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-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.

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.

10. All information that is pertinent to the AEFI but 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 P/T best practices.

12. Information in this section is not collected by all P/Ts.

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 1st 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

○ 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
❑ Pregnant at time of immunization Gestation _____ weeks ____ days

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: 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	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 ❑ Inappropriate interval between doses
❑ Inappropriate amount of diluent added ❑ 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)

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

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

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 Practitionner 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

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

❑ **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: ○ **Anaphylaxis** ○ **Oculo-Respiratory Syndrome (ORS)** ○ **Other allergic events**

Skin /mucosal	❑ Urticaria ❑ Erythema ❑ Pruritus ❑ Prickle sensation ❑ Flushing ❑ Other Rash ○ **Generalized** ○ **Localized *(site)*_____**	
	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** ❑ **Anaesthesia** ❑ **Paraesthesia** ❑ **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) ❑ CSF abnormality ❑ EEG abnormality ❑ EMG abnormality ❑ Neuroimaging abnormality
❑ Brain/spinal cord histopathologic abnormality ❑ Numbness ❑ Tingling ❑ Burning ❑ Formication 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 or 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	❑ **Parotitis** *(Parotid gland swelling with pain and/or tenderness*
	❑ **Rash *(Non-allergic)*** ○ Generalized ○ Localized (*Site*)_____
❑ **Persistent crying** (*Continuous and unaltered crying for ≥3 hours)*	

❑ *** Intussusception**	❑ **Thrombocytopenia*** ❑ Clinical evidence of bleeding ❑ Platelet count <150x10^9/L ❑ Petechial rash ❑ Other clinical evidence of bleeding
❑ **Arthritis** ❑ Joint redness ❑ Joint warm to touch ❑ Joint pain ❑ Joint swelling ❑ Inflammatory changes in synovial fluid	❑ **Severe vomiting** (Severe enough to interfere with daily routine)
	❑ **Severe diarrhea** (Severe enough to interfere with daily routine)

❑ **Fever ≥ 38.0^{0}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.

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

❑ **Vaccine-associated enhanced disease**

❑ **Multisystem inflammatory syndrome (MIS) in children (MIS-C)**

❑ **Multisystem inflammatory syndrome (MIS) in adults (MIS-A)**

❑ **Acute cardiovascular injury** (microangiopathy, heart failure**,**
stress cardiomyopathy, coronary artery disease arrhythmia, myocarditis/pericarditis)

❑ **Coagulation disorder (thromboembolism, haemorrhage)**

❑ **Acute kidney injury**

❑ **Acute liver injury**

❑ **Other, specify:_____**

❑ **Anosmia, ageusia**

❑ **Chilbain-like lesions**

❑ **Single organ cutaneous vasculitis**

❑ **Erythema multiforme**

❑ **Meningoencephalitis**

❑ **Acute disseminated encephalomyelitis**

❑ **Subacute thyroiditis**

❑ **Pancreatitis**

❑ 9f. Supplemental information for Adverse Events following smallpox vaccines

To collect only in case of immunization with smallpox vaccines:

a) Has the vaccine been received ❑ as pre-exposure prophylaxis or as ❑ post-exposure prophylaxis (PEP)

b) For PEP, specify days of symptoms onset since exposure (counting exposure as day 0):_____

c) Has client received previous doses of smallpox vaccine (first or second generation smallpox vaccines or Imvamune) ❑ Yes ❑ No

If Yes, please specify vaccine type, lot number and date of immunization:_____

_____

d) Specify clinical presentation, course and duration of illness, presumed diagnosis (if available) and treatments received:

_____

_____

_____

_____

e) Monkey pox testing results: ❑ Detected ❑ Not detected ❑ Not tested ❑ Pending

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)).*

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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: ( ) - (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