



Report of adverse events following immunization (AEFI)

Instructions: For more complete instructions and definitions, refer to the [user guide](#).

Report events which have a temporal association with a vaccine and which cannot be clearly attributed to other causes. A causal relationship does not need to be proven, and submitting a report does not imply causality.

Of particular interest are those AEFIs which:

- a) Meet one or more of the seriousness criteria
- b) Are unexpected regardless of seriousness

Refer to the [user guide](#), and background Information for additional clarification.

Note

- The numbers below correspond to the numbered sections of the form.
- All dates should be captured in the following format: YYYY / MM / DD.
- When reporting an AEFI, check one of the boxes on the top right hand corner of the first page of the AEFI form to indicate whether it is an initial or follow up report. For all follow up reports, please specify the Unique Episode Number.

- 1a) The **Unique Episode Number** is assigned by the Province/Territory. Leave it blank unless authorized to assign it.
- 1b) The **Region Number** is a number that corresponds to a given health unit. Leave it blank if it doesn't apply to your locale.
- 2) The **impact LIM** is assigned by IMPACT nurse monitors (LIN: Local Inventory Number).
- 3) The information provided in this section is confidential and should not be sent to the Public Health Agency of Canada.
- 4a) Indicate the Province/Territory where the vaccine was administered, abbreviations may be used.
- 4c) Provide all information as requested in the table. For the "Dose #," provide the number in series (1, 2, 3, 4, or 5) if known. For the Influenza vaccine, unless a patient receives two doses in one season, the "Dose #" should be recorded as "1".
- 7a) Indicate the highest impact of the AEFI on the patient's daily activities as assessed by the patient or the parent/caregiver.
- 7c) Provide details of any investigations or treatments in section 10. If the patient was already in hospital when immunized and the immunization resulted in a longer hospital stay, indicate "Resulted in prolongation of existing hospitalization" and provide the number of days by which the patient's hospital stay was prolonged. For all hospitalizations, indicate the date of admission and discharge.
- 8) MOH/MHO: Medical Officer of Health, MD: Medical Doctor, RN: Registered Nurse.
- 9) Choose, from section 9 (AEFI details), the description that best fits the AEFI being reported. Make sure to record the time of onset and duration of signs/symptoms using the most appropriate time unit: Days, Hours or Minutes. Provide additional details of any investigation, therapy, and other information as appropriate in section 10.
- 11) This section is to be completed by the MOH/MHO, MD, RN or their designate who are assigned to provide public health recommendations according to the P/T best practices.
- 12) Information in this section is not collected by all P/Ts. Return the completed form to your local public health unit address at

Return completed form to your [local public health unit address](#) at

Alberta (AB)	Northwest Territories (NT)	Quebec (QC)
British Columbia (BC)	Nova Scotia (NS)	Saskatchewan (SK)
Manitoba (MB)	Nunavut (NU)	Yukon (YT)
New Brunswick (NB)	Ontario (ON)	Canadian Forces Health Services (CFHS)
Newfoundland and Labrador (NL)	Prince Edward Island (PE)	Public Health Agency of Canada (PHAC)

2 | Report of adverse events following immunization (AEFI)

Initial report
Follow up report (unique episode #)

1a) Unique episode number: _____ **1b) Region number:** _____ **2) Impact LIN:** _____

3) Patient identification

First name: _____ Last name: _____ Health number: _____

Address of usual residence: _____

Province/Territory: _____ Postal code: _____ Phone: () (ext.)

Information Source: First name: _____ Last name: _____ Relation to patient: _____

Contact info, if different: _____

4) Information at time of immunization and AEFI onset

4a) At time of Immunization

Province/Territory of immunization: _____
Date vaccine administered (Y/M/D): ____|____|____ (hr: ____ am / pm)
Date of birth (Y/M/D): ____|____|____ Age: _____
Sex: Male Female Other

4b) Medical history (up to the time of AEFI onset)

(Check all that apply and provide details in section 10)

Concomitant medication(s)
Known medical conditions/allergies
Acute illness/injury

4c) Immunizing agent	Trade name	Manufacturer	Lot number	Dose #	Dosage/unit	Route	Site
					/		
					/		
					/		
					/		
					/		

5) Immunization Errors

Did this AEFI follow an incorrect immunization? No Unknown Yes
(If Yes, choose all that apply and provide details in section 10)

Given outside the recommended age limits Product expired Incorrect route
Wrong vaccine given Dose exceeded that recommended for age
Other, specify: _____

6) Previous AEFI

Did an AEFI follow a previous dose of any of the above immunizing agents (Table 4c)? (Choose one of the following)

No Yes (provide details in section 10)
Unknown Not applicable (no prior doses)

7) Impact of AEFI, outcome, and level of care obtained

7a) Highest impact of AEFI: (Choose one of the following)

Did not interfere with daily activities
Interfered with but did not prevent daily activities
Prevented daily activities

7b) Outcome at time of report:

Death[†] Date (Y/M/D): ____|____|____
Permanent disability/incapacity[†] Not yet recovered[†]
Fully recovered Unknown
[†](Provide details in section 10)

7c) Highest level of care obtained: (Choose one of the following)

Unknown None Telephone advice from a health professional Non-urgent visit Emergency visit
Required hospitalization (____ days) **OR** Resulted in prolongation of existing hospitalization (by ____ days)
Date of hospital admission: (Y/M/D): ____|____|____ Date of hospital discharge: (Y/M/D): ____|____|____

7d) Treatment received: No Unknown Yes (Provide details of all treatments including self treatment, in section 10)

8) Reporter Information

Setting: Physician office Public health Hospital Other, specify: _____

Name: _____ Phone: () (ext.) Fax: ()

Address: _____ City: _____

Province/Territory: _____ Postal code: _____ Date reported: (Y/M/D): ____|____|____

Signature: MD RN IMPACT Other, specify: _____

NOTE: Discuss with patient or his/her parent/caregiver reason for reporting and confidentiality of information.

3 | Report of adverse events following immunization (AEFI)

Unique episode number:		Region number:		Impact LIN:	
9) AEFI Details: Complete all sections as appropriate; for each, check all signs/symptoms that apply. Item(s) with asterisk (*) should be diagnosed by a physician. If not, provide sufficient information to support the selected item(s). Use Section 10 for additional information including, clinical details and test results.					
9a) Local reaction at or near vaccination site		Interval: → ___ Min ___ Hrs ___ Days from immunization to onset of 1 st symptom or sign Duration: → ___ Min ___ Hrs ___ Days from onset of 1 st symptom/sign to resolution of all symptoms/signs			
Infected abscess	Sterile abscess	Cellulitis	Nodule	Reaction crosses joint	Lymphadenitis
Other, specify: _____					
For any vaccination site reaction indicated above, check all that apply below and provide details in section 10:					
Swelling	Pain	Tenderness	Erythema	Warmth	Induration
Site(s) of reaction _____ (e.g. LA, RA)		Palpable fluctuance		Fluid collection shown by imaging technique (e.g. MRI, CT, ultrasound)	
Spontaneous/surgical drainage		Microbial results		Lymphangitic streaking	
Largest diameter of vaccination site reaction: ___ cm					
Regional lymphadenopathy					
9b) Allergic and Allergic-like events		Interval: → ___ Min ___ Hrs ___ Days from immunization to onset of 1 st symptom or sign Duration: → ___ Min ___ Hrs ___ Days from onset of 1 st symptom/sign to resolution of all symptoms/signs			
Chose one of the following: Anaphylaxis Oculo-Respiratory Syndrome (ORS) Other allergic events					
Skin/mucosal	Urticaria	Erythema	Pruritus	Prickle sensation	Rash (For these events, specify site of reaction)
	Angioedema:	Tongue	Throat	Uvula	Larynx
	Eyelids	Face	Limbs	Other, specify:	Eye(s): Red bilateral Red unilateral Itchy
Cardio-vascular	Measured hypotension	↓ central pulse volume	Capillary refill time >3 sec	Tachycardia	
	↓ or loss of consciousness (<i>Duration</i>): _____				
Respiratory	Sneezing	Rhinorrhea	Hoarse voice	Sensation of throat closure	Stridor
	Tachypnea	Wheezing	Indrawing/retractions	Grunting	Cyanosis
	Difficulty swallowing	Difficulty breathing		Chest tightness	Dry cough
	Sore throat				
Gastrointestinal	Diarrhea	Abdominal pain	Nausea	Vomiting	
9c) Neurologic events		Interval: → ___ Min ___ Hrs ___ Days from immunization to onset of 1 st symptom or sign Duration: → ___ Min ___ Hrs ___ Days from onset of 1 st symptom/sign to resolution of all symptoms/signs			
Meningitis*	Encephalopathy/Encephalitis*	Guillain-Barré Syndrome (GBS)*	Bell's Palsy*	Other paralysis*	Seizure
Other neurologic diagnosis*, specify: _____					
Depressed/altered level of consciousness	Lethargy	Personality change lasting ≥24hrs	Focal or multifocal neurologic sign(s)	Fever (≥38.0°C)	
CSF abnormality	EEG abnormality	EMG abnormality	Neuroimaging abnormality	Brain/spinal cord histopathologic abnormality	
Seizure details:	Witnessed by healthcare professional	Yes	No	Unknown	
	Sudden loss of consciousness	Yes	No	Unknown	
	Generalized (Specify: Tonic	Clonic	Tonic-clonic	Atonic	Absence
	Previous history of seizures	(Specify: Febrile	Afebrile	Unknown type)	Myoclonic) OR Partial
9d) Other events					
Hypotonic-Hyproresponsive Episode (age <2 years)		Interval: → ___ Min ___ Hrs ___ Days from immunization to onset of 1 st symptom or sign Duration: → ___ Min ___ Hrs ___ Days from onset of 1 st symptom/sign to resolution of all symptoms/signs			
Limppness	Pallor/cyanosis	↓ responsiveness/unresponsiveness			
Persistent crying (Continuous and unaltered crying for ≥3 hours)		Rash (Non-allergic) Generalized Localized (Site)			
Intussusception*		Thrombocytopenia* Platelet count <150x10 ⁹ /L Petechial rash			
Arthritis		Other clinical evidence of bleeding			
Joint redness	Joint warm to touch	Anaesthesia/Paraesthesia Numbness Tingling Burning			
Inflammatory changes in synovial fluid	Joint swelling	Formication Other, specify:			
Parotitis (Parotid gland swelling with pain and/or tenderness)		Generalized Localized (Site)			
Fever ≥38.0°C (Note: report ONLY if fever occurs in conjunction with a reportable event. For fever in a neurological event, use Section 9c)					
Other serious or unexpected event(s) not listed in the form (Specify and provide details in Section 10)					

3 | Report of adverse events following immunization (AEFI)

Unique episode number:

Region number:

Impact LIN:

10) SUPPLEMENTARY INFORMATION (Please indicate the section number when providing details. Please provide details of any investigation or treatment for the recorded AEFI).
If not, provide sufficient information to support the selected item(s).

11) Recommendation for future immunization(s) according to the federal/provincial/territorial best practices

(Provide comments, use section 10 if extra space needed)

No change to immunization
schedule Expert referral, specify:
Determine protective antibody level

Controlled setting for next immunization
No further immunizations with: _____, specify:
Active follow up for AEFI recurrence after next vaccine

Other, specify:

Name:

Professional status: MOH/MHO MD RN Other, specify:

Comments:

Phone: () (ext.) Date: (Y / M / D): _____ | _____ | _____ Signature:

12) Follow up information for a subsequent dose of same vaccine(s) (Provide details in section 10)

Vaccine administered without AEFI Vaccine administered with recurrence of AEFI Vaccine administered, other AEFI observed
Vaccine administered without information on AEFI Vaccine not administered