

# Report of Adverse Events Following Immunization (AEFI)

**INSTRUCTIONS:** For more complete instructions and definitions, refer to the *User Guide: Report of Adverse Events Following Immunization (AEFI)* available at: [www.manitoba.ca/health](http://www.manitoba.ca/health)

**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**

## 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 > 1 day; indicate in daysReport 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.
12. Information in this section is not collected by all Provinces/Territories (P/Ts).

**Return completed form to your Regional Medical Officer of Health (MOH) See attached list with contact information.**

Report of Adverse Events Following Immunization (AEFI) developed by the Public Health Agency of Canada and adapted with permission by Manitoba Health and Healthy Living

# Report of Adverse Events Following Immunization (AEFI)

Initial report     Follow up report (Unique episode #) \_\_\_\_\_

**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 detail 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 detail in section 10)*

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

### 6. Previous AEFI

Did an AEFI follow a previous dose of any of the above immunizing agents (in 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: YYYY / MM / DD     Permanent disability/incapacity<sup>†</sup>
  - Not yet recovered<sup>†</sup>     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*

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 Interval: \_\_\_\_ Min \_\_\_\_ Hrs \_\_\_\_ Days from immunization to onset of 1st symptom or sign  
**9c.**  Other allergic events Duration: \_\_\_\_ Min \_\_\_\_ Hrs \_\_\_\_ Days from onset of 1st symptom/sign to resolution of all symptoms/signs

Skin/mucosal	<input type="checkbox"/> Injection Site Urticaria	GENERALIZED: <input type="checkbox"/> Urticaria <input type="checkbox"/> Erythema <input type="checkbox"/> Pruritus <input type="checkbox"/> Prickle sensation
	<input type="checkbox"/> Red AND itchy eyes	ANGIOEDEMA: <input type="checkbox"/> Tongue <input type="checkbox"/> Throat <input type="checkbox"/> Uvula <input type="checkbox"/> Larynx <input type="checkbox"/> Lip <input type="checkbox"/> Eyelids <input type="checkbox"/> Limbs <input type="checkbox"/> Other, specify: _____

Cardiovascular  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 health care 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

<input type="checkbox"/> Hypotonic-Hyporesponsive Episode (age < 2 years)	<input type="checkbox"/> * Thrombocytopenia
<input type="checkbox"/> Limpness <input type="checkbox"/> Pallor/cyanosis <input type="checkbox"/> ↓ responsiveness/unresponsiveness	<input type="checkbox"/> Clinical evidence of bleeding Platelet count < 150 x10 <sup>9</sup> /L
<input type="checkbox"/> Persistent crying (Crying which is continuous and unaltered for ≥ 3 hours)	<input type="checkbox"/> Oculo-Respiratory Syndrome (ORS) (NOTE: this is different from allergic/respiratory symptoms)
<input type="checkbox"/> Rash <input type="checkbox"/> Generalized <input type="checkbox"/> Localized at non-injection site (NOTE: for Rash at injection site, use section 9a and for Rash in allergic reaction use section 9b/9c)	<input type="checkbox"/> Bilateral red eyes <input type="checkbox"/> Cough <input type="checkbox"/> Wheeze <input type="checkbox"/> Sore throat
<input type="checkbox"/> * Intussusception	<input type="checkbox"/> Difficulty swallowing <input type="checkbox"/> Difficulty breathing <input type="checkbox"/> Chest tightness
<input type="checkbox"/> Arthritis <input type="checkbox"/> Joint redness <input type="checkbox"/> Joint warm to touch	<input type="checkbox"/> Hoarseness <input type="checkbox"/> Facial Swelling (Provide details in section 10)
<input type="checkbox"/> Joint swelling <input type="checkbox"/> Inflammatory changes in synovial fluid	<input type="checkbox"/> Fever ≥ 38.0°C (NOTE: report ONLY if fever occurs in conjunction with another reportable event. For fever in a neurological event, use section 9d)
<input type="checkbox"/> Parotitis (Parotid gland swelling with pain and/or tenderness)	<input type="checkbox"/> Other severe event(s) not listed above (Describe in section 10)

