Report of adverse events following immunization (AEFI)

Instructions: For more complete instructions and definitions, refer to the user guide at: www.canada.ca/en/public-health/services/immunization/reporting-adverse-events-following-immunization/user-guide-completion-submission-aefi-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.

For additional information, please see the background information section in the user guide.

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

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 (PT). 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 PT 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, 5 or booster). 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: Minutes, Hours or Days. Provide additional details of any investigation, specialist referrals, therapy, and other information as appropriate in section 10.
10. All information that is pertinent to the AEFI but that has not been fully captured elsewhere or that needs further explanation should be recorded in this section. Document all known details of any investigations or treatments for the recorded AEFI.
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 PT best practices.
12. Information in this section is not collected by all PTs.

Return completed form to your local public health unit address at: British Columbia (BC), Manitoba (MB), New Brunswick (NB), Newfoundland and Labrador (NL), Northwest Territories (NT), Nova Scotia (NS), Nunavut (NU), Ontario (ON), Prince Edward Island (PE), Quebec (QC), Saskatchewan (SK), Yukon (YT), Canadian Forces Health Services (CFHS).

○ 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: (XXX)XXX-XXXX ext #:

Information Source: First name: Last name:

Relation to patient:

Contact information, if different:

4. Information at time of immunization and AEFI onset

4a. At time of immunization: Province/Territory of immunization:

Date vaccine administered: (hr: ○ am/ ○ pm)

Sex: ○ Male ○ Female ○ Other

Date of birth: **Age:**

☐ **Pregnant at time of immunization:** ☐ Gestation weeks days

☐ **Breastfeeding at time of immunization**

Race: Indicate which race category the patient says best describes themselves: (check all that apply)

☐ Black ☐ East/Southeast Asian ☐ Indigenous ☐ Latino ☐ Middle Eastern ☐ South Asian ☐ White

☐ Another race category ☐ Prefer not to answer ☐ Do not know ☐ Not asked

Indigenous status: If Indigenous, indicate which Indigenous identity the patient self-identifies as: (check all that apply)

☐ First Nations ☐ Métis ☐ Inuk/Inuit ☐ Other Indigenous ☐ Prefer not to answer ☐ Not asked

Canada

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

1a. Unique episode #: **1b. Region #:** **2. IMPACT LIN:**

4b. Medical history (up to the time of AEFI onset) [Check all that apply and provide details and descriptions including medical investigations, dates and timing prior to time of AEFI onset in section 10.]

☐ Concomitant medication(s), including prescription, over the counter, herbal supplements and traditional medicines.

☐ Known medical conditions (e.g. immunocompromised, chronic conditions, including those with intermittent symptoms).

☐ Allergies and reactions, including to previous vaccinations, medications or foods.

☐ Acute illness/injury.

☐ Prior COVID-19 infection: Test type: Date:

☐ COVID-19 immunization history: For COVID-19 vaccines, enter date of previous COVID-19 immunization, dose number, trade name and vaccine manufacturer.

Date of previous immunization	**Dose number**	**Vaccine trade name**	**Vaccine manufacturer**

4c. Immunizing agent: For COVID-19 vaccines **enter both immunizing agent and diluent information on separate lines below**. For vaccines requiring multiple doses, please include dose # in series.

Immunizing agent(s) and diluent (where applicable)	**Trade name**	**Manufacturer**	**Lot number**	**Expiry date** (yyyy/mm/dd)	**Dose #**	**Dosage/ unit**	**Route**	**Site**

Canada

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

1a. Unique episode #: **1b. Region #:** **2. IMPACT LIN:**

5. Immunization errors

Did this AEFI follow an incorrect immunization? ○ Yes ○ No ○ Unknown

(If Yes, choose all that apply and provide details in section 10)

☐ Given outside the recommended age limits ☐ Product expired ☐ Incorrect product storage
☐ Dose exceeded that recommended for age ☐ Wrong vaccine given ☐ Incorrect route
☐ Inappropriate dose of vaccine given ☐ Product preparation error
☐ Other, specify:

6. Previous AEFI: Did an AEFI follow a previous dose of any of the above immunizing agents (Table 4b or 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: (Provide details in section 10 for items with †)

○ Death† Date of death: ○ Permanent disability/incapacity† ○ Not yet recovered† ○ Fully recovered
○ Unknown

7c. Highest level of care obtained: (Choose one of the following)

○ Unknown ○ None ○ Telephone/virtual consultation with a health professional ○ Non-urgent visit
○ Emergency visit ○ Required hospitalization (days)
○ Resulted in prolongation of existing hospitalization (by days)
Date of hospital admission: Date of hospital discharge:

7d. Treatment received: ○ Yes ○ No ○ Unknown

(Provide details of all treatments, including self-treatment, in section 10)

8. Reporter information

Setting : ○ Long-term care home ○ Physician office ○ Nursing station ○ Public health ○ Pharmacy ○ Hospital
○ Workplace clinic ○ Other, specify:

Name: Phone: (XXX)XXX-XXXX ext #: Fax: (XXX)XXX-XXXX
Address:
City: Prov/Terr: Postal code:
Date reported:
Signature: ○ MD ○ RN ○ IMPACT ○ Pharmacist ○ Other, specify:

Canada

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

1a. Unique episode #: _____ **1b. Region #:** _____ **2. 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 reactions at or near vaccination site**

Interval: ____ Min ____ Hrs ____ Days from immunization to onset of 1st symptom/sign

Duration: ____ Min ____ Hrs ____ Days from onset of 1st symptom/sign to resolution of all symptoms/signs

☐ Infected abscess ☐ Sterile abscess ☐ Cellulitis ☐ Nodule ☐ Lymphadenitis
☐ Reaction stretches joint-to-joint ☐ Reaction crosses joint(s) (specify which joint(s) in Section 10)
☐ 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

☐ **9b. Allergic and allergic-like events**

Interval: ____ Min ____ Hrs ____ Days from immunization to onset of 1st symptom/sign

Duration: ____ Min ____ Hrs ____ Days from onset of 1st symptom/sign to resolution of all symptoms/signs

Choose one of the following: ○ **Anaphylaxis** ○ **Oculo-Respiratory Syndrome (ORS)** ○ **Other allergic events**
☐ Epinephrine administered

Skin /mucosal

☐ Urticaria (hives) ☐ Erythema ☐ Pruritus ☐ Paraesthesia (prickling or tingling) ☐ Flushing ☐ Other rash
○ **Generalized** ○ **Localized (site)** _____

Angioedema: ☐ Tongue ☐ Throat ☐ Uvula ☐ Larynx ☐ Lip ☐ Eyelids ☐ Face ☐ Limbs
☐ Other, specify: _____
○ **Visible swelling** ○ **Reported sensation of swelling**

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 ☐ Wheezing
☐ Dry cough ☐ Tachypnea ☐ Indrawing/retractions ☐ Grunting ☐ Increased use of accessory muscles
☐ Cyanosis ☐ Sore throat ☐ Difficulty swallowing ☐ Difficulty breathing ☐ Chest tightness

Gastrointestinal

☐ Diarrhea ☐ Abdominal pain ☐ Nausea ☐ Vomiting

Canada

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

1a. Unique episode #: **1b. Region #:** **2. IMPACT LIN:**

☐ **9c. Neurologic events**

Interval: ☐ Min ☐ Hrs ☐ Days from immunization to onset of 1st symptom/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 ☐ Myelitis/transverse myelitis* ☐ Subacute sclerosing panencephalitis*
☐ Other neurologic diagnosis*, specify:

☐ Depressed/altered level of consciousness ☐ Lethargy ☐ Personality change lasting ≥ 24hrs.
☐ Focal or multifocal neurologic sign(s) ☐ Fever (≥ 38.0°C)

Abnormal test results (Use Section 10 for details of abnormal test results):
☐ CSF abnormality ☐ EEG abnormality ☐ EMG abnormality ☐ Neuroimaging abnormality
☐ Brain/spinal cord histopathologic abnormality

☐ Anaesthesia (numbness) ☐ Burning ☐ Formication ☐ Paraesthesia (prickling or tingling)
(**Note:** Brief prickling or tingling immediately following immunization should be captured in section 9b under 'skin/mucosal')
☐ Other, specify

Type of seizure:
○ **Partial seizure or** ○ **Generalized seizure** (Specify: ○ Tonic ○ Clonic ○ Tonic-Clonic ○ Atonic ○ Absence ○ Myoclonic)
Seizure details: ☐ Sudden loss of consciousness ○ Yes ○ No ○ Unknown
☐ Witnessed by healthcare professional ○ Yes ○ No ○ Unknown
☐ Previous history of seizures (Specify: ○ Febrile ○ Afebrile ○ Unknown type)

☐ **9d. Other events**

Interval: ☐ Min ☐ Hrs ☐ Days from immunization to onset of 1st symptom/sign

Duration: ☐ Min ☐ Hrs ☐ Days from onset of 1st symptom/sign to resolution of all symptoms/signs

☐ **Hypotonic-hyporesponsive episode** (age <2 years) ☐ Limpness ☐ Pallor/cyanosis
☐ ↓ responsiveness/unresponsiveness

☐ **Persistent crying** (continuous and unaltered crying for ≥3 hours among young children)

☐ **Intussusception***

☐ **Arthritis** ☐ Joint redness ☐ Joint warm to touch ☐ Joint pain ☐ Joint swelling
☐ Inflammatory changes in synovial fluid

☐ **Parotitis** (parotid gland swelling with pain and/or tenderness)

☐ **Syncope with injury**

☐ **Rash** (non-allergic) ○ Generalized ○ Localized, specify site:

Canada

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

1a. Unique episode #: **1b. Region #:** **2. IMPACT LIN:**

☐ **Kawasaki disease***

☐ **Thrombocytopenia*** ☐ Petechial rash ☐ Platelet count <150 x 10^9/L, specify

Clinical evidence of bleeding, specify

☐ **Severe vomiting** (severe enough to interfere with daily routine)

☐ **Severe diarrhea** (severe enough to interfere with daily routine)

☐ **Fever ≥ 38°C** (Note: report **only** if fever occurs in conjunction with another reportable event. For fever in a neurological event, use section 9c)

☐ **Other serious or unexpected event(s) not listed in the form** (describe in section 10)

9e. COVID-19 Adverse Events of Special Interest (AESI)

Report following COVID-19 vaccine only. Please indicate if one of the following has been diagnosed by a physician. Please consult https://brightoncollaboration.us/covid-19/ for the most up-to-date list of COVID-19 AESIs and detailed case definitions. Provide in section 10 details on signs, symptoms and investigations leading to the diagnosis of the AESIs listed below.

☐ Vaccine-associated enhanced disease
☐ Multisystem inflammatory syndrome (MIS) in children (MIS-C)
☐ Multisystem inflammatory syndrome (MIS) in adults (MIS-A)
☐ Acute respiratory distress syndrome
☐ Acute cardiovascular injury (microangiopathy, heart failure, stress cardiomyopathy, coronary artery disease arrhythmia, myocarditis)
☐ Coagulation disorder
  ○ Thrombosis/Thromboembolism
  ○ Thrombocytopenia
  ○ Thrombosis with Thrombocytopenia syndrome
☐ Acute kidney injury
☐ Acute liver injury
☐ Anosmia
☐ Ageusia
☐ Chilblain – like lesions
☐ Single organ cutaneous vasculitis
☐ Erythema multiforme
☐ Meningoencephalitis
☐ Acute disseminated encephalomyelitis
☐ Subacute thyroiditis
☐ Acute pancreatitis
☐ Pancreatitis
☐ Rhabdomyolysis
☐ Acute aseptic arthritis
☐ Other, specify:

Canada

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

1a. Unique episode #: **1b. Region #:** **2. 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 additional space is required, please attach a separate sheet.)

Canada

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

1a. Unique episode #: **1b. Region #:** **2. IMPACT LIN:**

11. Recommendations 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: (XXX)XXX-XXXX ext #: Date: 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

Canada