

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 / Investigation #
(for local use only):

1 - CLIENT AND REPORTING SOURCE INFORMATION						
Client last name:		Given name(s):		Ontario Health Card #:	Date of Birth (yyyy/mm/dd):	
Sex:	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 of reporter (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 #	Lot exp. date (yyyy/mm/dd)	Dose #	Site	Route
Immunization error:		Previous history of AEFI:		Vaccine administered by (name and designation):			
No	Unknown	Yes*	No	Unknown	Yes*	Describe in Section 6	

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			Oculo-respiratory 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.

COVID-19 AESI	Specify minutes or hours or days		COVID-19 AESI	Specify minutes or hours or days	
	Time to onset of event	Duration of event		Time to onset of event	Duration of event
Vaccine-associated enhanced disease			Acute kidney injury		
Multisystem inflammatory syndrome in children or adults			Acute liver injury		
Acute respiratory distress syndrome			Acute pancreatitis		
Acute cardiovascular injury			Anosmia and / or ageusia		
Coagulation disorder (including thrombotic events)			Rhabdomyolysis		
Thrombosis with Thrombocytopenia Syndrome / Vaccine-Induced Immune Thrombotic Thrombocytopenia			Single organ cutaneous vasculitis		
			Subacute thyroiditis		
			Erythema multiforme		
			Chilblain like lesions		
			Myocarditis / Pericarditis		

5 - MEDICAL HISTORY

Please provide a detailed description of the client's medical history (e.g. immunocompromised, chronic illness / underlying medical conditions), concomitant medications, history of allergies.

Pregnant at the time of immunization: Yes No Unknown If yes, gestation (weeks):

6 - COMMENTS FURTHER DESCRIBING THE ADVERSE EVENT(S)

Please provide a detailed description of the event including all signs and symptoms, investigation, treatment, hospitalization details, and description of previous history of AEFI or immunization error if indicated in Section 2.

7 - 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: Name and address of facility where the event was attended to (e.g., hospital name):	
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)		
OUTCOME	Recovered	Not yet recovered (describe below)	Permanent disability / incapacity (describe below)	Unknown	Death (describe below)
Describe:				Date of outcome: (yyyy/mm/dd)	

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.

Client last name:	Date of Birth (yyyy/mm/dd):
Given name(s):	Page 2/3

FOR PUBLIC HEALTH UNIT USE ONLY - DO NOT TRANSMIT

8 - MEDICAL OFFICER OF HEALTH / ASSOCIATE MEDICAL OFFICER OF HEALTH (A / MOH) RECOMMENDATIONS

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

Check all that apply:

- No recommendation
- No change to immunization schedule
- Determine protective antibody levels (Specify)
- Active follow-up for AEFI recurrence after next vaccine
- Controlled setting for next immunization
- Expert referral (Specify)
- No further immunization
(Contraindication or series complete - Specify)
- Other (Specify)

A / MOH recommendation comments:

Medical Officer of Health (MOH) or Designate
Name:

Date (yyyy/mm/dd):

Signature: