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 following criteria:

a. Are of serious nature
b. Require urgent medical attention
c. Are unusual or unexpected events

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 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 days.
   Report the time in one time unit only. 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.

Return completed form to your local public health unit address at:

Alberta (AB) 
British Columbia (BC) 
Manitoba (MB) 
New Brunswick (NB) 
Newfoundland and Labrador (NL)
Northwest Territories (NT) 
Nova Scotia (NS) 
Nunavut (NU) 
Ontario (ON) 
Quebec (QC) 
Saskatchewan (SK) 
Yukon (YT) 
Public Health Agency of Canada (PHAC)

Date modified: 2010-10-04
REPORT OF ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFI)

1. 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>
</tr>
</thead>
</table>

Address of usual residence: 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: O Male O Female O Other

4b. Medical history (up to the time of AEFI onset)

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>
</table>

4d. Immunization Errors

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

Given outside the recommended age limits

Product expired

Wrong vaccine given

Incorrect route

Dose exceeded that recommended for age

Other, specify: _________

5. Immunization Errors

6. Previous AEFI

Did an AEFI follow a previous dose of any of the above immunizing agents (Table 4c)?

Choose one of the following

O No O Yes (Provide details in section 10)

O Unknown O 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)

O Did not interfere with daily activities

O Interfered with but did not prevent daily activities

O Prevented daily activities

7b. Outcome at time of report:

O Death * Date: YYYY / MM / DD O Permanent disability/incapacity *

O Not yet recovered * O Fully recovered O Unknown

(Provide details in section 10 for items with *)

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

O Unknown O None O Telephone advice from a health professional

O Non-urgent visit O Emergency visit

O Required hospitalization (____ days) OR O 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: O No O Unknown O Yes (Provide details of all treatments including self treatment, in section 10)

8. Reporter Information

Setting: O Physician office O Public health O Hospital 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 Other, specify:

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

Chose one of the following:

- Allergic-like events
- Swelling
- Rash
- Joint swelling
- Joint redness
- Other, specify: __________________

[9b. Allergic and Allergic-like events]

For any injection site reaction indicated above, check all that apply below and provide details in section 10:

- Swelling
- Rash
- Joint swelling
- Joint redness
- Other, specify: __________________

[9c. Neurologic events]

For any neurologic event indicated above, check all that apply below and provide details in section 10:

- Meningitis
- Encephalopathy/Encephalitis
- Guillain-Barre Syndrome (GBS)
- Bell's Palsy
- Other Paralysis
- Other neurologic diagnosis, specify: __________________

[9d. Other defined events of interest]

For all selected defined events of interest below, provide details in section 10:

- Hypotonic-Hyporesponsive Episode (age <2 years)
- Persistent crying (Continuous and unaltered crying for ≥3 hours)
- Intussusception
- Arthritis
- Parotitis (Parotid gland swelling with pain and/or tenderness)
- Rash (Non-allergic)
- Other severe or unusual event(s) not listed above
10. Supplementary information (Please indicate the section # when providing details. Please provide details of any investigation or treatment for the recorded AEFI).

<table>
<thead>
<tr>
<th>Unique episode #:</th>
<th>Region #:</th>
<th>IMPACT LIN:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

11. Recommendations for future immunization(s) according to the 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