

REPORT OF ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFI)

Protected when completed

A. PATIENT : Name : _____ Parent's/Guardian's name (if a child) : _____ Address (Street, City, Postal code): _____ Home phone # _____ Work phone # _____	DATE OF BIRTH _____/_____/_____ YYYY/MM/DD AGE _____	SEX <input type="checkbox"/> Male <input type="checkbox"/> Female DATE OF VACCINE ADMINISTRATION _____/_____/_____ YYYY/MM/DD
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Reason for Reporting: Check all that apply. (1, 2, AND 3 must apply to meet AEFI reporting criteria)
For additional guidance on completing form, call your local public health unit. Return completed form to your local public health unit.

- 1. Event temporally associated with immunization
- 2. Event has no other proven explanation
- 3. Event meets at least one of the following criteria:
 - Serious nature i.e. fatal, life-threatening, required hospitalization or resulted in residual disability
 - Required medical attention
 - Was expected, but has been observed to occur with greater than usual frequency
 - Was unusual or unexpected event

B. VACCINE (S) GIVEN (Trade name preferred)	DOSE NUMBER (if applicable)	SITE	ROUTE	DOSAGE	MANUFACTURER	LOT NUMBER

C. Information on Reporter	<ul style="list-style-type: none"> • Name of Individual submitting report _____ • Telephone Number: _____ • Professional Status: MD __, RN __, Pharmacist __, Other (specify) _____ • Address (Institution, Street, City, Province, Postal code) _____ • Signature _____ Date reported (yyyy/mm/dd) _____
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D. Case status at time of report	<i>Choose only one</i> <input type="checkbox"/> Fully recovered <input type="checkbox"/> Fatal <input type="checkbox"/> Not yet recovered <input type="checkbox"/> Unknown <input type="checkbox"/> Residual effects (please describe under Supplementary Information)
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E. Medical Attention (Provide details in Supplementary Information)	<i>Check highest level of care required as a result of AEFI.</i> <input type="checkbox"/> None <input type="checkbox"/> Telephone advice from a health professional <input type="checkbox"/> Primary care visit <input type="checkbox"/> Emergency Room (describe under Supplementary Information) <input type="checkbox"/> Hospital admission date ___/___/___ Total hospital days _____ yyyy/mm/dd
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F. Medical History Prior to Onset of Adverse Event	<i>Check all applicable boxes and provide details in Supplementary Information section</i> <input type="checkbox"/> Medication(s) _____ <input type="checkbox"/> Acute Illness / Injury _____ <input type="checkbox"/> Known medical conditions/allergies _____
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G. Public health Recommendations (Provide additional information in the Supplementary Information section)	Name _____ Phone: _____ Signature _____ Date: (yyyy/mm/dd) _____ <i>Recommendations: (Check all that apply)</i> <input type="checkbox"/> Controlled setting for next immunization <input type="checkbox"/> No change to immunization schedule <input type="checkbox"/> Expert referral (specify) _____ <input type="checkbox"/> Active follow-up for AEFI recurrence after next vaccine <input type="checkbox"/> Determine protective antibody level <input type="checkbox"/> No further immunizations (specify) _____ <input type="checkbox"/> Other (specify) _____
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H: AEFI: Complete the event details section (1-5) that best describes the AEFI (can tick >1), and provide detail about fever, investigation, therapy and other information as appropriate in the Supplementary Information section of this form.
 Events marked with an asterisk (*) require a physician diagnosis. Attach supporting documentation.

1. LOCAL REACTION at or near injection site. Symptoms/ signs. Check all that applies.

Temporal characteristics	<i>Choose the single most appropriate period of time (either Min, Hrs, or Days)</i> <input checked="" type="checkbox"/> Time from immunization to 1st symptom/sign onset: ___ Min ___ Hrs ___ Days <input checked="" type="checkbox"/> Time from onset of 1st symptom/sign to resolution of all symptoms/signs: ___ Min ___ Hrs ___ Days
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| <input type="checkbox"/> Swelling - Severe <ul style="list-style-type: none"> o Extending past nearest joint(s) o Lasting fewer than 4 days o Lasting 4 days or more <input type="checkbox"/> Infected Abscess <ul style="list-style-type: none"> o Purulent discharge o Positive gram stain or culture o Erythema, o Resolution on antimicrobial therapy | <input type="checkbox"/> Pain - Severe <ul style="list-style-type: none"> o Lasting fewer than 4 days o Lasting 4 days or more <input type="checkbox"/> Sterile Abscess <ul style="list-style-type: none"> o Non-purulent fluid <input type="checkbox"/> Nodule <ul style="list-style-type: none"> o Discrete, well-demarcated, firm soft tissue mass or lump |
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2. ANAPHYLAXIS OR OTHER ALLERGIC REACTION: Choose the one that best fits the AEFI and provide details in Supplementary Information section.

Temporal characteristics	Choose the single most appropriate period of time (either Min, Hrs, or Days) <input type="checkbox"/> Time from immunization to 1st symptom/sign onset: <u> </u> Min <u> </u> Hrs <u> </u> Days <input type="checkbox"/> Time from onset of 1st symptom/sign to resolution of all symptoms/signs: <u> </u> Min <u> </u> Hrs <u> </u> Days
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- *Anaphylaxis:** Rapid onset and involving at least 2 body systems. Check all involved systems below and list specific symptoms/signs for each checked box in the Supplementary Information section.
 Dermatologic/Mucosal Cardiovascular Respiratory Gastrointestinal
- Other Allergic Reaction** Describe in Supplementary Information section

3. NEUROLOGIC REACTION: Check all applicable boxes; provide details in Supplementary Information section.

Temporal characteristics	Choose the single most appropriate period of time (either Min, Hrs, or Days) <input type="checkbox"/> Time from immunization to 1st symptom/sign onset: <u> </u> Min <u> </u> Hrs <u> </u> Days <input type="checkbox"/> Time from onset of 1st symptom/sign to resolution of all symptoms/signs: <u> </u> Min <u> </u> Hrs <u> </u> Days
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- *Encephalopathy / Encephalitis** Check all that apply. Add details in Supplementary Information section.
 - Depressed/altered level of consciousness, lethargy or personality change lasting for ≥24hrs
 - focal or multifocal neurologic sign(s)
 - CSF pleocytosis >5 wbc/mm³
 - EEG consistent with encephalitis
 - Brain pathology consistent with encephalitis
 - Fever ≥ 38.0C
 - Seizures (if present, provide details in seizure section below)
 - Neuroimaging consistent with encephalitis
- *Meningitis** Record symptoms and CSF results in Supplementary Information section.
- Seizure(s)** Check all that apply and provide a detailed description of the seizure in the Supplementary Information section (generalized, focal, or focal progressing to generalized; tonic, clonic, tonic-clonic or atonic motor manifestations; automatisms (e.g. drooling, lip smacking); loss of awareness (fixed stare, eye deviation, inability to communicate).
 - Sudden loss of consciousness -if ticked was it:
 - Witnessed by healthcare professional OR By report only
 - Associated with fever History of seizures before immunization: febrile afebrile unknown type
- *Guillain-Barré Syndrome** (Indicate in Supplementary Information section whether EMG and/or LP done. and results, as well as any other relevant investigation including tests to look for possible causes, especially Campylobacter)
- *Bell's Palsy**
- *Paralysis other than Bell's Palsy** Describe in Supplementary Information section.

4. OTHER DEFINED AEFIS OF INTEREST: Complete temporal characteristics, check all applicable boxes and provide any important additional details in Supplementary Information section.

Temporal characteristics	Choose the single most appropriate period of time (either Min, Hrs, or Days) <input type="checkbox"/> Time from immunization to 1st symptom/sign onset: <u> </u> Min <u> </u> Hrs <u> </u> Days <input type="checkbox"/> Time from onset of 1st symptom/sign to resolution of all symptoms/signs: <u> </u> Min <u> </u> Hrs <u> </u> Days
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- Hypotonic-Hyporesponsive Episode:** (NOTE: only if <2yrs old. If older, check "other severe or unusual event" and describe in Supplementary Information section) Check all that apply
 - Limpness Reduced responsiveness / unresponsiveness Pallor/Cyanosis
- Persistent Crying** (Crying which is continuous and unaltered for ≥ 3 hours)
- Rash** Generalized Localized at injection site Localized at non-injection site
- Arthritis** (joint pain lasting at least 24 hours). Check all that apply:
 - Joint swelling Joint redness
 - Sensation of warmth over joint Inflammatory changes in synovial fluid
- Thrombocytopenia:** Lowest platelet count
- Parotitis** (parotid gland swelling with pain and/or tenderness)
- Oculo-respiratory syndrome (ORS)** Bilateral red eyes AND at least one respiratory sign/symptom with or without facial edema, occurring within 24 hours of influenza vaccination

5. OTHER SEVERE OR UNUSUAL EVENT(S) NOT LISTED in 1-4 ABOVE Complete temporal characteristics below and describe the event in the Supplementary Information section.

Temporal characteristics	Choose the single most appropriate period of time (either Min, Hrs, or Days) <input type="checkbox"/> Time from immunization to 1st symptom/sign onset: <u> </u> Min <u> </u> Hrs <u> </u> Days <input type="checkbox"/> Time from onset of 1st symptom/sign to resolution of all symptoms/signs: <u> </u> Min <u> </u> Hrs <u> </u> Days
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SUPPLEMENTARY INFORMATION:

Please use additional pages if necessary