

## REPORT OF ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFI)

**INSTRUCTIONS:** For more complete instructions and definitions, refer to the user guide at: [www.phac-aspc.gc.ca/im/aeafi-form-eng.php](http://www.phac-aspc.gc.ca/im/aeafi-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:

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

Refer to the user guide, Background Information and 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 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: 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 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)

# REPORT OF ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFI)

Initial report  
Follow up report (*Unique episode number*)

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<sup>†</sup> Date (Y / M / D): \_\_\_\_ | \_\_\_\_ | \_\_\_\_Permanent disability/incapacity<sup>†</sup> Not yet recovered<sup>†</sup>

Fully recovered Unknown

<sup>†</sup>(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.

# 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.

<b>9a) Local reaction at or near vaccination site</b>	Interval: → ___ Min ___ Hrs ___ Days from immunization to onset of 1 <sup>st</sup> symptom or sign
	Duration: → ___ Min ___ Hrs ___ Days from onset of 1 <sup>st</sup> symptom/sign to resolution of all symptoms/signs
<input type="checkbox"/> Infected abscess <input type="checkbox"/> Sterile abscess <input type="checkbox"/> Cellulitis <input type="checkbox"/> Nodule <input type="checkbox"/> Reaction crosses joint <input type="checkbox"/> Lymphadenitis <input type="checkbox"/> Other, <i>specify</i> :	

For any vaccination 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 vaccination 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		

<b>9b) Allergic and Allergic-like events</b>	Interval: → ___ Min ___ Hrs ___ Days from immunization to onset of 1 <sup>st</sup> symptom or sign
	Duration: → ___ Min ___ Hrs ___ Days from onset of 1 <sup>st</sup> symptom/sign to resolution of all symptoms/signs

Chose one of the following:    **Anaphylaxis**    **Oculo-Respiratory Syndrome (ORS)**    **Other allergic events**

Skin/mucosal	<input type="checkbox"/> Urticaria <input type="checkbox"/> Erythema <input type="checkbox"/> Pruritus <input type="checkbox"/> Prickle sensation <input type="checkbox"/> Rash ( <i>For these events, specify site of reaction</i> )
	<b>Angioedema:</b> <input type="checkbox"/> Tongue <input type="checkbox"/> Throat <input type="checkbox"/> Uvula <input type="checkbox"/> Larynx <input type="checkbox"/> Lip <input type="checkbox"/> Eye(s): <input type="checkbox"/> Red bilateral <input type="checkbox"/> Red unilateral <input type="checkbox"/> Itchy <input type="checkbox"/> Eyelids <input type="checkbox"/> Face <input type="checkbox"/> Limbs <input type="checkbox"/> Other, <i>specify</i> :
Cardio-vascular	<input type="checkbox"/> Measured hypotension <input type="checkbox"/> ↓ central pulse volume <input type="checkbox"/> Capillary refill time >3 sec <input type="checkbox"/> Tachycardia <input type="checkbox"/> ↓ or loss of consciousness ( <i>Duration</i> ):
Respiratory	<input type="checkbox"/> Sneezing <input type="checkbox"/> Rhinorrhea <input type="checkbox"/> Hoarse voice <input type="checkbox"/> Sensation of throat closure <input type="checkbox"/> Stridor <input type="checkbox"/> Dry cough <input type="checkbox"/> Tachypnea <input type="checkbox"/> Wheezing <input type="checkbox"/> Indrawing/retractions <input type="checkbox"/> Grunting <input type="checkbox"/> Cyanosis <input type="checkbox"/> Sore throat <input type="checkbox"/> Difficulty swallowing <input type="checkbox"/> Difficulty breathing <input type="checkbox"/> Chest tightness
Gastrointestinal	<input type="checkbox"/> Diarrhea <input type="checkbox"/> Abdominal pain <input type="checkbox"/> Nausea <input type="checkbox"/> Vomiting

<b>9c) Neurologic events</b>	Interval: → ___ Min ___ Hrs ___ Days from immunization to onset of 1 <sup>st</sup> symptom or sign
	Duration: → ___ Min ___ Hrs ___ Days from onset of 1 <sup>st</sup> symptom/sign to resolution of all symptoms/signs

<input type="checkbox"/> Meningitis* <input type="checkbox"/> Encephalopathy/Encephalitis* <input type="checkbox"/> Guillain-Barré Syndrome (GBS)* <input type="checkbox"/> Bell's Palsy* <input type="checkbox"/> Other paralysis* <input type="checkbox"/> Seizure
<b>Other neurologic diagnosis*, specify:</b>
<input type="checkbox"/> Depressed/altered level of consciousness <input type="checkbox"/> Lethargy <input type="checkbox"/> Personality change lasting ≥24hrs <input type="checkbox"/> Focal or multifocal neurologic sign(s) <input type="checkbox"/> Fever (≥38.0°C)
<input type="checkbox"/> CSF abnormality <input type="checkbox"/> EEG abnormality <input type="checkbox"/> EMG abnormality <input type="checkbox"/> Neuroimaging abnormality <input type="checkbox"/> Brain/spinal cord histopathologic abnormality
<b>Seizure details:</b>
<input type="checkbox"/> Witnessed by healthcare professional <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
<input type="checkbox"/> Sudden loss of consciousness <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
<input type="checkbox"/> Generalized ( <i>Specify</i> : <input type="checkbox"/> Tonic <input type="checkbox"/> Clonic <input type="checkbox"/> Tonic-clonic <input type="checkbox"/> Atonic <input type="checkbox"/> Absence <input type="checkbox"/> Myoclonic) <b>OR</b> <input type="checkbox"/> Partial
<input type="checkbox"/> Previous history of seizures ( <i>Specify</i> : <input type="checkbox"/> Febrile <input type="checkbox"/> Afebrile <input type="checkbox"/> Unknown type)

<b>9d) Other events</b>	Interval: → ___ Min ___ Hrs ___ Days from immunization to onset of 1 <sup>st</sup> symptom or sign
	Duration: → ___ Min ___ Hrs ___ Days from onset of 1 <sup>st</sup> symptom/sign to resolution of all symptoms/signs

<b>Hypotonic-Hyporesponsive Episode (age &lt;2 years)</b>	<input type="checkbox"/> Rash ( <i>Non-allergic</i> ) <input type="checkbox"/> Generalized <input type="checkbox"/> Localized ( <i>Site</i> )
	<input type="checkbox"/> Limpness <input type="checkbox"/> Pallor/cyanosis <input type="checkbox"/> ↓ responsiveness/unresponsiveness
<b>Persistent crying</b> ( <i>Continuous and unaltered crying for ≥3 hours</i> )	<input type="checkbox"/> Thrombocytopenia* <input type="checkbox"/> Platelet count <150x10 <sup>9</sup> /L <input type="checkbox"/> Petechial rash <input type="checkbox"/> Other clinical evidence of bleeding
<b>Intussusception*</b>	<input type="checkbox"/> Anaesthesia/Paraesthesia <input type="checkbox"/> Numbness <input type="checkbox"/> Tingling <input type="checkbox"/> Burning
<input type="checkbox"/> Arthritis <input type="checkbox"/> Joint redness <input type="checkbox"/> Joint warm to touch <input type="checkbox"/> Joint swelling <input type="checkbox"/> Inflammatory changes in synovial fluid	<input type="checkbox"/> Formication <input type="checkbox"/> Other, <i>specify</i> :
<input type="checkbox"/> Parotitis ( <i>Parotid gland swelling with pain and/or tenderness</i> )	<input type="checkbox"/> Generalized <input type="checkbox"/> Localized ( <i>Site</i> )
<b>Fever ≥38.0°C</b> ( <i>Note: report ONLY if fever occurs in conjunction with a reportable event. For fever in a neurological event, use Section 9c</i> )	

**Other serious or unexpected event(s) not listed in the form** (*Specify and provide details in Section 10*)

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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