Public Health Agency of Canada | Agence de santé publique du Canada

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/aefi-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. Are of serious nature
b. Require urgent medical attention
c. Are unusual or unexpected events

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:
- If the interval is <1 hour, indicate in minutes;
- If it is ≥ 1 hour but <1 day; indicate in hours;
- If it is ≥1 day; indicate in days.

Report the time in one time unit only. 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)	Public Health Agency of Canada (PHAC)
Newfoundland and Labrador (NL)	Prince Edward Island (PE)	

Canada

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○ Initial report
○ Follow up report (Unique episode #)

REPORT OF ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFI)

1a. Unique episode #: **1b. Region #:** **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: YYYY / MM / DD (hr: am/pm)
Date of birth: YYYY / MM / DD **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
❑ Wrong vaccine given ❑ Incorrect route
❑ 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: YYYY / MM / DD ○ Permanent disability/incapacity ♦
○ Not yet recovered ♦ ○ Fully recovered ○ Unknown
(Provide details in section 10 for items with ♦)

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 YYYY / MM / DD Date of hospital discharge YYYY / MM / DD

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: Prov/Terr: Postal code: Date reported: YYYY / MM / DD
Signature: _____ ○ MD ○ RN ○ IMPACT ○ Other, *specify*: _____

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

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Unique episode #: **Region #:** **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 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

❑ 9b. Allergic and Allergic-like 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

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

For a chosen event, check all that apply below and provide details in section 10:

Skin /mucosal	❑ Urticaria ❑ Erythema ❑ Pruritis ❑ Prickle sensation ❑ Rash *(For these events, specify site of reaction)*	
	ANGIOEDEMA: ❑ Tongue ❑ Throat ❑ Uvula ❑ Larynx ❑ Lip ❑ 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 (*Duration*) _____	
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 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)

❑ 9d. 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

For all selected defined events of interest below, provide details in section 10:

❑ Hypotonic-Hyporesponsive Episode (age <2 years)
❑ Limpness ❑ Pallor/cyanosis ❑ ↓responsiveness/unresponsiveness

❑ Persistent crying (*Continuous and unaltered crying for ≥3 hours*)

❑ * Intussusception

❑ Arthritis ❑ Joint redness ❑ Joint warm to touch
❑ Joint swelling ❑ Inflammatory changes in synovial fluid

❑ Parotitis *(Parotid gland swelling with pain and/or tenderness)*

❑ Rash (*Non-allergic*) ○ Generalized ○ Localized (*Site*)_____

❑*Thrombocytopenia ❑ Platelet count <150x10^9/L
❑ Petechial rash ❑ Other clinical evidence of bleeding

❑ Anaesthesia/Paraesthesia (❑ Numbness ❑ Tingling
❑ Burning ❑ Formication ❑ Other, *specify:* _____)
○ 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 severe or unusual event(s) not listed above

Unique episode #: **Region #:** **IMPACT LIN:**

10. Supplementary information *(Please indicate the section # when providing details. Please provide details of any investigation or treatment for the recorded AEFI).*

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11. Recommendations for future immunization(s) according to the Provincial/Territorial best practices.
(*Provide comments, use section 10 if extra space needed*)

❑ No change to immunization schedule	❑ Controlled setting for next immunization	❑ Other, *specify:* _____
❑ Expert referral, *specify:* _____	❑ No further immunizations with: _____ *(specify)* _____	
❑ Determine protective antibody level	❑ Active follow up for AEFI recurrence after next vaccine	

Name: Professional status: ○ MOH/MHO ○ MD ○ RN ○ Other, *specify:* _____

Comments:

Phone: ( ) - (ext #:) Date: YYYY / MM / DD 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