Internal Use Only:	□ AEFI □ Non AEFI	Page 1 of 4
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Indigenous Services Canada / Services aux Autochtones Canada

Initial Report □ Follow up Report (Unique Episode #) □

REPORT OF ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFI)

Reports events which have an 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. All dates should be captured in following way: YYYY/MM/DD. When reporting an AEFI, check one of the boxes on the top right hand corner of the first page of this form to indicate whether it is an INITIAL or FOLLOW UP report.

Of particular interest are those AEFI's 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**

1. Patient Identification

First name: Last name: Health #:

Treaty #: Band:

Date of birth (y/m/d): Sex: □ Male □ Female □ Other Age at time of immunization:

Address of usual residence:

Province/Territory: Postal code: Phone #: ( ) ext#:

Information source □ Self □ Other **(If other please provide details below)**

First name: Last name: Relation to client:

Contact info (if different):

2. Reporter Information

Setting: □ Public Health - provide clinic name:

□ Hospital - provide hospital name: □ Other (specify):

Name: Phone #: ( ) ext#:

Fax #: Address: City:

Province/Territory: Postal code: Date reported (y/m/d):

Signature: □ MD □ RN □ IMPACT □ Other (specify):

3. Information at Time of Immunization and AEFI Onset

3a. At Time of Immunization:

Province/Territory of immunization:

Date vaccine administered (y/m/d):

Time vaccine administered: am/pm

3b. Medical History Up To The Time of AEFI Onset:

(check all that apply and provide details in section 9)

□ Concomitant medication(s) □ Known allergies

□ Known medical conditions □ Unknown

□ Acute illness/injury □ None of the above

3c. Immunizing Agent	Trade Name	Manufacturer	Lot #	Dosage	Expiry Date	Route	Site

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

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4. Immunization Errors

Did this AEFI follow an incorrect Immunization? □ Unknown □ No □ **Yes**
(If **Yes**, choose all that apply and provide details in section 9)
□ Given outside the recommended age limits □ product expired
□ Wrong vaccine given □ Incorrect route
□ Dose exceeded that recommended for age
□ Other (specify)

5. Previous AEFI

Did an AEFI follow a previous dose of any of the immunizating agents in table 3?
(Choose one of the following)
□ No □ Unknown
□ Yes (provide details in section 9)
□ Not applicable

6. Previous Reactions

Did an AEFI follow a previous dose of any other immunizing agent?
□ Yes □ No □ Unknown

Has there been a pre-existing history of a reaction following any immunization not reported in AEFI form?
□ Yes □ No □ Unknown **(Please attach a copy of current immunization record)**

Was there evidence of any anxieties or other factors which may have contributed to the post immunization event?
□ Yes □ No □ Unknown **(If yes, provide details in section 9)**

Was there travel outside of Canada prior to/post immunization that may be related to the post immunization event?
□ Yes □ No □ Unknown **(If yes, provide details in section 9)**

7. Impact of AEFI, Outcome, and Level of Care Obtained (provide details in section 9 for items with *)

7a. Highest Impact of AEFI: (choose one)
□ Did not interfere with daily activities
□ Interfered with but didn't prevent daily activities*
□ Prevented daily activities *

7b. Outcome at time of report:
□ Death* date (y/m/d) □ Unknown
□ Permanent disability/incapacity* □ Fully recovered
□ Not yet recovered*

7c. Highest level of care obtained: (Choose one of the following) (Provide hospitalization details in section 9)
□ Unknown □ None □ Telephone advice from a health professional □ Non-urgent visit to HPC
□ Emergency visit □ Required hospitalization (days) □ Resulted in prolongation of existing hospitalization
Date of hospital admission (y/m/d) Date of hospital discharge (y/m/d)
Name of health care professional involved:_____ Name of hospital:_____

7d. Treatment received: □ Unknown □ No □ Yes (provide details of all treatment including self treatment, in section 9)

8. 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 9 for additional information including clinical details and test results.

8a. Local reaction at or near injection

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 all local reactions at or near the injection site, check all that apply below and provide details in Section 9:
□ Swelling □ Pain □ Tenderness □ Erythema □ Warmth □ Induration □ Rash □ Palpable fluctuance
□ Spontaneous/surgical drainage □ Microbial results
□ Largest diameter of injection site reaction: _____cm Site of reaction: _____(e.g. LA, RA)
□ Fluid collection shown by imagining technique (e.g. MRI, CT, ultrasound)
□ Lymphangitic streaking □ Regional lymphadenopathy

8b. 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
For a chosen event, check all that apply below and provide details in section 9

Skin/mucosal

□ Urticaria □ Erythema □ Pruritis □ Prickle sensation □ Rash
Please specify reaction site:

ANGIOEDEMA: □ Tongue □ Throat □ Uvula □ Larynx □ Lip
□ Eyelids □ Face □ Limbs □ Other, specify _____

EYE(S): □ Red bilateral
□ Red unilateral □ Itchy

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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

8c.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 □ * Other neurologic diagnosis, specify: _____

For any neurologic event indicated above, check all that apply below and provide details in section 9:

□ Depress/altered level of consciousness, lethargy or personality change lasting ≥ 24hrs
□ Focal or multifocal neurologic sign(s)
□ Fever (≥ 38°C) □ CSF abnormality □ EEG abnormality □ EMG abnormality
□ Neuroimaging abnormality □ Brain/spinal cord histopathologic abnormality
Seizure details: □ Witnessed by healthcare professional □ Yes □ No □ Unknown
□ Focal **OR** □ Generalized (specify: □ Tonic □ Clonic □ Tonic-Clonic □ Atonic)
□ Previous history of seizures (specify: □ Febrile □ Afebrile □ Unknown type)

8d. Other defined events of interest	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

For all selected defined events of interest below, provide details in section 9:

□ Hypotonic-Hyporesponsive episode (age < 2 years) □ Limpness □ Pallor/Cyanosis □ ↓ Responsiveness/Unresponsiveness	□ * Thrombocytopenia □ Platelet count < 150 x 10^9/L □ Petechial rash □ Other clinical evidence of bleeding
□ Persistent crying (continuous & unaltered crying for ≥ 3 hr)	□ Anaesthesia/Paraesthesia (□ Numbness □ Tingling
□ * Intussusception	□ Burning □ Formication □ Other, specify_____)
□ Arthritis □ Joint redness □ Joint warm to touch	□ Generalized □ Localized (site):_____
□ Joint swelling □ Inflammatory changes in synovial fluid	□ Fever(> 38◦C) (Note: report **ONLY** if fever occurs in conjunction with a reported event. Fever (neurological event use section 9)
□ Parotitis (Parotid gland swelling with pain and/or tenderness)	
□ Rash (Non-allergic) □ Generalized □ Localized (site):___	□ Other severe or unusual event(s) not listed above

If there is a pruritic maculopapular vesicular rash which appears within 28days following a dose of MMRV or Varicella, please indicate if there are household members who are:
□ Immune compromised □ Pregnant □ Under age 1 □ Also symptomatic (please provide details in section 9)

9. **Supplementary information** (Please indicate the section # when providing details. Please provide details of any investigation or treatment for the recorded AEFI) **Please write clearly.**

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