[redacted]

Adverse Event Following Immunization (AEFI)

panorama

Personal Details

Last Name: _____ **First Name:** _____ **Client ID:** _____

DOB (yyyy/mm/dd)**:** _____ **Gender:** _____ **Health Card No:** _____

Address: _____ **Phone No:** _____

_____

IMPACT Local Inventory Number (LIN): _____

Organization: _____ **SDL:** _____

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) Is of a serious nature, b) Requires urgent medical attention, c) Is an unusual or unexpected event

*Reporting Source

***Reporter:** **Date Reported:** _____

Setting: ☐ Physician Office ☐ Public Health ☐ Hospital ☐ Other_____

Provider who is in the index: ☐ Enter info below **Provider who is non-indexed:** ☐ Enter info below

***Last Name:** _____ ***First Name:** _____

***Email Address:** _____ ***Or Phone:** _____

***Address:** _____

City: _____ **Province/Territory:** _____

Postal Code: _____ **Professional Status:** _____

***Source of Information:** ☐ Same as Reporter ☐ Client ☐ Other

*Immunization Data

Selected Immunization: _____ **Immunization Date:** _____ **Dose #** ____ **Lot #** _____

Selected Immunization: _____ **Immunization Date:** _____ **Dose #** ____ **Lot #** _____

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*Information at Time of Immunization and AEFI Onset

Did an AEFI follow a previous dose o fany of the above immunizing agents?

☐ No ☐ No Prior Dose ☐ Unknown ☐ Yes (provide details)

Comments: _____

_____

_____

Did this AEFI follow an incorrect immunization?

☐ No ☐ Unknown ☐ Yes (If Yes, choose all that apply and provide details below)

☐ Given outside the recommended age limits ☐ Incorrect route ☐ Product expired
☐ Dose # exceeded that recommended for age ☐ Wrong vaccine given ☐ Other, specify

Comments: _____

_____

Client ID: _____

Medical history (up to the time of AEFI onset): (check all that apply and provide details for each.)

☐ Concomitant medication(s) ☐ Known medical conditions/allergies ☐ Acute illness/injury

Comments: _____

_____

_____

*AEFI Details

Local reaction at or near injection site

***Onset:** mins _____ hours _____ days _____

***Duration:** Mins _____ hours _____ days _____ ☐ Unresolved

☐ Infected abscess ☐ Sterile abscess ☐ Cellulitis ☐ Nodule ☐ Reaction crosses joint ☐ Lymphadenitis ☐ Other, specify

Comments: _____

_____

_____

For any injection site reaction indicated above, check all that apply below and provide details in the comments area in this section:

☐ Swelling ☐ Pain ☐ Tenderness ☐ Erythema ☐ Warmth

☐ Induration ☐ Rash ☐ Largest diameter of injection site reaction (cm):_____ ☐ Site(s) of reaction _____ ☐ Palpable fluctuance

☐ Fluid collection shown by imaging technique (e.g. MRI, CT, ultrasound) ☐ Spontaneous/surgical drainage ☐ Microbial results ☐ Lymphangitic streaking ☐ Regional lymphadenopathy

Comments: _____

_____

_____

Anaphylaxis or Other allergic events:

☐ Anaphylaxis ☐ Other allergic events

***Onset:** mins _____ hours _____ days _____

***Duration:** Mins _____ hours _____ days _____ ☐ Unresolved

☐ **Skin/Mucosal**

❍ **GENERALIZED**

☐ At injection site ☐ Non-injection site ☐ Urticaria

☐ Pruritus ☐ Prickle sensation ☐ Erythema

❍ **LOCALIZED**

☐ At injection site ☐ Non-injection site ☐ Urticaria

☐ Pruritus ☐ Prickle sensation ☐ Erythema

❍ **EYES**

☐ Red ☐ Itchy

❍ **ANGIOEDEMA**

☐ Tongue ☐ Throat ☐ Uvula ☐ Larynx

☐ Lip ☐ Eyelids ☐ Limbs ☐ Other, specify_____

Client ID: _____

☐ **Cardio-vascular** ☐ Measured hypotension ☐ Decreased central pulse volume ☐ Capillary refill time > 3sec
☐ Decreased or loss of consciousness ☐ Tachycardia

☐ **Respiratory** ☐ Sneezing ☐ Rhinorrhea ☐ Hoarse voice ☐ Sensation of throat closure
☐ Stridor ☐ Dry cough ☐ Tachypnea ☐ Wheezing
☐ Indrawing/retractions ☐ Grunting ☐ Cyanosis

☐ **Gastro intestinal** ☐ Diarrhea ☐ Abdominal pain ☐ Nausea ☐ Vomiting

Comments: _____

_____

_____

Neurologic event

***Onset:** mins _____ hours _____ days _____

***Duration:** Mins _____ hours _____ days _____ ☐ Unresolved

☐ **Seizure(s)** (check all that apply)

☐ Witnessed by healthcare professional ❍ Yes ❍ No ❍ Unknown
☐ Sudden loss of consciousness ❍ Yes ❍ No ❍ Unknown
❍ Focal ❍ Tonic ❍ Clonic ❍ Tonic-Clonic ❍ Atonic
❍ Generalized ❍ Tonic ❍ Clonic ❍ Tonic-Clonic ❍ Atonic
☐ Previous history of seizures ❍ Febrile ❍ Afebrile ❍ Unknown type

☐ **> Meningitis** *This must be diagnosed by a physician*

☐ **> Encephalopathy/Encephalitis** *This must be diagnosed by a physician*

☐ **> Guillain-Barre Syndrome (GBS)** *This must be diagnosed by a physician*

☐ **> Bell's Palsy** *This must be diagnosed by a physician*

☐ **> Other Paralysis** *This must be diagnosed by a physician*

☐ **> Other neurologic diagnosis, specify** _____ *This must be diagnosed by a physician*

For any neurologic event indicated above, check all that apply below and provide details in the comments area in this section:

☐ Depressed/altered level of consciousness, lethargy or personality change lasting >= 24hrs
☐ Focal or multifocal neurologic sign(s)
☐ Fever (>=38.0C)
☐ CSF abnormality
☐ EEG abnormality
☐ EMG abnormality
☐ Neuroimaging abnormality
☐ Brain/spinal cord histopathologic abnormality

Comments: _____

Other defined events of interest

***Onset:** mins _____ hours _____ days _____

***Duration:** Mins _____ hours _____ days _____ ☐ Unresolved

☐ **Hypotonic-Hyporesponsive Episode (age<2 years)**

☐ Limpness ☐ Pallor/cyanosis ☐ Reduced responsiveness/unresponsiveness

☐ **Persistent crying (crying which is continuous and unaltered for >= 3hrs)**

☐ **Rash (for Rash at injection site or Rash in allergic reaction, use other section)**

❍ Generalized ❍ Localized at non-injection site

☐ **> Intussusception**

☐ **Arthritis (check all that apply)**

☐ Joint redness ☐ Joint warm to touch ☐ Joint swelling ☐ Inflammatory changes in synovial fluid

☐ **Parotitis (Parotid gland swelling with pain and/or tenderness)**

Client ID: _____

☐ **> Thrombocytopenia**

☐ Clinical evidence of bleeding ☐ Platelet count <150 x 10^9/L

☐ **Oculo-Respiratory Syndrome (ORS) (Note: this is different from allergic/respiratorysymptoms)**

☐ Bilateral red eyes ☐ Cough ☐ Wheeze ☐ Sore throat

☐ Difficulty swallowing ☐ Difficulty breathing ☐ Chest tightness ☐ Hoarseness

☐ Facial swelling

☐ **Fever >= 38.0C**

☐ **Other severe events not listed above**

Comments: _____

Impact of AEFI, Outcome and level of care

Highest impact of AEFI: ☐ Did not interfere with daily activities ☐ Interfered with but did not prevent daily activities ☐ Prevented Daily activities

Outcome at time of report: ☐ Fatal: Date of death:_____ ☐ Fully recovered ☐ Not yet recovered

☐ Permanent Disability/Incapacity ☐ Unknown

Medical Attention

Highest level of care required: ☐ Admitted to hospital ☐ Emergency visit ☐ Non urgent visit to a health professional ☐ None

☐ Resulted in prolongation of existing hospitalization ☐ Telephone advice from a health professional ☐ Unknown

Complete below where applicable:

Date of admission _____ **Date of discharge** _____

Days spent in hospital due to adverse event _____

Treatment received: ☐ No ☐ Unknown ☐ Yes (provide details of all treatments, including self treatment)

Comments: _____

Public Health Recommendations

AEFI Status: ☐ Submitted for review ☐ Review complete **Last Review Date:** _____ **Eligible for reporting to PHAC:** ☐

Reviewer ☐ On behalf of Health Service Provider **Provider Name:** _____

Public Health Recommendations ☐ No change to immunization schedule ☐ Expert referral, specify

☐ Determine protective antibody level ☐ Controlled setting for next immunization

☐ No further immunizations, specify ☐ Active follow-up for AEFI recurrence after next vaccine

☐ Other, specify ☐ No recommendations

Comments: _____

Document Management

File name: _____ **Document Title:** _____

Effective Date: _____ **Status:** _____