BC Centre for Disease Control
Provincial Health Services Authority

ADVERSE EVENT FOLLOWING IMMUNIZATION (AEFI) CASE REPORT

INSTRUCTIONS

- Complete this reporting form for AEFI listed in the BC Immunization Manual, Part 5 - Section 6. Summary of Reporting Criteria in a vaccine recipient. Reported AEFI should occur after immunization, and should not be clearly attributed to other causes. A causal relationship to vaccine or immunization need not be proven.
- Public health staff: Report using Panorama (PARIS in VCH).
- Community vaccine providers: Submit the completed form to local public health. Complete all pertinent fields except for Section G & H. Submit the form as indicated here.
- For additional information on reporting criteria, clinical management and interpretation of AEFIs, as well as implications for subsequent immunization, please refer to BC Immunization Manual, Part 5 – Adverse Events Following Immunization.

REPORTING TIPS

Refer to the User Guide for Completion and Submission of AEFI Reports for full instructions.

REPORTER INFORMATION

Health Authority
◯ FHA ◯ IHA ◯ NHA ◯ VCH ◯ VIHA ◯ PHSA ◯ FNHA

Setting ◯ Physician office ◯ Hospital ◯ Health authority workplace health ◯ Public health ◯ Pharmacy ◯ Other (specify)

Last Name	First Name	Phone Number (including area code) Ext.

Email Address	Fax Number (including area code)

Address (including Unit Number, Street Number, and Street Name)	Province/Territory	Postal Code

Branch Office (if applicable)

Signature ◯ MD ◯ RN ◯ IMPACT ◯ Pharmacist ◯ Other (specify)

Date Reported (YYYY / MM / DD)	Reported to public health unit by
	◯ Reporter ◯ Client ◯ Other, ***complete Section A***

Reporter is the health care provider who received and reported the AEFI information to the public health unit.

A. SOURCE OF INFORMATION

Only complete Section A if "Other" is selected for "Reported to public health unit by"

Last Name	First Name	Phone Number (including area code) Ext.

Email Address	Relationship to Client

Address (including Unit Number, Street Number, and Street Name)	Province/Territory	Postal Code

Source of information can be the same as reporter, the client, or a secondary source such as a parent/guardian.

B. CLIENT INFORMATION

Last Name	First Name	Middle Name(s)

Date of Birth (YYYY / MM / DD)	Gender	Health Card Number (PHN)
	◯ Male ◯ Female ◯ Transgender ◯ Unknown	

Phone Number(s) (include area code, and extension if applicable)	Alternate Name(s) (if applicable)

Address (including Unit Number, Street Number, and Street Name)	Province/Territory	Postal Code

Country of Residence (if not Canada)

ADVERSE EVENT ID	IMPACT LIN	PARIS ID

Adverse event ID and PARIS ID are system generated IDs, not reportable to local public health.

Enter IMPACT Local Inventory Number if the report was received from IMPACT; otherwise leave it blank.

Patient's Physician (or Primary Care Provider)

Last Name	First Name	Phone Number (including area code) Ext.

Address (including Unit Number, Street Number, and Street Name)	Province/Territory	Postal Code

C. IMMUNIZATION DATA

Date Vaccine Administered^ (YYYY / MM / DD)	Immunizing Agent	Trade Name	Manufacturer	Lot Number	Dose Number	Dosage/ Unit	Route	Site

^Date of vaccine administered should be the same for all vaccines associated with a single AEFI report.

Name of Health Care Provider who administered the vaccine

Phone Number (including area code) Ext.

Address

Province/Territory

Postal Code

D. INFORMATION AT TIME OF IMMUNIZATION AND AEFI ONSET

Breastfeeding at time of immunization ‡

◯ No ◯ Unknown ◯ Yes

Pregnant at time of immunization

◯ No ◯ Unknown ◯ Yes

‡Refers to whether the adult for whom the AEFI is being reported was lactating/ breastfeeding a child at the time of immunization.

Did an AEFI follow a previous dose of any of the above immunizing agents listed in section C?

◯ No ◯ No Prior Doses ◯ Unknown ◯ Yes (if Yes, provide details below)

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 ☐ Product expired ☐ Dose exceeded that recommended for age

☐ Wrong vaccine given ☐ Incorrect route ☐ Other, specify

Comments

Medical history (up to time of AEFI onset) Check all that apply and provide details below.

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

☐ No known medical condition(s) ☐ Unknown at time of report

Comments

E. AEFI DETAILS

Complete all sections as appropriate. For each event 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 I for additional information including clinical details and test results.

E1. Local Reaction at or Near Injection Site

Onset - from immunization to onset of 1st symptom/sign

_____ Min. or _____ Hrs. or _____ Days

Duration - from 1st symptom/sign to resolution of all symptoms/signs

_____ Min. or _____ Hrs. or _____ Days ☐ Unresolved

☐ Infected abscess* ☐ Sterile abscess* ☐ Cellulitis* ☐ Nodule ☐ Reaction stretches joint-to-joint ☐ Rash

☐ Pain or redness or swelling extends past the nearest joint ☐ Adenopathy/Lymphadenitis*

☐ Pain or redness or swelling persisting for 10 days or more ☐ Other, specify:

Select applicable local reaction(s) before selecting symptoms/signs on the following page.

For tips on where to report rash see Section L.

Local reaction section continues on the next page.

E. AEFI DETAILS *continued*

E1. Local Reaction at or Near Injection Site *continued*

If an injection site reaction is reported on page 2, check all symptoms/signs that apply and provide details below.

☐ Swelling ☐ Pain ☐ Tenderness ☐ Erythema ☐ Warmth ☐ Induration

Largest diameter of vaccination site reaction _____ cm Site(s) of reaction (e.g., LA, RA) _____

☐ Palpable fluctuance ☐ Fluid collection show by imaging technique (e.g., MRI, CT, ultrasound)

☐ Spontaneous/surgical drainage ☐ Microbial results (specify) ☐ Lymphangitic streaking ☐ Regional lymphadenopathy

Only select local signs/ symptoms if one or more local reaction is reported.

Specify Microbial results in comment box.

Comments

E2. Anaphylaxis and Other Allergic Events

Onset - from immunization to onset of 1st symptom/sign

_____ Min. or _____ Hrs. or _____ Days

Duration - from 1st symptom/sign to resolution of all symptoms/signs

_____ Min. or _____ Hrs. or _____ Days ☐ Unresolved

☐ Anaphylaxis ☐ Oculo-Respiratory Syndrome (ORS) ☐ Other allergic events

☐ Epinephrine administered

For the event indicated above, select all symptoms/signs that apply and provide details in comments below.

Skin/mucosal	☐ **Generalized**	☐ At injection site	☐ Non-injection site	☐ Urticaria	☐ Erythema	
		☐ Pruritus	☐ Prickle sensation	☐ Rash		
	☐ **Localized**	☐ At injection site	☐ Non-injection site	☐ Urticaria	☐ Erythema	
		☐ Pruritus	☐ Prickle sensation	☐ Rash		
	☐ **Eyes**	☐ Red bilateral	☐ Red unilateral	☐ Itchy		
	☐ **Angioedema**	☐ Tongue	☐ Throat	☐ Uvula	☐ Larynx	☐ Lip
		☐ Eyelids	☐ Face	☐ Limbs	☐ Reported sensation of swelling	
		☐ Visible swelling	☐ Other, specify:			
Cardiovascular	☐ Measured hypotension	☐ ↓ central pulse volume	☐ Capillary refill time >3 sec			
	☐ Tachycardia	☐ ↓ or loss of consciousness				
Respiratory	☐ Sneezing	☐ Rhinorrhea	☐ Hoarse voice	☐ Sensation of throat closure	☐ Stridor	
	☐ Dry cough	☐ Tachypnea	☐ Wheezing	☐ Increased use of accessory muscles		
	☐ Grunting	☐ Cyanosis	☐ Sore throat	☐ Indrawing/retractions		
	☐ Difficulty swallowing		☐ Chest tightness	☐ Difficulty breathing		
Gastrointestinal	☐ Diarrhea	☐ Abdominal pain	☐ Nausea	☐ Vomiting		
Laboratory	☐ Mast cell tryptase elevation > upper normal limit					

Choose allergic signs/ symptoms only if an allergic event (anaphylaxis, ORS, or Other allergic events) is being reported.

If a client only reports GI symptoms that are not allergic in nature, report in the appropriate event in the "Other event" section.

For tips on where to report rash see Section L.

Comments

Inform the person on whom this information is being collected that we are collecting your personal information under the authority of sections 26 (c) and (e) of the BC *Freedom of Information and Protection of Privacy Act* ("FIPPA"). The information you provide to us will be used for public health surveillance purposes. Questions regarding the collection of your personal information or requests for records may be directed to the Information Access Privacy office that supports BCCDC at privacyandfoi@phsa.ca or 604.707.5833.

E. AEFI DETAILS *continued*

E3. Neurologic Event

Onset - from immunization to onset of 1st symptom/sign

_____ Min. or _____ Hrs. or _____ Days

Duration - from 1st symptom/sign to resolution of all symptoms/signs

_____ Min. or _____ Hrs. or _____ Days ☐ Unresolved

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

☐ Febrile ☐ Afebrile ☐ Unknown type

☐ Focal/Partial

or

☐ Generalized, *specify:* ☐ Tonic ☐ Clonic ☐ Tonic-clonic ☐ Atonic ☐ Myoclonic ☐ Absence

☐ Witnessed by health care professional: ◯ Yes ◯ No ◯ Unknown

☐ Sudden loss of consciousness: ◯ Yes ◯ No ◯ Unknown

☐ Previous history of seizures: ◯ Febrile ◯ Afebrile ◯ Unknown type

☐ **Anaesthesia/Paraesthesia (check all that apply)**

◯ Generalized OR ◯ Localized

☐ Numbness ☐ Tingling ☐ Burning ☐ Formication ☐ Other, specify:

☐ **Meningitis*** ☐ **Encephalopathy/Encephalitis*** ☐ **Guillain-Barre Syndrome (GBS)*** ☐ **Bell's Palsy***

☐ **Myelitis/Transverse myelitis*** ☐ **Other paralysis*** ☐ **Other neurological diagnosis*, specify:**

☐ **Subacute sclerosing panencephalitis**

For any neurological event indicated above, check all that apply and provide details in comments below.

☐ Depressed/altered level of consciousness/Lethargy/ Personality change lasting ≥24 hrs

☐ Focal or multifocal neurologic sign(s) ☐ Fever (≥38°C) ☐ CSF abnormality ☐ EEG abnormality

☐ EMG abnormality ☐ Neuroimaging abnormality ☐ Brain/spinal cord histopathologic abnormality

Item(s) with asterisk (*) should be diagnosed by a physician.

Select the appropriate neurological event, before choosing corresponding descriptors.

Report "ADEM or SSPE" as "Other neurological diagnosis, specify".

Report Vaccine-associated Paralytic Poliomyelitis as "Other paralysis".

Comments

E4. Other Defined Events of Interest

Onset - from immunization to onset of 1st symptom/sign

_____ Min. or _____ Hrs. or _____ Days

Duration - from 1st symptom/sign to resolution of all symptoms/signs

_____ Min. or _____ Hrs. or _____ Days ☐ Unresolved

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

☐ Limpness ☐ Pallor/cyanosis

☐ Reduced responsiveness/unresponsiveness

☐ **Persistent crying** (continuous and unaltered crying for ≥3 hours)

☐ **Rash** (Refer to Immunization Manual, Part 5 for reporting criteria. For rash at injection site or rash in allergic reaction, use sections above.)

☐ Generalized ☐ Localized at non-injection site

☐ **Intussusception***

☐ **Hematochezia***

☐ **Arthritis***

☐ Joint redness ☐ Joint warm to touch ☐ Joint swelling

☐ Inflammatory changes in synovial fluid

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

☐ **Orchitis***

☐ **Kawasaki disease***

☐ **Thrombocytopenia***

☐ Platelet count <150×109/L ☐ Petechial rash

☐ Other clinical evidence of bleeding

☐ **Thrombosis***

☐ **Thromboembolism***

☐ **Fever ≥38°C** (Report only if fever occurs in conjunction with reportable event. For a neurological event use section above.)

☐ **Syncope with injury**

☐ **Severe vomiting**

☐ **Severe diarrhea**

☐ **Myocarditis and/or Pericarditis***

☐ **Other serious or unexpected event(s) not listed above** (Specify and provide details in comments below)

Item(s) with asterisk (*) should be diagnosed by a physician.

Comments

F. IMPACT OF AEFI, OUTCOME AND LEVEL OF CARE OBTAINED

Highest impact of AEFI (Choose one of the following):

◯ Did not interfere with daily activities ◯ Interfered but did not prevent daily activities ◯ Prevented daily activities

Outcome at time of report (Choose one of the following): YYYY / MM / DD

◯ Permanent disability/incapacity ◯ Not yet recovered ◯ Fully recovered ◯ Unknown ◯ Death (specify date):

Highest level of care obtained (Choose one of the following):
(Report assessment in an emergency room setting without formal admission to hospital as "Emergency Visit".)

◯ Emergency visit ◯ Non-urgent visit ◯ Telephone advice from a health professional ◯ None ◯ Unknown

◯ Admitted to Hospital (_____ days) ◯ Resulted in prolongation of existing hospitalization (by _____ days)

Hospital Name	Hospital Admission Date (YYYY / MM / DD)	Hospital Discharge Date (YYYY / MM / DD)

Treatment received (If Yes, provide details of treatment, including self-treatment)

◯ No ◯ Unknown ◯ Yes

G. REPORTABILITY – *FOR PUBLIC HEALTH USE ONLY*

Does the event reported meet reporting criteria? (See Section J)

◯ Yes (enter as an AEFI) ◯ No (do not enter as an AEFI. If AEFI report was previously started in the public health information system, set status to "Does not meet reporting criteria")

H. PUBLIC HEALTH RECOMMENDATIONS – *FOR PUBLIC HEALTH USE ONLY (Provide comments; use Section I if extra space needed)*

☐ No change to immunization schedule
☐ Determine protective antibody level (specify)
☐ No further immunizations (specify)
☐ Expert referral (specify)
☐ Controlled setting for next immunization (specify)
☐ Active follow up for AEFI recurrence after next vaccine (specify)
☐ Other (specify)
☐ No recommendations (specify)

Comments

Name of MOH or Designate making the recommendation	Professional Status ◯ MOH/MHO ◯ MD ◯ RN ◯ Other (specify)

Phone (including area code)	Date (YYYY / MM / DD)	**Signature**

Send a copy to

☐ BCCDC ☐ Client's Physician ☐ Other (specify)

I. SUPPLEMENTARY INFORMATION

Please indicate the section letter when providing details. Provide details of any investigation or treatment for the recorded AEFI. Provide sufficient information to support the selected item(s). Append information on additional pages if required.

Section	Comments

Save Print Clear Form

J. ADVERSE EVENTS FOLLOWING IMMUNIZATION – REPORTABILITY

Reportable: Any event listed in the BC Immunization Manual, Part 5 - Section 6. Summary of Reporting Criteria in a vaccine recipient which follows immunization that cannot be clearly attributed to other causes. A causal relationship with the administration of the vaccine does not need to be proven.

Does not meet reporting criteria: Any event which follows immunization that has been clearly attributed to other causes **OR** does not meet reporting criteria (e.g., not serious such as mild vomiting or diarrhea, temporal relationship incompatible with association with vaccine receipt).

K. ADVERSE EVENTS FOLLOWING IMMUNIZATION – TEMPORAL CRITERIA

The length of time between vaccine administration and onset of symptoms is an important consideration in causality assessment. Temporal criteria guidelines in this table are generally agreed upon approximate timelines.

Reaction Type	Adverse Event Following Immunization	Temporal Criteria	
		Inactivated Vaccines	Live Attenuated Vaccines
Local Reactions at Injection Site	Infected Abscess	0-7 days	
	Sterile Abscess	0-7 days	
	Cellulitis	0-7 days	
	Nodule	0-7 days	
	Pain or Redness or Swelling	0-48 hours	
Systemic Reactions	Adenopathy/Lymphadenopathy	0-7 days	MMR: 5 - 30 days; Varicella: 5 - 42 days
	Fever	Timing in conjunction with other reportable adverse events	
	Hypotonic-Hyporesponsive Episode (HHE)	0-48 hours	
	Parotitis	Not applicable	MMR: 5-30 days
	Orchitis	Not applicable	MMR: 5-30 days
	Rash	0-7 days	MMR: 0 - 30 days; Varicella: 0 - 42 days
	Screaming/Persistent crying	0-72 hours	
	Severe Vomiting/Diarrhea	0-72 hours	0-72 hours; 0-7days for Rotavirus vaccines
Allergic Reactions	Anaphylaxis	0-24 hours	
	Oculo-respiratory Syndrome (ORS)	0-24 hours	
	Other Allergic Reactions	0-48 hours	
Neurological Events	Anaesthesia/Paraesthesia	0-15 days	MMR: 0 - 30 days; Varicella: 0 - 42 days
	Bell's Palsy	0-3 months	
	Convulsion/Seizure	0-72 hours	MMR: 5 - 30 days; Varicella: 5 - 42 days
	Encephalopathy/Encephalitis, Myelitis/Transverse myelitis or Acute Disseminated Encephalomyelitis (ADEM)	0-42 days	MMR: 5 - 30 days; Varicella: 5 - 42 days
	Guillain-Barré syndrome (GBS)	0-56 days	
	Meningitis	Not applicable	MMR: 5 - 30 days; Varicella: 5 - 42 days
	Paralysis	Not applicable	OPV: 5 - 30 days; Varicella: 5 - 42 days
Other Events of Interest	Arthritis	0-30 days	MMR: 5 - 30 days; Varicella: 5 - 42 days
	Kawasaki disease	0-15 days	
	Intussusception or Hematochezia	Not applicable	Rotavirus: 0 - 42 days
	Thrombocytopenia	0-30 days	
	Thrombosis/Thromboembolism	0-37 days	
	Syncope with injury	0-30 minutes	
	Myocarditis and/or Pericarditis	0-21 days	
	Other severe or unusual	A temporal association to immunization and for which there is no other known cause and not covered under the other categories	

L. RASH REPORTING TIPS

Localized rash at the injection site: Local reaction at or near injection site > Rash > Select details that apply > Specify any additional details in local comments.

Localized allergic rash: Anaphylaxis and other allergic events > Skin/mucosal > Localized > Select "At injection site" or "Non-injection site"> Select "Rash" > Specify details in allergic comments.

Generalized allergic rash: Anaphylaxis and other allergic events > Skin/mucosal > Generalized > Select "At injection site" and/or "Non-injection site" > Select "Rash" > Specify details in allergic comments.

Generalized rash: Other defined events of interest > Rash > Generalized > Specify details in other comments.

Localized rash at non-injection site: Other defined events of interest > Rash > Localized at non-injection site > Specify details in other comments.

NOTE: Additional relevant training materials and data standards are available on the Panorama SharePoint (https://phsa.sp.gov.bc.ca/sites/PPHIS) (login required).