muscles/chest wall retractions/grunting			
	Cyanosis			
	Drooling (in children)			
	Dry cough, NEW onset and persistent			
	Sneezing and/or runny nose, NEW onset and persistent			
	Hoarse voice			
	Sensation of throat closure			
	Chest tightness/discomfort, sensation of			
Cardiovascular	Tachycardia			
	Decreased level of consciousness (LOC) or loss of consciousness - OTHER than a brief self-resolving LOC			
	Hypotension (if equipment on site)			
	Tachycardia (rapid heart rate for age)			
Gastrointestinal	Nausea			
	Vomiting – NEW onset with 2 or more episodes			
	Diarrhea -NEW onset with 2 or more episodes			
	Abdominal pain			
Other/ comments				

Client Information: Name: _____ Date of Birth: ___ / _____ / _____
(Last name, First Name) YYYY / MM / DD

Person completing the form

Clinic site: _____

Printed Name: _____ Designation: _____
(Last name, First name)

Signature: _____ Date: _____