### REPORT OF ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFI)

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


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 seriousness criteria
- 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.
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:

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

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

## 3. Patient Identification

<table>
<thead>
<tr>
<th>First name:</th>
<th>Last name:</th>
<th>Health number:</th>
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<tbody>
<tr>
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</table>

Address of usual residence:

<table>
<thead>
<tr>
<th>Province/Territory:</th>
<th>Postal code:</th>
<th>Phone: ( ) - (ext #: )</th>
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<tbody>
<tr>
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</table>

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

<table>
<thead>
<tr>
<th>Trade name</th>
<th>Manufacturer</th>
<th>Lot number</th>
<th>Dose #</th>
<th>Dosage/unit</th>
<th>Route</th>
<th>Site</th>
</tr>
</thead>
<tbody>
<tr>
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</table>

## 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)

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

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

8. Reporter Information

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

Name: _______________________________ Phone: (____) - (Ext #: ) Fax: (____) -

Address:

City: _______________________________ Prov/Terr: _______________________________ Postal code: ________ Date reported: [YYYY/MM/DD]

Signature: _________________________ O MD O RN O IMPACT O Pharmacist O 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 #:  
IMPA CT LIN:

9b. Allergic and Allergic-like events

<table>
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<th>Duration:</th>
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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

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

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Meningitis
- Encephalopathy/Encephalitis
- Guillain-Barre Syndrome (GBS)
- Bell’s Palsy

Other Paralysis
- Seizure
- Anaesthesia
- Paraesthesia
- 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
- Generalized Seizure (Specify: Tonic, Clonic, Tonic-Clonic, Atonic, Absence, Myoclonic)

Seizure details:

- Sudden loss of consciousness
- Witnessed by healthcare professional
- Previous history of seizures

9d. Other events

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

- Parotitis (Parotid gland swelling with pain and/or tenderness)
- Rash (Non-allergic)

- Persistent crying (Continuous and unaltered crying for ≥23 hours)

- Thrombocytopenia
- Clinical evidence of bleeding
- Platelet count <150x10⁹/L
- Petechial rash
- Other clinical evidence of bleeding

- * Intussusception

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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)).

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

12) Follow up information for a subsequent dose of same vaccine(s) (Provide details in section 10)