Report of Adverse Event Following Immunization (AEFI)

Public Health Ontario | Santé publique Ontario

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* Describe in Section 6	☐ 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

Local Reaction at the Injection Site	Time to onset of event	Duration of event
☐ Pain/redness / swelling extending past nearest joint		
☐ Pain/redness / swelling lasting **4 days or more**		
☐ Infected abscess*		
☐ Sterile abscess*		
☐ Nodule		
☐ Cellulitis*		

Systemic Reactions	Time to onset of event	Duration of event
☐ Fever greater than 38.0ºC (Only reportable in conjunction with another event)		
☐ Rash		
☐ Adenopathy / lymphadenopathy*		
☐ Hypotonic-hyporesponsive episode (HHE)*		
☐ Persistent crying / screaming		
☐ Severe vomiting / diarrhea (3 episodes/24 hours)		
☐ Parotitis*		

Specify minutes or hours or days

Allergic Reactions	Time to onset of event	Duration of event
☐ Event managed as anaphylaxis		
☐ Oculorespiratory syndrome (ORS)		
☐ Allergic reaction - skin (E.g. hives)		

Neurologic Events	Time to onset of event	Duration of event
☐ Convulsions / seizure		
☐ Encephalopathy / encephalitis*		
☐ Meningitis*		
☐ Anaesthesia / paraesthesia*		
☐ Paralysis*		
☐ Bell's Palsy*		
☐ Guillian-Barré Syndrome (GBS)*		
☐ Myelitis / Transverse Myelitis*		
☐ Acute disseminated encephalomyelitis*		

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		

 Describe all events in Section 6

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: Time to onset of event	Specify minutes or hours or days: Duration of event
☐ Vaccine-associated enhanced disease		
☐ Multisystem inflammatory syndrome in children or adults		
☐ Acute respiratory distress syndrome		
☐ Acute cardiovascular injury		
☐ Coagulation disorder (including thrombotic events)		
☐ Thrombosis with Thrombocytopenia Syndrome / Vaccine-Induced Immune Thrombotic Thrombocytopenia		

COVID-19 AESI	Specify minutes or hours or days: Time to onset of event	Specify minutes or hours or days: Duration of event
☐ Acute kidney injury		
☐ Acute liver injury		
☐ Acute pancreatitis		
☐ Anosmia and / or ageusla		
☐ Rhabdomyolysis		
☐ 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)

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 health professional attending the event:

Name and address of facility where the event was attended to (e.g., hospital name):

OUTCOME ☐ Recovered ☐ Not yet recovered (describe below) ☐ Persistent or significant 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):

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: