

Enhanced reporting form for events managed as anaphylaxis following immunization

Please complete this form for any reported adverse event following immunization (AEFI) that meets the criteria for “event managed as anaphylaxis” in Section 5.0 (C.1) of [Appendix B: Provincial Case Definitions for Adverse Events Following Immunization \(AEFI\)](#). (See Criteria for Provincial Reporting of Anaphylaxis)

This form is designed for use by public health units for provincial surveillance purposes only. It is *supplementary* to Public Health Ontario's [Report of Adverse Events Following Immunization \(AEFI\) Form](#) which should be completed in addition to this form.

All events managed as anaphylaxis should be reported in iPHIS. Once completed, please save and send this form via iPHIS referral to Public Health Ontario. If you have any questions about investigation of an event managed as anaphylaxis or completion of the form please contact the Immunization & Vaccine-Preventable Diseases team at IVPD@oahpp.ca.

Date of report Date of event

Person completing form Contact email / phone #

Health Unit Health Unit incident form completed

CLIENT INFORMATION

Date of birth Sex Female Male

CLIENT HISTORY

Prior anaphylaxis? Yes No Prior allergic reaction(s)? Yes No

Details (severity & allergen)

IMMUNIZATION INFORMATION

Date of vaccine administration Time of vaccine administration (24 hr clock)

Vaccine(s) administered

Details about vaccine(s) administered completed on the [Report of Adverse Events Following Immunization \(AEFI\) Form](#).

EVENT INFORMATION

	Yes/No/Unknown	Time(24hr)	Pulse(per min.)	Resp.(per min.)	Blood pressure	Dose	Administered by
Epinephrine #1	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Epinephrine #2	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Epinephrine #3	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Other (specify)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Additional details

EVENT INFORMATION (continued)

Time of first symptom onset (24 hr clock)	<input type="text"/>	Attended by paramedics?	<input type="radio"/> Yes	<input type="radio"/> No
Transfer to hospital?	<input type="radio"/> Yes	<input type="radio"/> No	Time of transfer (24 hr clock)	<input type="text"/>
Details of ER assessment, treatment & diagnosis	<input type="text"/>			

OUTCOME

Date of recovery (Indicate below if not yet recovered)	<input type="text"/>	Time of recovery (24 hr clock)	<input type="text"/>
<input type="radio"/> Not yet recovered	Referral to specialist (e.g. Allergist)?	<input type="radio"/> Yes	<input type="radio"/> No
Details of referral/ additional follow-up	<input type="text"/>		

SIGNS & SYMPTOMS Please check all signs & symptoms that were present during the event. See Glossary for definition of terms.

<input type="checkbox"/> Sudden onset	<input type="checkbox"/> Rapid progression of symptoms
SKIN/MUCOSAL * Indicates major criteria as per Brighton/Appendix B	
<input type="checkbox"/> Angioedema (swelling); localized or generalized*	<input type="checkbox"/> Erythema (redness); generalized*
<input type="checkbox"/> Urticaria (hives); generalized*	<input type="checkbox"/> Urticaria (hives); localized at injection site
<input type="checkbox"/> Pruritus; generalized <i>with skin rash</i> *	<input type="checkbox"/> Pruritus; generalized <i>without skin rash</i>
<input type="checkbox"/> Prickle sensation; generalized	<input type="checkbox"/> Red, itchy eyes
RESPIRATORY	
<input type="checkbox"/> Bilateral wheeze (bronchospasm) ; assessed with stethoscope*	<input type="checkbox"/> Stridor*
<input type="checkbox"/> Upper airway swelling (lips, tongue, throat, uvula, larynx)*	<input type="checkbox"/> Difficulty breathing <i>without</i> wheeze or stridor (sensation of chest tightness)
<input type="checkbox"/> Tachypnea	<input type="checkbox"/> Sensation of throat closure
<input type="checkbox"/> Recession	<input type="checkbox"/> Increased use of respiratory accessory muscles
<input type="checkbox"/> Cyanosis	<input type="checkbox"/> Grunting
<input type="checkbox"/> Persistent dry cough	<input type="checkbox"/> Sneezing, rhinorrhea
	<input type="checkbox"/> Hoarse voice
CARDIOVASCULAR	
<input type="checkbox"/> Hypotension (measured, documented)*	
<input type="checkbox"/> Tachycardia	<input type="checkbox"/> Capillary refill time >3 seconds
<input type="checkbox"/> Decreased level of consciousness	<input type="checkbox"/> Loss of consciousness
GASTROINTESTINAL	
<input type="checkbox"/> Abdominal pain	<input type="checkbox"/> Nausea
<input type="checkbox"/> Diarrhea	<input type="checkbox"/> Vomiting
Other signs & symptoms not listed above	<input type="text"/>

SUPPLEMENTARY INFORMATION (For reference only. Do not transmit)

GLOSSARY OF TERMS

Sudden onset: an event that occurred unexpectedly and without warning leading to a marked change in a clients's previously stable condition

Rapid progression: This is a conventional clinical term which refers to a wide range of signs and symptoms. There is no exact time frame therefore it must be assessed based on the circumstances of each event.

DERMATOLOGIC AND MUCOSAL (SKIN)

Angioedema: Areas of deeper swelling of the skin and/or mucosal tissues in either single or multiple sites which may not be well circumscribed and is usually not itchy. Typical sites in anaphylaxis include tongue, lips, around the eyes (periorbital), eyelids. Do not include hereditary angioedema.

Erythema: Abnormal redness of the skin without any raised skin lesions

Pruritus or prickle sensation: An unpleasant skin sensation that provokes the desire to rub and/or scratch to obtain relief

Red and itchy eyes: Redness of the whites of the eyes (sclera) with sensation that provokes the desire to rub and/or scratch to obtain relief.

Urticaria (hives): Localized redness of superficial layers of skin that is itchy, raised, sharply demarcated and transient (skin changes at any location are usually present for less than 12 hours)

Body location terms applicable to urticaria, erythema, pruritus, prickle sensation

Generalized: Involving >1 body site with each limb counted separately as are the abdomen, back, head and neck.

Localized: Involving one body site, as defined above

Injection site urticaria: Urticaria which is continuous with the injection site or within a few centimeters of where the immunization was given

RESPIRATORY

Bilateral wheeze (bronchospasm): A whistling, squeaking, musical, or puffing sound on expiration. Bilateral wheezing can only be confirmed on chest auscultation with a stethoscope or other direct listening device.

Chest wall retractions: Inward movement of the intercostal area upon inspiration

Cyanosis: A dark bluish or purplish discoloration most easily seen in the facial or perioral area or tongue.

Stridor: A harsh vibrating sound heard during respiration in cases of obstruction of the air passage

Difficulty breathing: A sensation of difficulty breathing

Grunting: A sudden and short noise with each breath when breathing out

Hoarse voice: An unnaturally harsh cry in an infant or vocalisation in a child or adult

Increased use of accessory (respiratory) muscles: Vigorous movement of the muscles of breathing, generally best seen in the lower part of the neck (supra-clavicular or tracheal tug) or below the chest (sub-costal). The movements are usually a sign of difficulty with breathing

Persistent dry cough: Rapid expulsion of air from the lungs and not accompanied by expectoration (a non-productive cough) that will not abate during the period of observation including through measures such as taking a sip of water

Recession (sternal): A clinical sign of respiratory distress which occurs as increasingly negative intrathoracic pressures cause indrawing of the part of the chest.

Rhinorrhea: Discharge of thin nasal mucus

Sensation of throat closure: Feeling or perception of throat closing with a sensation of difficulty breathing

Sneezing: An involuntary (reflex), sudden, violent, and audible expulsion of air through the mouth and nose

Tachypnea: An increased rate of respiration that is above normal range for age and circumstance (as follows)

Infants/Children

<1 year	30-60 breaths/minute
1-3 years	24-40
4-5 years	22-34
6-12 years	18-30
13-18 years	12-16

Adults

12-16 breaths/minute

GASTROINTESTINAL

Nausea: An unpleasant sensation vaguely referred to the upper abdominal region (upper region of the abdomen) and the abdomen, with a tendency to vomit

Abdominal pain: Sensation of discomfort or pain in the abdominal region

Vomiting: The reflex act of ejecting the contents of the stomach through the mouth

Diarrhea: Loose or watery stool

CARDIOVASCULAR

Documented hypotension: An abnormally low blood pressure (BP) documented by appropriate measurement (see below) or > 30% decrease in BP

<u>Infants/Children</u>	<u>Systolic BP</u>	<u>Adults</u>
Neonates (0 to 28 days)	<60 mm Hg	Systolic BP of <90 mm Hg
1-12 months	<70 mm Hg	
1 to 10 years	<70 mm Hg + (2 × age in years)	
≥10 years of age	<90 mm Hg	

Tachycardia: A heart rate that is above normal range (see below) for age and circumstance.

<u>Infants/Children</u>		<u>Adults</u>
0-3 months	85-205 beats/minute	60-100 beats/minute
3 months-2 years	100-190	
2 years-10 years	60-140	
>10 years	60-100	

Capillary refill time of greater than 3 seconds: The capillary refill time is the time required for the normal skin colour to reappear after a blanching pressure is applied. It is usually performed by pressing on the nail bed to cause blanching and then counting the time it takes for the blood to return to the tissue, indicated by a pink colour returning to the nail. Normally it is 3 seconds or less

Decreased central pulse volume: Absent or decreased pulse in one of the following vessels - carotid, brachial or femoral arteries

Loss of consciousness: Total suspension of conscious relationship with the outside world as demonstrated by an inability to perceive and respond to verbal, visual or painful stimulus

Decreased level of consciousness: Partial suspension of conscious relationship with the outside world as demonstrated by a decreased ability to perceive and respond to verbal, visual or painful stimulus.

CRITERIA FOR PROVINCIAL REPORTING OF ANAPHYLAXIS

APPENDIX B: PROVINCIAL CASE DEFINITIONS FOR REPORTABLE DISEASES (ADVERSE EVENTS FOLLOWING IMMUNIZATION)

C.1 Event Managed as Anaphylaxis

Anaphylaxis should be reported if it is managed as anaphylaxis (e.g., epinephrine administered) at the time of occurrence.

Temporal criteria:

Anaphylaxis occurring within 24 hours of immunization.

REFERENCES

1. Gold MS, Gidudu J, Erlewyn-Lajeunesse M, Law B, Brighton Collaboration Working Group on Anaphylaxis. Can the Brighton collaboration case definitions be used to improve the quality of adverse event following immunization (AEFI) reporting? *Vaccine*. 2010 Jun 17;28(28):4487-98.
2. Infectious Diseases Protocol, 2013 (or as current). Appendix B: Provincial Case Definitions for Reportable Diseases. Disease: Adverse Events Following Immunization (AEFIs) [Internet]. Toronto: Ministry of Health & Long-Term Care; 2013 [updated Jan.1, 2013; 2014 Apr 17]. Available from: http://www.health.gov.on.ca/en/pro/programs/publichealth/oph_standards/docs/aeft_cd.pdf.
3. British Columbia Centre for Disease Control. Communicable disease control manual. Vancouver, BC: BCCDC; 2013 [cited 2014 Apr 17]. Section IX, Adverse events following immunization. Available from: http://www.bccdc.ca/NR/rdonlyres/D8098B26-CD7B-4A65-914C-AA98B15CC004/0/SectionIX_AdverseEventsFollowingImmunizationsFeb2013.pdf
4. American Heart Association & American Academy of Pediatrics. PALS. Pediatric Advanced Life Support. 2010. Available from: http://www.heart.org/HEARTORG/CPRAndECC/HealthcareProviders/Pediatrics/Pediatrics_UCM_001282_SubHomePage.jsp
5. Simel DL. Approach to the patient: history and physical examination. In: Goldman L, Schafer AI, eds. *Goldman's Cecil Medicine*. 24th ed. Philadelphia, Pa: Saunders Elsevier; 2011:chap 6.