

## REPORT OF ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFI)

**INSTRUCTIONS:** For more complete instructions and definitions, refer to the user guide at:

<http://www.phac-aspc.gc.ca/im/aei-form-eng.php>

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 meet one or more of the following criteria:

- a. Is of a serious nature
- b. Requires urgent medical attention
- c. Is an unusual or unexpected event

Refer to the user guide, 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: Year/Month/Day.
  - 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 LIN**” 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:
- If the interval is <1 hour, indicate in minutes;
  - If it is >1 hour but <1 day; indicate in hours;
  - If it is  $\geq$  1 day; indicate in days
- Report the time in one time unit only. Provide additional detail about associated fever, 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 provides public health recommendations. Additional comments may be provided in section 10 when applicable.
- 12b.** Information in this section is not collected by all P/Ts.

### **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)	Public Health Agency of Canada (PHAC)
Newfoundland and Labrador (NL)	Prince Edward Island (PE)	



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<b>1a. Unique episode #:</b>		<b>1b. Region #:</b>		<b>2. IMPACT LIN:</b>			
<b>3. Patient Identification</b>							
First name:		Last name:		Health number:			
Address of usual residence:							
Province/Territory:		Postal code:		Phone: ( ) -		(ext#: )	
<b>Information Source:</b> First name:		Last name:		Relation to patient:			
Contact info, if different:							
<b>4. Information at Time of Immunization and AEFI Onset</b>							
<b>4a. At Time of Immunization</b>				<b>4b. Medical History (up to the time of AEFI onset)</b> <i>(Check all that apply and provide detail in section 10)</i>			
Province/Territory of immunization: _____				<input type="checkbox"/> Concomitant medication(s)			
Date vaccine administered: YYYY / MM / DD (hr: am/pm)				<input type="checkbox"/> Known medical conditions/allergies			
Date of Birth: YYYY / MM / DD Age: _____				<input type="checkbox"/> Acute illness/injury			
Sex: <input type="radio"/> Male <input type="radio"/> Female <input type="radio"/> Other							
<b>4c. Immunizing agent</b>	<b>Trade name</b>	<b>Manufacturer</b>	<b>Lot number</b>	<b>Dose #</b>	<b>Dosage/unit</b>	<b>Route</b>	<b>Site</b>
					/		
					/		
					/		
					/		
					/		
<b>5. Immunization Errors</b>				<b>6. Previous AEFI</b>			
<b>Did this AEFI follow an incorrect immunization?</b> <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/> Yes <i>(If Yes, choose all that apply and provide detail in section 10)</i> <input type="checkbox"/> Given outside the recommended age limits <input type="checkbox"/> Product expired <input type="checkbox"/> Dose # exceeded that recommended for age <input type="checkbox"/> Incorrect route <input type="checkbox"/> Wrong vaccine given <input type="checkbox"/> Other, specify: _____				<b>Did an AEFI follow a previous dose of any of the above immunizing agents (in Table 4c)?</b> <i>(Choose one of the following)</i> <input type="radio"/> No <input type="radio"/> Yes <i>(Provide details in section 10)</i> <input type="radio"/> Unknown <input type="radio"/> Not applicable (no prior doses)			
<b>7. Impact of AEFI, Outcome and Level of Care Obtained</b>							
<b>7a. Highest impact of AEFI:</b> <i>(Choose one of the following)</i>				<b>7b. Outcome at time of report:</b>			
<input type="radio"/> Did not interfere with daily activities				<input type="radio"/> Death * Date: YYYY / MM / DD <input type="radio"/> Permanent disability/incapacity *			
<input type="radio"/> Interfered with but did not prevent daily activities				<input type="radio"/> Not yet recovered * <input type="radio"/> Fully recovered <input type="radio"/> Unknown			
<input type="radio"/> Prevented daily activities				<i>(Provide details in section 10 for items with *)</i>			
<b>7c. Highest level of care obtained:</b> <i>(Choose one of the following)</i>							
<input type="radio"/> Unknown <input type="radio"/> None <input type="radio"/> Telephone advice from a health professional <input type="radio"/> Non-urgent visit <input type="radio"/> Emergency visit							
<input type="radio"/> Required hospitalization (----- Days) <b>OR</b> <input type="radio"/> Resulted in prolongation of existing hospitalization (by ----- Days)							
Date of hospital admission YYYY / MM / DD				Date of hospital discharge YYYY / MM / DD			
<b>7d. Treatment received:</b> <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/> Yes <i>(Provide details of all treatments, including self treatment in section 10)</i>							
<b>8. Reporter Information</b>							
Setting : <input type="radio"/> Physician Office <input type="radio"/> Public Health <input type="radio"/> Hospital <input type="radio"/> Other, specify: _____							
Name:		Phone: ( ) -		(ext#: )		Fax: ( ) -	
Address:							
City:		Prov/Terr:		Postal code:		Date reported: YYYY / MM / DD	
Signature: _____ <input type="radio"/> MD <input type="radio"/> RN <input type="radio"/> IMPACT <input type="radio"/> Other, specify: _____							

Unique episode #:

Region #:

IMPACT LIN:

9. AEFI Details: Complete sections a, b, c, d and/or e as appropriate; for each, check all signs/symptoms that apply. Use section 10 for clinical details and test results. Any item marked with asterisk (\*) must be diagnosed by a physician.

9a. Local reaction at or near injection site
Interval: -> \_\_\_Min \_\_\_Hrs \_\_\_Days from immunization to onset of 1st symptom or sign
Duration: -> \_\_\_Min \_\_\_Hrs \_\_\_Days from onset of 1st symptom/sign to resolution of all symptoms/signs

Infected abscess Sterile abscess Cellulitis Nodule Reaction crosses joint Lymphadenitis Other, specify:

For any injection site reaction indicated above, check all that apply below and provide details in section 10:

Swelling Pain Tenderness Erythema Warmth Induration Rash Largest diameter of injection site reaction: \_\_\_ cm
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 Regional lymphadenopathy

Choose one of the following:
9b. Anaphylaxis
9c. Other allergic events
Interval: -> \_\_\_Min \_\_\_Hrs \_\_\_Days from immunization to onset of 1st symptom or sign
Duration: -> \_\_\_Min \_\_\_Hrs \_\_\_Days from onset of 1st symptom/sign to resolution of all symptoms/signs

Skin /mucosal
Injection Site Urticaria GENERALIZED: Urticaria Erythema Pruritus Prickle sensation
Red AND itchy eyes ANGIOEDEMA: Tongue Throat Uvula Larynx Lip Eyelids Limbs Other, specify:

Cardio-vascular
Measured hypotension ↓ central pulse volume Capillary refill time >3 sec Tachycardia
↓ or loss of consciousness

Respiratory
Sneezing Rhinorrhea Hoarse voice Sensation of throat closure Stridor
Dry cough Tachypnea Wheezing Indrawing/retractions Grunting Cyanosis

Gastrointestinal
Diarrhea Abdominal pain Nausea Vomiting

9d. Neurologic events
Interval: -> \_\_\_Min \_\_\_Hrs \_\_\_Days from immunization to onset of 1st symptom or sign
Duration: -> \_\_\_Min \_\_\_Hrs \_\_\_Days from onset of 1st symptom/sign to resolution of all symptoms/signs

\* Meningitis \* Encephalopathy/Encephalitis \* Guillain-Barre Syndrome (GBS) \* Bell's Palsy \* Other Paralysis
Seizure \* Other neurologic diagnosis, specify:

For any neurologic event indicated above, check all that apply below and provide details in section 10:

Depressed/altered level of consciousness, lethargy or 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
Focal OR Generalized (Specify: Tonic Clonic Tonic-Clonic Atonic)
Previous history of seizures (Specify: Febrile Afebrile Unknown type)

9e. Other defined events of interest
Interval: -> \_\_\_Min \_\_\_Hrs \_\_\_Days from immunization to onset of 1st symptom or sign
Duration: -> \_\_\_Min \_\_\_Hrs \_\_\_Days from onset of 1st symptom/sign to resolution of all symptoms/signs

Hypotonic-Hyporesponsive Episode (age <2 years)
Limpness Pallor/cyanosis ↓responsiveness/unresponsiveness
Persistent crying (Crying which is continuous and unaltered for ≥ 3 hours)
Rash Generalized Localized at non-injection site
Intussusception
Arthritis Joint redness Joint warm to touch
Joint swelling Inflammatory changes in synovial fluid
Parotitis (Parotid gland swelling with pain and/or tenderness)

\* Thrombocytopenia
Clinical evidence of bleeding Platelet count <150 x10^9/L
Oculo-Respiratory Syndrome (ORS)
Bilateral red eyes Cough Wheeze Sore throat
Difficulty swallowing Difficulty breathing Chest tightness
Hoarseness Facial Swelling
Fever ≥ 38.0°C
Other severe event(s) not listed above

