

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

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

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.

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, <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		

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 (<i>For these events, specify site of reaction</i>)		
	Angioedema:	Tongue	Throat	Uvula	Larynx	Lip	Eye(s): Red bilateral Red unilateral Itchy
	Eyelids	Face	Limbs	Other, <i>specify</i> :			
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	Dry cough
	Tachypnea	Wheezing	Indrawing/retractions	Grunting		Cyanosis	Sore throat
	Difficulty swallowing	Difficulty breathing		Chest tightness			
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*, <i>specify</i>:						
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 (<i>Specify</i> : Tonic	Clonic	Tonic-clonic	Atonic	Absence	Myoclonic) OR Partial
	Previous history of seizures (<i>Specify</i> : Febrile	Afebrile	Unknown type)			

9d) Other 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

Hypotonic-Hyporesponsive Episode (age <2 years)	Rash (Non-allergic)	Generalized	Localized (<i>Site</i>)
Limpness	Pallor/cyanosis	↓ responsiveness/unresponsiveness	
Persistent crying (<i>Continuous and unaltered crying for ≥3 hours</i>)	Thrombocytopenia*	Platelet count <150x10 ⁹ /L	Petechial rash
	Other clinical evidence of bleeding		
Intussusception*	Anaesthesia/Paraesthesia	Numbness	Tingling
	Formication	Other, <i>specify</i> :	
Arthritis	Generalized	Localized (<i>Site</i>)	
Joint redness	Joint warm to touch	Joint swelling	
Inflammatory changes in synovial fluid			
Parotitis (<i>Parotid gland swelling with pain and/or tenderness</i>)	Fever ≥38.0°C (<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