BC Centre for Disease Control
Provincial Health Services Authority

Adverse Event Following Immunization (AEFI)
Case Report Form

INSTRUCTIONS

- **Complete this reporting form for AEFIs 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.**
- **Public health staff: Enter into the public health information system used for AEFI in your region.**
- **Community vaccine providers: Submit the completed form to local public health. Complete all pertinent fields except for Section G & H. See the AEFI reporting map here for instructions on where to send the form according to health authority.**
- **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 Public health Hospital Pharmacy Health authority workplace health

Other, *specify:*

Name: *Last First*	Phone Number: ( ) - ext.
Email:	Fax Number ( ) -
Address:	Branch Office: *(if applicable)*
Province/Territory:	Postal code:
Date reported: *YYYY / MM / DD*	
Signature:	MD RN IMPACT Pharmacist Other, *specify:*
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" selected for "Reported to public health unit by"

Name: *Last First*	Phone Number: ( ) - ext.
Email:	Relationship to client:
Address: *Unit # Street # Street Name City*	
Postal Code:	Province:

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

B. CLIENT INFORMATION

Name: *Last First Middle*	
Date of Birth: *YYYY / MM / DD*	Gender: Male Female Transgender Unknown

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Health Card Number:	Alternate Name(s):	
Phone Number (home/work/mobile): ( ) - ext.		
Address: *Unit # Street # Street Name City*		
Postal Code:	Province:	Country of Residence (*if not Canada*):
ADVERSE EVENT ID:	IMPACT LIN:	PARIS ID:
PATIENT'S PHYSICIAN (OR PRIMARY CARE PROVIDER)		
Name: *Last First*	Phone Number ( ) - Ext.	
Address:		

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.

C. IMMUNIZATION DATA

Date vaccine administered^ *YYYY/MM/DD*	Immunizing agent	Trade name	Manufacturer	Lot number	Dose #	Dosage/ unit	Route	Site

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

Health Care Provider who administered the vaccine:	Phone:
Address: *Unit # Street # Street Name City*	

D. INFORMATION AT TIME OF IMMUNIZATION AND AEFI ONSET

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

No Not applicable (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 conditions(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: ___ Min. *or* __ Hrs. *or* __ Days from immunization to onset of 1st symptom/sign

Duration: ___ Min. *or* __ Hrs. *or* __ Days from 1st symptom/sign to resolution of all symptoms/signs Unresolved

Infected abscess*	Sterile abscess*	Cellulitis*	Nodule	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 above, 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 shown by imaging technique (e.g., MRI, CT, ultrasound)		
Spontaneous/surgical drainage	Microbial results, *specify*	Lymphangitic streaking	Regional lymphadenopathy

Comments:

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

Specify Microbial results in comment box.

E2. Anaphylaxis and other allergic events

Onset: ____ Min. *or* __ Hrs. *or* __ Days from immunization to onset of 1st symptom/sign

Duration: ____ Min. *or* __ Hrs. *or* __ Days from 1st symptom/sign to resolution of all symptoms/signs Unresolved

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

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	Prickly sensation	Rash		
	Localized:	At injection site	Non-injection site	Urticaria	Erythema	
		Pruritus	Prickly sensation	Rash		
	Eye(s):	Red bilateral	Red unilateral	Itchy		
	Angioedema:	Tongue	Throat	Uvula	Larynx	Lip
		Eyelids	Face	Limbs	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					

Comments:

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.

E. AEFI DETAILS *continued*

E3. Neurologic event

Onset: ____ Min. *or* __ Hrs. *or* __ Days from immunization to onset of 1st symptom/sign

Duration: ____ Min. *or* __ Hrs. *or* __ Days from 1st symptom/sign to resolution of all symptoms/signs Unresolved

Seizure(s) ***(Check all that apply):***

Febrile Afebrile Unknown type

Focal
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***

Other paralysis* **Other neurological diagnosis*, *specify:***

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

Comments:

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

Select the appropriate neurological event, before choosing corresponding descriptors.

Report "Myelitis/ Transverse myelitis, ADEM or SSPE" as "Other neurological diagnosis, specify".

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

E4. Other defined events of interest

Onset: ___ Min. *or* __ Hrs. *or* __ Days from immunization to onset of 1st symptom/sign

Duration: ___ Min. *or* __ Hrs. *or* __ Days from 1st symptom/sign to resolution of all symptoms/ signs 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*:

Item(s) with

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

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

Orchitis*

Thrombocytopenia*:

Platelet count <150×10⁹/L Petechial rash Other clinical evidence of bleeding

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

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

Comments:

asterisk (*) should be diagnosed by a physician.

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):*

Permanent disability/incapacity Fully recovered

Not yet recovered Unknown

Death; *specify date:*

YYYY/MM/DD

Highest level of care obtained *(Choose one of the following):*

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

Admitted to Hospital (days) **OR** Resulted in prolongation of existing hospitalization (by days)

Hospital name:

Hospital admission date: *YYYY / MM / DD* Hospital discharge date: *YYYY / MM / DD*

Report assessment in an emergency room setting without formal admission to hospital as "Emergency Visit".

Treatment received: No Unknown Yes

Provide details of treatment, including self-treatment:

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"*

For public health use only.

H. PUBLIC HEALTH RECOMMENDATIONS *(Provide comments. Use section I if extra space is required.)* ***FOR PUBLIC HEALTH USE ONLY***

No change to immunization schedule	Expert referral, *specify*	**For public health use only.**
Determine protective antibody level, *specify*	Controlled setting for next immunization, *specify*	Provide name of MOH or designate making the recommendation.
No further immunizations, *specify*	Active follow up for AEFI recurrence after next vaccine, *specify*	
Other, *specify*	No recommendations	
Comments:		

Name: Phone: ( ) -	Professional status: MOH/MHO MD RN Other, *specify*: Date *YYYY / MM / DD*	**Signature:**
Send a copy to: BCCDC Client's Physician Other:		

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	

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	Infected Abscess	0-7 days	
	Sterile Abscess	0-7 days	
	Cellulitis	0-7 days	

Injection Site	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	Rotavirus: 0-7 days
Allergic Reactions	Anaphylaxis	0-24 hours	
	Oculo-respiratory Syndrome (ORS)	0-24 hours	
	Other Allergic Reactions	0-48 hours	
Neurological Events	Anaesthesia/Paraethesia	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 or Encephalitis or Acute Disseminated Encephalomyelitis (ADEM)	0-42 days	MMR: 5 - 30 days Varicella: 5 - 42 days
	Guillain-Barré syndrome (GBS)	0-8 weeks	
	Meningitis	0-15 days	MMR: 5 - 30 days Varicella: 5 - 42 days
	Subacute sclerosing panencephalitis (SSPE)	Not applicable	Up to 10 years following a measles-containing vaccine
	Paralysis	0-15 days	OPV: 5 - 30 days Varicella: 5-42 days
Other Events of Interest	Arthritis	0-30 days	MMR: 5 - 30 days Varicella: 0 - 42 days
	Intussusception or Haematochezia	Not applicable	Rotavirus: 0-42 days
	Syncope with injury	0-30 minutes	
	Thrombocytopenia	0-30 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).