User Guide for Completion and Submission of Adverse Events Following Immunization (AEFI) Reports

Last updated February 5, 2025

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1. Purpose

This user guide is intended to be used as a reference by community vaccine providers and public health providers who report an Adverse Event Following Immunization (AEFI) in BC using the AEFI case report form or the Panorama AEFI form. This guide complements the Panorama Reference Guide – Immunization, AEFI, which provides step-by-step instructions on moving through the Panorama AEFI reporting screens from an information systems perspective. *In this guide, some Panorama specific guidance is provided in italics.*

For additional information on reporting criteria, clinical management and interpretation of AEFIs, and implications for subsequent immunization, refer to BC Communicable Disease Control Manual, Chapter 2, Immunization, Part 5 AEFI.

2. Reporting Adverse Events Following Immunization (AEFI)

As of January 1, 2019, a health professional who is aware of an adverse event following immunization must report the event to the medical health officer as per the Reporting Information Affecting Public Health Regulation, Part 2, Division 1, Section 5 of the Public Health Act.

Events that **must be reported** are outlined in BC Communicable Disease Control Manual, Chapter 2, Immunization, Part 5 AEFI.

Adverse events associated with non-vaccine pharmaceuticals:

The BC AEFI case report form and Panorama AEFI form have been designed specifically for recording and reporting of adverse events following receipt of vaccines (active immunizing agents) to the province. Adverse events related to passive immunizing agents (immunoglobulins) and TB skin tests (Tuberculin Purified Protein Derivative – Mantoux - Tubersol™) should be reported to Health Canada.

If an adverse event occurs in an individual who received both vaccine and a passive immunizing agent or TB skin test, and the health care provider is uncertain about which product was causally associated with the event, the event should be reported both as a vaccine-related AEFI and as an adverse drug reaction to the Canada Vigilance Program using the Side Effect Reporting Form (online/fillable PDF) at Health Canada. When reporting the AEFI, include details of the concomitant TB skin test or immunoglobulins as concomitant medication(s) in the medical history section of the AEFI form. For users of the BC Patient Safety and Learning System (BCPSLS), adverse reactions to medications other than immunizations should be reported in the BCPSLS. BCPSLS is a system that collects adverse patient events, including adverse drug reactions, which are reviewed and forwarded to Health Canada on behalf of the health authorities.

3. General Fields

Adverse Event ID

A unique episode number is assigned to each AEFI report in Panorama. *AEFI reports entered in Panorama automatically receive a system generated identifier labelled the "Adverse Event ID".*

Unique Episode Number – Panorama only

Do not use. The unique episode number should be left blank.

Pediatrics Surveillance Reference Number 'Pediatrics Surveillance Ref# (SPRINT-KIDS ID)'– For AEFIs received from SPRINT-KIDS only

Unique identifier assigned to a client identified as an AEFI through the SPRINT-KIDS team at BC Children's Hospital. Provide this number if the report was received from SPRINT-KIDS; otherwise leave blank. The number is used by the Public Health Agency of Canada to reconcile reports received both from the province and from SPRINT-KIDS directly.

Client address – Case Report Form or *Health Region – Panorama only*

Enter the client address of residence. Address of residence is used to determine the public health unit responsible for management, follow-up, and reporting of the AEFI.

The AEFI health region should usually correspond to where the client resides. The branch office selected should be the branch office responsible for the management/ follow up and reporting of the adverse event. This will usually correspond with the branch office associated with the address of residence of the client.

By default, the value in this field is the branch office corresponding to that of the logged-in Panorama user. The branch office should be changed from the default selection if the branch office of the logged in user differs from the branch office responsible for the management/ follow up and reporting of the adverse event.

Refer to "[Procedures for reporting Adverse Events Following Immunization (AEFI) when the Province/Territory (P/T) of residence, administration of vaccine and/or occurrence of AEFI differ](#)" standard operation procedure (SOP) resource for AEFIs that occur outside P/T of residence and/or immunization administration.

AEFIs for inmates in Federal Correctional Facilities should be reported to local health authorities and will follow the same reporting workflow as other AEFIs reported by local health authorities.

Service Delivery Location – Panorama only

By default, the value in this field is the SDL corresponding to that of the logged-in Panorama user. The SDL should reflect the branch office responsible for the management/ follow up and reporting of the adverse event.

AEFI Report Status – Panorama only

Indicates the status of the AEFI report.

Select the option from the following list that best describes the AEFI report status:

'Draft': *Saved as draft, not submitted.*

'Submitted for review': *Submitted, but review not yet started.*

'Review in progress': *Started review, but review is not yet complete.*

'Information required': *Review begun and more information has been requested.*

'Consultation requested': *Reviewed and requested further consultation.*

'Review complete': *Report reviewed, recommendation provided and AEFI report complete.*

'Disregard-Entered in Error': *AEFI report incorrectly created, e.g., wrong client selected.*

'Does not meet reporting criteria': *Any reported event in a vaccine recipient which follows immunization that has been clearly attributed to other causes, OR does not meet reporting criteria (e.g., mild vomiting).*

If the medical health officer requires a consultation from BCCDC Immunization Programs and Vaccine Preventable Diseases Service (IPVPDS), email VPD.Epi@bccdc.ca and include the client ID and Adverse Event ID in your email with subject line 'Request for AEFI Consultation'; do not use the 'assigned to' function within Panorama for this purpose.

4. AEFI Reported By

Reporter refers to the health care provider who received and reported the AEFI information to the public health unit. This may or may not be the same person as the user who enters the information in Panorama.

Date Reported

Date on which the adverse event was reported to the health authority.

Date Reported defaults to the date when report is created. If the AEFI information has been reported before the current date, then record the earlier date. If this date is before immunization date, a logic error will appear and it cannot be entered.

Setting

Setting in which the reporter is employed (i.e., '**Physician Office'**, '**Public Health'**, '**Hospital'**, '**Pharmacy'**, '**Workplace Health'**, '**Other'**).

Reporter

Name and title of the reporter. Reporter refers to the health care provider who received and reported the AEFI information to the public health unit. This may or may not be the same person as the user who enters the information in Panorama.

In Panorama, this field is labelled "Provider". If the reporter is not indexed, identification information must be provided in the 'non-indexed provider' fields. When the non-indexed provider option is selected, the lower level fields will be enabled. Proceed to complete the prompted fields.

Source of Information

Source of information can be the client, the immunizer (PHN, physician, pharmacist), or a secondary source such as parent of a child recipient. If source of information is different than the reporter or client, provide their name, relation to the patient and contact information.

If 'Other' is selected, demographic and identification questions will be asked (name, email, and address are required questions).

5. Immunization Data

Provide all information pertaining to the vaccine(s) administered prior to the onset of the reported AEFI. Any concomitant passive immunizing and/or diagnostic agent(s) should be reported in medical history, **not** the immunization data section.

When completing this section, provide all information as outlined below:

'Date vaccine administered': Indicate the date of vaccine administration.

'Immunizing agent(s)': Please record the proper name or abbreviation as outlined in [Chapter 2: Immunization](#) of the BC Communicable Disease Control Manual.

'Trade name': Indicate the trade name of all vaccine(s) received.

'Manufacturer': Specify the name of the manufacturer as indicated on the product label.

'Lot number': Document the complete lot number including all letters and numbers. This information is essential for conducting future risk assessments.

'Dose number': Provide the number in series (1, 2, 3, 4, or 5), if known. For the Influenza vaccine, the Dose Number should ordinarily be recorded as one, unless the client receives more than one dose in one season, which is then recorded accordingly.

'Dosage/unit': Indicate the quantity administered for each vaccine, usually in units of volume (i.e., milliter or ml).

'Route': Specify the route of administration for each vaccine received.

'Site': Indicate the site of injection for each vaccine administered.

All of the immunizations given at the same appointment may be associated with the reported event(s). If it was a <u>local reaction</u> at the site where only 1 or 2 vaccines were given, select the appropriate agent(s) accordingly. If the client had a <u>systemic reaction</u> and a specific vaccine cannot be definitively associated with the event, then all vaccines administered at that appointment should be selected (even if client also had a local reaction associated with only one of the vaccines).

If multiple episodes of an adverse event are reported at one time that occurred following multiple prior immunization appointments (e.g., after 2, 4, and 6 month vaccines), separate AEFI reports should be created for each episode.

In Panorama, immunizations must first be entered before selecting the vaccine(s) associated with the AEFI. View all existing immunization records to determine if the record(s) already exist. If missing, create a new immunization record. If a record exists but additional details on the immunization are provided on the AEFI form that are not recorded in Panorama (e.g., trade name, lot #, dose, route, site), go to the immunization record(s) and update the immunization. If the lot # is not available in the drop-down list, include the lot # in the immunization comments field.

Once an immunization record has been associated with an AEFI report, a second AEFI report on that same agent/date combination cannot be made. All events associated with that agent/ date combination must be entered in the same AEFI report.

6. Information at time of immunization and AEFI onset

Breastfeeding at time of immunization

Indicate whether the adult for whom the AEFI is being reported was lactating/breastfeeding a child at the time of immunization by choosing one of **'No'**, **'Unknown',** or **'Yes'**.

Pregnant at time of immunization

Indicate whether the client was pregnant at the time of immunization by choosing one of **'No'**, **'Unknown'**, or **'Yes'**.

Did an AEFI follow a previous dose of any of the immunizing agents associated with this

AEFI report?

Indicate whether the client had ever experienced an AEFI following a previous dose of any of the vaccines associated with this AEFI report. Choose <u>one</u> of the values listed below.

'No': Previously immunized with one or more of the vaccines associated with this report and had not experienced a subsequent AEFI.

'Not applicable (No prior dose)': Never previously immunized with any of the vaccines associated with this report.

'Unknown': It is unknown if the client previously received any of the associated vaccines and/or if an AEFI followed.

'Yes': Previously immunized with one or more of vaccines associated with this report and experienced a subsequent AEFI.

If the answer is yes, provide as much detail of the prior AEFI in the comment box including onset and duration, AEFI details, severity of AEFI, whether event was less or more severe than the event following the current dose, dose number, and date of vaccination. *If a comment is recorded, record the response which it accompanies, e.g. "Unknown. Client does not recall whether previously received this vaccine…" Once a comment is added, it cannot be updated or deleted.*

Did this AEFI follow an incorrect immunization?

Indicate whether the AEFI followed an incorrect immunization by choosing <u>one</u> of **'No'**, **'Unknown'**, or **'Yes'**. If yes, choose <u>all</u> of the following options that apply and provide details in the comment box.

'Given outside the recommended age limits': The vaccine was administered to an individual who was not within the recommended age limits for a specific vaccine.

'Dose exceeded that recommended for age': A larger dose of vaccine was administered than is recommended for the patient's age group.

'Incorrect route': The vaccine was administered via a route not recommended for its administration (e.g., subcutaneous vs. intramuscular).

'Wrong vaccine given': An unintended vaccine was administered.

'Product expired': The vaccine was administered after the expiry date as indicated on the vaccine label by the manufacturer and/or after the recommended amount of time elapsed between the first use of a multi-dose vial and the last use.

'Other': An error has occurred that is not accurately reflected in the list of provided errors. Provide all details in the corresponding comment box.

Medical history (up to time of AEFI onset)

Indicate the client's medical history prior to the time of AEFI onset by choosing <u>all</u> of options that apply in the list below and provide details in the comment box.

'Concomitant medication(s)': Provide name of all medications, including prescription, over the counter and herbal supplements, which the client had been taking immediately prior to the time of AEFI onset. When available, provide the dose, frequency, route of administration and reason f or taking each concomitant medication. If a passive immunizing agent or TB skin test was administered at the same visit as the vaccine(s) provide the details of the passive immunizing agent or TB skin test, including lot number when available.

'Known medical conditions/allergies': Indicate all known medical conditions and/or allergies, including pregnancy, that the client experienced prior to the time of immunization with a corresponding date/month/or year of onset. Include any conditions for which the client is taking a concomitant medication including chronic conditions with intermittent symptoms such as migraine headaches.

'Acute illness/injury': Indicate if client had an acute illness and/or injury immediately prior to the

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time of immunization and specify a corresponding date/month/or year of onset.

'No known medical condition(s)': Client's medical history prior to time of AEFI onset was assessed and no concomitant medications or medical conditions/allergies were identified. Do not select any other options if this selected.

'Unknown at time of report': Client's medical history prior to time of AEFI onset is unknown. Do not select any other options if this selected.

*Panorama requires details in the comment box when a value from this list is selected. If **'No known medical condition(s)'** or **'Unknown at time of report'** is reported, copy and paste the value in the comment box.*

7. AEFI Details

Indicate the details of the AEFI being reported by checking all that apply. Include pertinent details (results of medical investigations, laboratory test results, etc.) in the corresponding comment box.

Events with an asterisk (*) *or "(MD)" in Panorama* must be diagnosed by a physician, or where appropriate and based on current scope of practice, the diagnosis may be made by a Nurse Practitioner. If not diagnosed by a physician or nurse practitioner, provide sufficient information to support the selected event(s).

For more in depth information around Clinical Management Guidelines, please refer to the BC Communicable Disease Control Manual, Chapter 2, Immunization, Part 5 AEFI.

For all AEFIs, indicate the time to onset (time from immunization to onset of first symptom/sign) and the duration (time from onset of first symptom/sign to resolution of all signs and symptoms). If the AEFI is not yet resolved at the time of the report, do not document any duration, and check **'Unresolved'**.

Onset

Interval of time between administration of the vaccine(s) associated with the event and the onset of the first symptoms or signs of the event.

Record minute or hour or day parameter. It is not necessary to record more than one time parameter. Record minutes if event onset < 1 hour post-vaccination, hours if event onset < 24 hours post-vaccination, and days if event onset 1 or more days post-vaccination. If hours or days are recorded, record the number of **complete** hours or days between vaccine administration and onset of event.

Duration

Interval of time from the onset of the first symptom until all the symptoms resolved. If unresolved, leave this blank and must check '**Unresolved'** on the right. Record minute or hour or day parameter.

7.1 Local reaction at or near vaccination site

(For non-allergic local reactions only)

Time to **onset** and, unless the unresolved checkbox is selected, **duration** of signs and symptoms are mandatory. The time to onset and the duration of the signs and symptoms of the specified AEFI should be documented using the appropriate time unit (day, hour, or minute).

Indicate the local reactions by choosing all that apply. Refer to the BC Communicable Disease Control Manual, Chapter 2, Immunization, Part 5 AEFI for definitions and reporting criteria.

'Infected abscess*': Must be diagnosed by a physician.

'Sterile abscess*': Must be diagnosed by a physician.

'Cellulitis*': Must be diagnosed by a physician.

'Nodule'

'Rash'

'Reaction stretches joint-to-joint'

'Pain or redness or swelling extends past the nearest joint'

'Pain or redness or swelling persisting for 10 days or more'

'Adenopathy/Lymphadenitis*': Must be diagnosed by a physician.

'Other': Examples of "other" local reactions that may be reported here include necrosis, papule, etc. Specify details of the 'other' local reaction being reported in the comment box.

In Panorama, specify the other reaction in the general local reaction comment box in the following format "Other local reaction: [Describe reaction here]".

For all local reactions at or near the vaccination site, describe the signs and symptoms by selecting all that apply from the list below. At least one local reaction must be selected before selecting any corresponding signs or symptoms.

'Swelling'

'Pain'

'Tenderness'

'Erythema'

'Warmth'

'Induration'

'Largest diameter of vaccination site reaction': Indicate the diameter (in centimetres) of the largest vaccination site reaction that is present.

'Site(s) of reaction': Site(s) of the local reaction if known.

'Palpable fluctuance': Wavelike motion on palpation due to presence of liquid content.

'Fluid collection shown by imaging technique'

'Spontaneous/surgical drainage'

'Microbial results': Select "Microbial results" only if the result is positive. Record the laboratory result in the comments field associated with this section (e.g., positive for *S. aureus*).

'Lymphangitic streaking': Red streaks below the skin's surface that follows the path of lymph draining from the site of infection via lymphatic vessels to regional lymph nodes.

'Regional lymphadenopathy': Abnormal enlargement of the lymph nodes closest to the vaccination site.

Provide any additional pertinent details in the comment box for this section.

If an event is selected in the local section, Panorama requires either a sign/symptom or comment to be in this section to save the record. If signs/symptoms are unknown, or none of the options apply, users can report "No additional details", or describe the signs/symptoms, in the local comment box, as applicable. In Panorama, once a comment is added, it cannot be modified or deleted.

7.2 Anaphylaxis and other allergic events

The clinical signs and symptoms to be recorded in this section are closely aligned to the Brighton Criteria for anaphylaxis. For events managed and reported as anaphylaxis, the completed anaphylaxis worksheet can be uploaded and attached to the AEFI report in Panorama if desired.

Time to **onset** and, unless the unresolved checkbox is selected, **duration** of signs and symptoms are mandatory. The time to onset and the duration of the signs and symptoms of the specified AEFI should

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be documented using the appropriate time unit (day, hour, or minute).

Choose <u>one</u> of the following events:

'Anaphylaxis': Any event **managed** as anaphylaxis following immunization, regardless of how or whether it meets the Brighton Criteria should be reported as anaphylaxis.

'Ocular-Respiratory Syndrome (ORS)': Bilateral red eyes AND respiratory symptoms following influenza vaccine.

'Other allergic events': Encompasses all allergic reactions that are neither anaphylaxis nor ocular-respiratory syndrome.

'Epinephrine Administered': Select if epinephrine was used for treatment of the allergic event.

For the allergic event reported, describe the signs and symptoms by selecting all that apply from the list below.

'Skin/Mucosal'

'Generalized': A reaction involving in two or more body locations (e.g., both arms) and cannot only affect the injection site. User must select **'Non-injection site'** alone or **'At injection site'** AND **'Non-injection site',** but not **'At injection site'** only. If the event occurred only at the injection site, it should be reported as **'Localized'**.

'Localized': An event occurring in only one body location. User must select **'Non-injection site'** only or **'At injection site'** only**,** but not both**.**

If client has both '**Generalized'** and **'Localized'** skin/mucosal symptoms, use **'Generalized'.**

Users should select <u>at least one</u> of the following signs and symptoms:

'Urticaria' (hives): Localized swelling of superficial layers of skin that is itchy, raised, sharply demarcated, and transient (usually <12 hours).

'Erythema': Abnormal redness of the skin without any raised skin lesions.

'Pruritus': An unpleasant skin sensation that provokes the desire to rub and/or scratch to obtain relief.

'Prickly sensation': Tingling or smarting (stinging) sensation.

'Rash'

'Eyes': Select **'Red bilateral'**, **'Red unilateral'**, or **'Itchy'** if applicable.

'Angioedema': Areas of deeper swelling of the skin and/or mucosal tissues in either single or multiple sites which may not be well circumscribed and is usually not itchy. Typical sites in anaphylaxis include tongue, lips, around the eyes (periorbital), eyelids. Do not include hereditary angioedema.

Angioedema should not be reported unless this was a visible objective sign, i.e., provider-observed skin or mucosal swelling. If these are experienced as symptoms (subjective descriptions by the client such as "my tongue feels thick") but not observable as signs, do not report 'angioedema'.

Check all the locations where angioedema is seen '**Tongue**', **'Throat'**, **'Uvula'**, **'Larynx'**, **'Lip'**, **'Eyelids'**, **'Face'**, **'Limbs'**, **'Reported sensation of swelling'**, **'Visible swelling',** '**Other'**, if applicable. If **'Other'** is checked, provide details.

'Cardiovascular'

'Measured hypotension': An abnormally low blood pressure documented by appropriate measurement.

- Infants and children - low systolic blood pressure (age specific) or >30% decrease in BP.
- Adults – systolic blood pressure of less than 90mm Hg or >30% decrease from that persons' normal BP.

'Decreased central pulse volume': Absent or decreased pulse in one of the following vessels – carotid, brachial or femoral arteries.

'Capillary refill time > 3 sec': The capillary refill time is the time required for the normal skin colour to reappear after a blanching pressure is applied. It is usually performed by pressing on the nail bed to cause blanching and then counting the time it takes for the blood to return to the tissue, indicated by a pink colour returning to the nail. Normally it is 3 seconds or less.

'Tachycardia': A heart rate that is abnormally high for age and circumstance.
- Infants and children- A heart rate that is above the upper limit expected for age 4:
  - <1 year: 160
  - 1 to 2 years: 150
  - 2 to 5 years: 140
  - 5 to 12 years: 120
  - >12 yrs: 100
- Adults and adolescents - The term is usually applied to a heart rate >100 beats/min.

'Decreased or loss of consciousness': Partial suspension of conscious relationship with the outside world as demonstrated by a decreased ability to perceive and respond to verbal, visual or painful stimulus.

'Respiratory'

'Sneezing': An involuntary (reflex), sudden, violent, and audible expulsion of air through the mouth and nose.

'Rhinorrhea': Discharge of thin nasal mucus.

'Hoarse voice': An unnaturally harsh cry in an infant or vocalisation in a child or adult.

'Sensation of throat closure': Feeling or perception of throat closing with a sensation of difficulty breathing.

'Stridor': A harsh vibrating sound heard during respiration in cases of obstruction of the air passage.

'Dry cough': Rapid expulsion of air from the lungs and not accompanied by expectoration (a non-productive cough) that will not abate during the period of observation including through measures such as taking a sip of water.

'Tachypnea': Abnormally rapid breathing which is high for age and level of physical activity
- Infants and children - A respiratory rate that is above the upper limit expected for age
- Adults – A respiratory rate in excess of 25 breaths per minute

'Wheezing': A whistling, squeaking, musical, or puffing sound on expiration (bilateral – both lungs).

'Increased use of accessory muscles': Vigorous movement of the muscles of breathing, generally best seen in the lower part of the neck (supra-clavicular or tracheal tug) or below the chest (sub-costal). The movements are usually a sign of difficulty with breathing.

'Grunting': A sudden and short noise with each breath when breathing out.

'Cyanosis': A dark bluish or purplish discolouration most easily seen in the facial or perioral area or tongue.

'Difficulty breathing': A sensation of difficulty breathing.

'Indrawing/retractions': Inward movement of the intercostal area upon inspiration

'Chest tightness': Inability or perception of not being able to move air in or out of the lungs.

'Difficulty swallowing': Sensation or feeling of difficulty in the passage of solids and liquids down to the stomach.

'Sore throat': Discomfort or pain in the throat.

'Gastrointestinal'

Only report GI signs/symptoms associated with an allergic event here. Report isolated GI signs/symptoms in the **'Other Defined Events of Interest'** section.

'Diarrhea': Loose or watery stool.

'Abdominal pain': Sensation of discomfort or pain in the abdominal region.

'Nausea': An unpleasant sensation vaguely referred to the upper abdominal region (upper region of the abdomen) and the abdomen, with a tendency to vomit.

'Vomiting: The reflex act of ejecting the contents of the stomach through the mouth.

'Laboratory'

'Mast cell tryptase elevation': Mast cell tryptase levels above upper normal limit. *In Panorama, record '***Mast cell tryptase elevation'** *in the comment box for this section.*

Provide any additional pertinent details in the comment box for this section. *In Panorama, once a comment is added, it cannot be modified or deleted.*

7.3 Neurologic events

Time to **onset** and, unless the unresolved checkbox is selected**, duration** of signs and symptoms are mandatory. The time to onset and the duration of the signs and symptoms of the specified AEFI should be documented using the appropriate time unit (day, hour, or minute).

Indicate the neurologic event by choosing all that apply. Refer to the BC Communicable Disease Control Manual, Chapter 2, Immunization, Part 5 AEFI for definitions and reporting criteria. Events with an asterisk (*) *(or 'MD' in Panorama)* must be diagnosed by a physician, or where appropriate and based on current scope of practice, the diagnosis may be made by a Nurse Practitioner.

- **'Seizure(s)'**. Sudden loss of consciousness in conjunction with involuntary generalized motor manifestations. If seizure is selected, users must provide additional details:

Choose only <u>one</u> of:

- **'Febrile'**: Select if seizure being reported with fever.
- **'Afebrile'**: Select if seizure being reported in absence of fever.
- **'Unknown type'**: Select if unknown whether the seizure being reported was febrile or afebrile.

Select either:

- **'Focal/Partial'**: Seizure that originates from a localized area of the cerebral cortex and involves neurologic symptoms specific to the affected area of the brain (also called partial seizures, which can be divided into simple and complex partial seizures).

  In Panorama, users must also select the redundant 'Focal/Partial' sub-option.
- **'Generalized'**: Bilateral, with more than minimal muscle involvement.

  For generalized seizures users must specify one of the following:

  'Tonic': Sustained increase in muscle contraction lasting a few seconds to minutes.

  'Clonic': Sudden, brief (<100 milliseconds) involuntary contractions of the same muscle groups, regularly repetitive at a frequency of about two to three contractions/second.

  'Tonic-clonic': A sequence consisting of a tonic followed by a clonic phase.

  'Atonic': Sudden loss of tone in postural muscles often preceded by a myoclonic jerk and precipitated by hyperventilation (in the absence of Hypotonic-Hyporesponsive Episode, syncope, or myoclonic jerks).

  'Myoclonic': Involuntary shock-like contractions, irregular in rhythm and amplitude, followed by relaxation, of a muscle or a group of muscles.

'Absence': The occurrence of an abrupt, transient loss of impairment of consciousness (which may not be remembered), sometimes with light twitching, fluttering eyelids, etc.

Provide the following details:

- **'Witnessed by healthcare professional' ('Yes', 'No', 'Unknown')**
- **'Sudden loss of consciousness' ('Yes', 'No', 'Unknown')**
- **'Previous history of seizures' ('Febrile', 'Afebrile', 'Unknown type')**

- **'Anaesthesia/Paresthesia'.** Indicate whether the '**Anaesthesia/Paresthesia'** was '**Generalized'** or '**Localized'** and choose the appropriate signs/symptoms:
  - **'Numbness'**
  - **'Tingling'**
  - **'Burning'**
  - **'Formication'**
  - **'Other'**

- **'Meningitis*'** Must be diagnosed by a physician.
- **'Encephalopathy/Encephalitis*'** Must be diagnosed by a physician.
- **'Guillain-Barre Syndrome (GBS)*'** Must be diagnosed by a physician.
- **'Bell's Palsy*'** Must be diagnosed by a physician.
- **'Myelitis/Transverse myelitis*'** Must be diagnosed by a physician.
- **'Subacute sclerosing panencephalitis*'** Must be diagnosed by a physician.
- **'Other Paralysis*'.** Must be diagnosed by a physician. Includes vaccine-associated paralytic poliomyelitis.
- **'Other neurologic diagnosis*'.** Must be diagnosed by a physician Includes ADEM and SSPE. Specify details in comments.

For neurologic events describe the signs, symptoms, and test results from the following list:

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

Provide any additional pertinent details in the comment box for this section. *In Panorama, once a comment is added, it cannot be modified or deleted.*

If an event is selected in the neurologic section, Panorama requires either a sign/symptom or comment to be in this section to save the record. If signs/symptoms are unknown, or none of the options apply, users can report "No additional details", or describe the signs/symptoms, in the neurologic event comment box, as applicable

7.4 Other defined events of interest

Time to **onset** and, unless the unresolved checkbox is selected, **duration** of signs and symptoms are mandatory. The time to onset and the duration of the signs and symptoms of the specified AEFI should be documented using the appropriate time unit (day, hour, or minute).

Indicate the event by choosing the events that apply. For a selected event, describe the signs and symptoms by checking all the sub-level items that apply.

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- **'Hypotonic-Hyporesponsive Episode (age <2 years)*':** Must be diagnosed by physician. Select all sign/symptoms that apply:
    - **'Limpness'**
    - **'Pallor/cyanosis'**
    - **'Reduced responsiveness/unresponsiveness'**
- **'Persistent crying (crying which is continuous and unaltered for >= 3hrs)'**
- **'Rash':** Only report rash here if both not localized at injection site and non-allergic. Otherwise report the rash in the appropriate earlier section as above. Check whether the rash is **'Generalized'** or **'Localized at non-injection site'**, and when possible provide a written description of the rash primary lesion(s) (bulla, cyst, macule, nodule, papule, plaque, pustule, vesicle, wheal), and/or secondary skin change(s) (scaling, atrophy, excoriation, fissure ulcer). If localized at non-injection site is selected, specify the location of the site in 'Comments'.
- **'Intussusception*':** Must be diagnosed by physician.
- **'Hematochezia*':** Must be diagnosed by physician.
- **'Arthritis*':** Must be diagnosed by physician. Select at least one of the following sub-items:
    - **'Joint redness'**
    - **'Joint warm to touch'**
    - **'Joint swelling'**
    - **'Inflammatory changes in synovial fluid'**
- **'Parotitis*':** Parotid gland swelling with pain and/or tenderness after mumps-containing vaccine. Must be diagnosed by physician.
- **'Orchitis*':** Must be diagnosed by physician.
- **'Kawasaki disease*':** Must be diagnosed by physician.
- **'Thrombocytopenia*':** Must be diagnosed by physician. Select at least one of the following sub-items:
    - **'Platelet count <150x10^9/L'**
    - **'Petechial rash'**
    - **'Other clinical evidence of bleeding'**
- **'Thrombosis*':** Must be diagnosed by physician.
- **'Thromboembolism*':** Must be diagnosed by physician.
- **'Fever ≥ 38°C':** For fever occurring with non-neurologic conditions. Only reportable in conjunction with another reportable event.
- **'Syncope with injury'**
- **'Severe vomiting'**
- **'Severe diarrhea'**
- **'Myocarditis and/or Pericarditis*':** Must be physician diagnosed.
- **'Other serious or unexpected event(s) not listed above':** Choose this category ONLY if the event cannot be reported using a more appropriate existing category. If selected, must provide a description and any other pertinent additional details in the corresponding comment box that could guide possible classification of the event.

Provide any additional pertinent details in the comment box for this section. When **'Other serious or unexpected event(s) not listed above'** is selected details must be provided in the comment box. *In Panorama, once a comment is added, it cannot be modified or deleted.*

8. Impact of AEFI, outcome, and level of care

Highest impact of AEFI

Indicate the highest impact of the AEFI to the client's daily activities, definitions of daily activities differ between adult (work, exercise, social commitment, etc.) and child (eating, sleeping, playing, etc.). Choose from: **'Did not interfere with daily activities'**, **'Interfered with but did not prevent daily activities'**, or **'Prevented daily activities'**

Outcome at time of report

Indicate the outcome of the AEFI at the time of completion of the report.

'Fatal': Client died. Record the date of death (if known) or date at which found out about fatal outcome (if date of death unknown) in the respective date field.

'Permanent disability/incapacity': An injury which impairs the physical and/or mental ability of a person to perform his/her normal work or non-occupational activities supposedly for the remainder of his/her life.

'Fully recovered': All signs and symptoms have resolved. Duration fields for the appropriate section(s) should be complete for this outcome.

'Not yet recovered': Residual signs and/or symptoms remain at the time of completion of the report. Select this if at least one of the reported AEFIs is unresolved.

'**Unknown'**: The outcome of the AEFI is unknown (e.g., client lost to follow-up) or unclear.

If the outcome is fatal, after recording the AEFI, also follow Panorama standards to update the client's record.

Highest level of care required

Indicate the highest level of care obtained for the reported AEFI by selecting one of the provided response options:

'Admitted to hospital': Must have been admitted to hospital, not seen on an outpatient basis or only visited ER. If hospitalized, enter admission and discharge dates for analysis of length of stay, which is used as a seriousness criterion.

'**Emergency visit':** The client was seen by a health care professional for an emergency visit for the assessment and/or treatment of the reported AEFI. Emergency visits are not considered admission to hospital and therefore, admission and discharge dates are not required.

'Non urgent visit': Seen by a health care professional (e.g., at a physician's office or walk in clinic) for the assessment and/or treatment of the reported AEFI.

'Resulted in prolongation of existing hospitalization': Patient was already in hospital at the time of immunization and the AEFI resulted in a longer hospital stay. Indicate the number of additional days stayed in hospital as a result of the AEFI.

'Telephone advice from a health professional': The client received telephone advice from a health care professional (e.g., nurse, nurse practitioner, physician, etc.) regarding the reported AEFI.

'None': No care was received for the reported AEFI.

'Unknown': It is unknown if the patient received care for the reported AEFI. None: Telephone advice from a health professional.

Provide any additional pertinent details in the corresponding comment box. *In Panorama, once a*

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comment is added, it cannot be modified or deleted.

Treatment received

Indicate whether the patient received any treatment, including self-treatment, for the reported AEFI by choosing **'No'**, **'Unknown'** or **'Yes'**. Provide details of all treatments received following the onset of the AEFI in the comments box when applicable.

9. Public Health Recommendations

Public health recommendations for AEFI reports should be completed by the regional Medical Health Officer (MHO) or their designate. Skip this section if you are reporting the AEFI to the regional MHO/designate.

In Panorama, this section displays upon saving and submitting the AEFI for review. MHOs or their designate can complete this section after the AEFI is submitted and saved. After completing the review, if the client has contraindication to a vaccine or needs precautionary arrangement before the next immunization visit for a vaccine, the reporter should enter the relevant information in Special Considerations.

Eligible for reporting to PHAC – Do not use
Leave this field blank. Note: AEFI reports entered in Panorama are reported to the Public Health Agency of Canada.

On behalf of Health Service Provider

If the user is entering recommendations on behalf of an MHO or designate enter the name of the individual who made the recommendation(s). Click 'Find' and enter the name of the MHO or designate providing the recommendations.

Public Health Recommendations

Select the recommendation(s) given by the regional MHO/designate for this AEFI report that apply, and specify additional information when requested:

'No change to immunization schedule'

'Determine protective antibody level'

'No further immunizations': Specify agent(s) in corresponding comment box. Also enter information under **Special Considerations** as a contraindication.

'Expert referral': Specify details in the corresponding comment box.

'Controlled setting for next immunization': Enter information under **Special Considerations** a precaution.

'Active follow-up for AEFI recurrence after next vaccine'

'Other': Specify details in corresponding comment box. Enter information under **Special Considerations** as contraindication, exemption, or precaution.

'Review Complete - Follow-up Required': Select when Public Health needs to know how the patient reacts to another dose to make a recommendation. The clinician administering the next dose should complete this section after the next dose, then set status to 'Submitted for review'.

'No recommendations': Client lost to follow-up and insufficient information available to make a recommendation, or client is deceased.

Select at least one recommendation and click 'Add Recommendations'. If that selection includes

'specify', you must provide a comment or you will be prompted to do so before going to the next step.

*When the Public Health Recommendation for an AEFI report is "No further immunizations", or "Controlled setting for next immunization", or "Other, specify" where the client has a contraindication, exemption or needs precaution, a **Special Consideration** should be created for the client. This section is separate from the AEFI report. Refer to the Special Considerations – Reference Guide – Immunizations, for entry guidance.*

Recommendation Comments

Provide any additional pertinent details in the comment box for this section.