

REPORT OF ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFI)

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

https://www.canada.ca/en/public-health/services/immunization/reporting-adverse-events-following-immunization/user-guide-completion-submission-ae-fi-reports.html

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 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 captured in this section is confidential and is intended for use ONLY by the regional and/or provincial/territorial health officials.
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.

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An AEFI is a reportable event in New Brunswick and should be reported to a Regional Medical Officer of Health (NBIPG Policy 2.7).

Timeline for reporting is within **1 working day for serious AEFIs** and within **5 working days for other AEFIs**

Return the completed form to your local Public Health Office:

Zone	Address	Phone	Fax
Zone 1 - Moncton	81 Albert Street, Bureau/Suite 300 Moncton, NB E1C 1B3	506-856-2401	506-856-3101
Zone 2 – Saint John	55 Union Street Saint John, NB E2L 5B7	506-658-2454	506-658-3067
Zone 3 - Fredericton	P.O. Box 500 300 St Mary's Street Room 1200 Fredericton, NB E3B 5H1	506-453-5200	506-444-5108
Zone 4 - Edmunston	121 Church Street Unit 330 Edmundston, NB E3V 1J9	506-735-2065	506-735-2340
Zone 5 - Campbellton	6 Arran Street 1 st Floor Campbellton, NB E3N 1K4	506-789-2266	506-789-2349
Zone 6 - Bathurst	165 St. Andrew Street Bathurst, NB E2A 1C1	506-547-2062	506-547-7459
Zone 7 - Miramichi	1780 Water Street Suite 300 Miramichi, NB E1N 1B6	506-778-6102	506-773-6611

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- 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	
<p>4a. At time of immunization Province/Territory of immunization: _____</p> <p>Date vaccine administered (YYYY/MM/DD): ____ ____ ____ (hr: am/pm)</p> <p>Date of birth (YYYY/MM/DD): ____ ____ ____ Age: _____</p> <p>Sex: <input type="radio"/> Male <input type="radio"/> Female <input type="radio"/> Other</p> <p><input type="checkbox"/> Pregnant at time of immunization Gestation ____ weeks ____ days</p>	<p>4b. Medical history (up to the time of AEFI onset)</p> <p><i>(Check all that apply and provide details in section 10)</i></p> <p><input type="checkbox"/> Concomitant medication(s)</p> <p><input type="checkbox"/> Known medical conditions/allergies</p> <p><input type="checkbox"/> Acute illness/injury</p>

4c. Immunizing agent	Trade name	Manufacturer	Lot number	Dose #	Dosage/unit	Route	Site
					/		
					/		
					/		
					/		
					/		
					/		
					/		

<p>5. Immunization Errors</p> <p>Did this AEFI follow an incorrect immunization? <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/> Yes</p> <p><i>(If Yes, choose all that apply and provide details in section 10)</i></p> <p><input type="checkbox"/> Given outside the recommended age limits <input type="checkbox"/> Product expired</p> <p><input type="checkbox"/> Wrong vaccine given <input type="checkbox"/> Incorrect route</p> <p><input type="checkbox"/> Dose exceeded that recommended for age <input type="checkbox"/> Other, specify: _____</p>	<p>6. Previous AEFI</p> <p>Did an AEFI follow a previous dose of any of the above immunizing agents (Table 4c)?</p> <p><i>(Choose one of the following)</i></p> <p><input type="radio"/> No <input type="radio"/> Yes <i>(Provide details in section 10)</i></p> <p><input type="radio"/> Unknown <input type="radio"/> Not applicable (no prior doses)</p>
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Note: Discuss with patient or his/her parent/caregiver reason for reporting and confidentiality of information

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Unique episode #:

Region #:

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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/Nurse Practitioner office Public health Hospital Workplace Clinic Other, specify:

Name: _____ Phone: () - (Ext #:) Fax: () -

Address:

City: _____ Prov/Terr: _____ Postal code: _____ Date reported: (YYYY/MM/DD): ____ | __ | __ |

Signature: _____ MD RN IMPACT Pharmacist Other, specify: _____

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 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 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

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<input type="checkbox"/> 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
Choose one of the following: <input type="radio"/> Anaphylaxis <input type="radio"/> Oculo-Respiratory Syndrome (ORS) <input type="radio"/> 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"/> Flushing <input type="checkbox"/> Other Rash <input type="radio"/> Generalized <input type="radio"/> Localized (site) _____ 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"/> Face <input type="checkbox"/> Limbs <input type="checkbox"/> Other, specify: _____ Eye(s): <input type="checkbox"/> Red bilateral <input type="checkbox"/> Red unilateral <input type="checkbox"/> Itchy
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 (Duration) _____
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
<input type="checkbox"/> 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
<input type="checkbox"/> Meningitis* <input type="checkbox"/> Encephalopathy/Encephalitis* <input type="checkbox"/> Guillain-Barre Syndrome (GBS)* <input type="checkbox"/> Bell's Palsy* <input type="checkbox"/> Other Paralysis* <input type="checkbox"/> Seizure <input type="checkbox"/> Anaesthesia <input type="checkbox"/> Paraesthesia <input type="checkbox"/> Other neurologic diagnosis*, specify: _____	
<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 <input type="checkbox"/> Numbness <input type="checkbox"/> Tingling <input type="checkbox"/> Burning <input type="checkbox"/> Formication <input type="checkbox"/> Other, specify _____ Type of Seizure: <input type="checkbox"/> Partial Seizure OR <input type="checkbox"/> Generalized Seizure (Specify: <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) Seizure details: <input type="checkbox"/> Sudden loss of consciousness <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="checkbox"/> Witnessed by healthcare professional <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="checkbox"/> Previous history of seizures (Specify: <input type="checkbox"/> Febrile <input type="checkbox"/> Afebrile <input type="checkbox"/> Unknown type)	
<input type="checkbox"/> 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
<input type="checkbox"/> Hypotonic-Hyporesponsive Episode (age <2 years) <input type="checkbox"/> Limpness <input type="checkbox"/> Pallor/cyanosis <input type="checkbox"/> ↓responsiveness/unresponsiveness	<input type="checkbox"/> Parotitis (Parotid gland swelling with pain and/or tenderness) <input type="checkbox"/> Rash (Non-allergic) <input type="radio"/> Generalized <input type="radio"/> Localized (Site) _____
<input type="checkbox"/> Persistent crying (Continuous and unaltered crying for ≥3 hours)	<input type="checkbox"/> Thrombocytopenia* <input type="checkbox"/> Clinical evidence of bleeding <input type="checkbox"/> Platelet count <150x10 ⁹ /L <input type="checkbox"/> Petechial rash <input type="checkbox"/> Other clinical evidence of bleeding
<input type="checkbox"/> * Intussusception	

