

Report of Adverse Event Following Immunization (AEFI)

When completed, please send the form to your local [Public Health Unit](#) by a secure means.

For more information about AEFI reporting in Ontario visit the [Public Health Ontario website](#).

The form should be used to capture AEFIs for all vaccines, including COVID-19 vaccines.

Case ID
(for local use only):

1 - CLIENT INFORMATION						
Client last name:		Given name(s):		Ontario Health Card #:	Date of Birth (yyyy/mm/dd):	
Gender:	Male	Female	Other	Unknown	Parent/guardian/caregiver full name, as applicable:	Telephone #:
Address:			City:		Postal Code:	
Reported to public health by:			Relationship with case:		Date of report (yyyy/mm/dd):	
Form completed by:			Contact information (if different from above):			

2 - IMMUNIZATION INFORMATION For Pfizer-BioNTech COVID-19 vaccine enter both vaccine and diluent information here.							
Date (yyyy/mm/dd)	Time (24hr - HH:MM)	Agent and Manufacturer	Lot #	Exp. date (yyyy/mm/dd)	Dose #	Site	Route
Immunization error: No Unknown Yes* Describe in Section 5			Previous history of AEFI: No Unknown Yes* Describe in Section 5			Vaccine administered by:	

3 - ADVERSE EVENT INFORMATION (ALL VACCINES. FOR ADDITIONAL COVID-19 VACCINE SPECIFIC EVENTS SEE SECTION 4)

Report only events which cannot be attributed to co-existing conditions. Reactions marked with an asterisk (*) must be diagnosed by a physician. Record the **time to onset of the event** (time between vaccine administration and onset of each event) and the **duration** of each event in **minutes** or **hours** or **days**. If the interval / duration is less than one hour record in minutes, if less than 24 hours record in hours, if greater than or equal to 24 hours record in days.

	Specify minutes or hours or days			Specify minutes or hours or days	
Local Reaction at the Injection Site	Time to onset of event	Duration of event	Allergic Reactions	Time to onset of event	Duration of event
Pain/redness / swelling extending past nearest joint			Event managed as anaphylaxis		
Pain/redness / swelling lasting 4 days or more			Oculorespiratory syndrome (ORS)		
Infected abscess*			Allergic reaction - skin (E.g. hives)		
Sterile abscess*			Neurologic Events	Time to onset of event	Duration of event
Nodule			Convulsions / seizure		
Cellulitis*			Encephalopathy / encephalitis*		
Systemic Reactions	Time to onset of event	Duration of event	Meningitis*		
Fever greater than 38.0°C (Only reportable in conjunction with another event)			Anaesthesia / paraesthesia*		
Rash			Paralysis*		
Adenopathy / lymphadenopathy*			Bell's Palsy*		
Hypotonic-hyporesponsive episode (HHE)*			Guillain-Barré Syndrome (GBS)*		
Persistent crying / screaming			Myelitis / Transverse Myelitis*		
Severe vomiting / diarrhea (3 episodes/24 hours)			Acute disseminated encephalomyelitis*		
Parotitis*			Other events of interest	Time to onset of event	Duration of event
			Thrombocytopenia*		
			Arthritis / arthralgia		
			Intussusception*		
			Kawasaki Disease*		
			Syncope (fainting) with injury		
			Other severe or unusual events		

4 - COVID-19 ADVERSE EVENT(S) OF SPECIAL INTEREST

In addition to the adverse events listed on the page one, please indicate occurrence of any of the following reactions associated with administration of COVID-19 vaccine. These reactions should only be used for AEFIs reported following receipt of COVID-19 vaccine.

Specify minutes or hours or days			Specify minutes or hours or days		
COVID-19 AESI	Time to onset of event	Duration of event	COVID-19 AESI	Time to onset of event	Duration of event
Vaccine-associated enhanced disease			Acute kidney injury		
Multisystem inflammatory syndrome in children			Acute liver injury		
Acute respiratory distress syndrome			Anosmia and / or ageusia		
Acute cardiovascular injury			Chilblain like lesions		
Coagulation disorder			Single organ cutaneous vasculitis		
			Erythema multiforme		

5 - COMMENTS FURTHER DESCRIBING THE ADVERSE EVENT(S)

Please provide a detailed description of the event including all signs and symptoms, medical history (e.g. immunocompromised, chronic illness/underlying medical conditions), concomitant medications, investigation, treatment, hospitalization details and description of previous history of AEFI or immunization error if indicated in Section 2.

6 - HEALTH CARE UTILIZATION & OUTCOME

Please provide information about health care utilization related to the event. Outcome to be updated by the Public Health unit when the investigation is complete.

Medical consultation (non-urgent)	Yes	No	Date (yyyy/mm/dd)	Name and address of health professional attending the event	
Seen in emergency department	Yes	No	Date (yyyy/mm/dd)		
Admitted to hospital because of event	Yes	No	Admission Date (yyyy/mm/dd) Discharge Date (yyyy/mm/dd)		
				Name and address of facility where the event was attended to (e.g., hospital name)	
OUTCOME	Recovered	Not yet recovered (describe below)	Permanent disability / incapacity (describe below)	Unknown	Death (describe below)
Describe:				Date of outcome: (yyyy/mm/dd)	

7 - MEDICAL OFFICER OF HEALTH (MOH) RECOMMENDATIONS

For Public Health Unit use only. To be completed by the MOH or designate.

Check all that apply: <input type="checkbox"/> No recommendation <input type="checkbox"/> No change to immunization schedule <input type="checkbox"/> Determine protective antibody levels (Specify) <input type="checkbox"/> Active follow-up for AEFI recurrence after next vaccine <input type="checkbox"/> Controlled setting for next immunization <input type="checkbox"/> Expert referral (Specify) <input type="checkbox"/> No further immunization (Contraindication or series complete - Specify) <input type="checkbox"/> Other (Specify)	MOH recommendation comments:	
	Medical Officer of Health (MOH) or Designate Name: _____ Date (yyyy/mm/dd) _____	
	Signature: _____	

The personal health information provided on this form is collected under the authority of the *Health Protection and Promotion Act* and O. Reg 569. The personal health information is used to signal adverse events that may require more in-depth investigation and to ensure the continued safety of vaccines on the Canadian market by monitoring adverse events following immunization with vaccines. The information collected may be shared with the Public Health Agency of Canada. If you have questions about the collection of this personal health information please contact your local public health unit.